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Specific Contract: The second independent evaluation of the ECDC in accordance with its Founding Regulation (European Parliament and Council Regulation (EC) no 851/2004

**FINAL REPORT
Volume 1 – Main Text**

submitted by

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ABBREVIATIONS AND ACRONYMS

AF	Advisory Forum
(S)MAP	(Strategic) Multi-annual Programme
AER	Annual epidemiological report
AIDS	Acquired Immune Deficiency Syndrome
AMR-HAI	Antimicrobial Resistance and Hospital Associated Infections
CB	Competent Body
CCB	Coordinating Competent Body
CD	Communicable diseases
CDTR	Communicable Diseases Threats Reports
CNRL	Community National Reference Laboratory
CRM	Customer Relationship Management
DG SANCO	Directorate General for Health & Consumers
DP	Disease Programme
DSN	Dedicated Surveillance Network
EAP	EPIET-Associated Programmes
EC	European Commission
ECDC	European Centre for Disease Prevention and Control
EEA	European Economic Area
EEAD	European Antibiotic Awareness Day
EFSA	European Food Safety Authority
EHAC	National Environmental Health Science & Protection Accreditation Council
EHEC	Enterohaemorrhagic Escherichia Coli
EI	Epidemic Intelligence
EMCDDA	European Monitoring Centre for Drugs and Drug Addiction
EMA	European Medicines Agency
EP	European Parliament
EPIET	European Programme for Intervention Epidemiology Training
EPIS	Epidemic Intelligence Information System
EQA	External Quality Assessment
ESCAIDE	European Scientific Conference on Applied Infectious Disease Epidemiology
EU	European Union
EUPHEM	European Programme for Public Health Microbiology Training
EWRS	Early warning and response system
FEM Wiki	Field Epidemiology Manual
FP(s)	Focal Point(s)
FWD	Food and waterborne Disease
GOARN	Global Outbreak Alert and Response Network
HSC	Health Security Committee
IHR	International Health Regulations
M&E	Monitoring and Evaluation
MB	Management Board
MoU	Memorandum of Understanding
MS	Member State(s)
NC	National Coordinator
NFP	National Focal Point
NGO	Non-Governmental Organisation
OCP	Operational Contact Point
PHE	Public Health Emergencies
PHI	Public Health Institutes
PH	Public Health
P&R	Preparedness and Response
QA	Quality Assurance
RASFF	Rapid Alert System for Food and Feed
RA	Risk Assessment
RC	Risk Communication
RM	Risk Management
RRA	Rapid Risk Assessment

RTR	Round Table Report(s)
SARMS	Scientific Advice Repository and Management System
SOP	Standard Operating Procedures
STI	Sexually Transmitted Infection(s)
SWOT	Strength, Weaknesses, Opportunities, Threats
TAP	Technical Analysis Plan
TB	Tuberculosis
TESSy	The European Surveillance System
ToR	Terms of Reference
TTT	Threat Tracking Tool
VPD	Vaccine-Preventable Diseases
WHO	World Health Organization
WHO/Europe	WHO Regional Office for Europe
WISO	Weekly Influenza Surveillance Overview

EXECUTIVE SUMMARY

Purpose and Scope of the Evaluation

This is the Final Report submitted by *Economisti Associati* as part of the assignment titled “*The second independent external evaluation of ECDC in accordance with its Founding Regulation*”, undertaken on behalf of the European Centre for Disease prevention and Control (ECDC). This exercise is the second mandatory external evaluation of the Centre since its establishment and covers the activities carried out between 2008 (when the implementation of the ECDC’s Strategic Multi-annual Programme 2007-2013 started) until the end of 2012.

The objectives of this assignment are those of *ex-post* evaluations, and namely: (1) to assess the ECDC’s overall achievements with respect to intended results and impact, (2) to inform ECDC and its Management Board on any lessons to be learned from past Centre’s performance, and (3) to fulfil the accountability requirements of the Founding Regulation (851/2004) by informing EU policy-makers of the benefits and impact of their past decisions and of options for future ECDC’s role and functioning. In particular, this evaluation is intended to ultimately serve as an input for implementing the *Strategic Multi-Annual Programme* for the period 2014-2020.

The Study addresses ECDC’s core institutional activities impacting on all 28 EU Member States plus Norway and Iceland. Evaluative activities were structured along nine ‘core tasks’ laid down in the Study’s terms of reference, which regard precisely: (1) the Disease Programmes and their networks; (2) the Organisational, Administrative and legal Framework; (3) Surveillance; (4) Scientific Advice; (5) Preparedness and response; (6) Capacity Building; (7) Health Communication; (8) Partnership; and (9) Governance. In addition, the Study reviews the extent of implementation of the past evaluation of ECDC, and includes a general analysis of the Centre’s mission, mandate and task and possible needs for change.

Approach and Methodology

The data and the evidence used in this evaluation were collected through five main sources of information, namely:

- an extensive in-depth interview programme covering 110 key informants from MS, EU Institutions, International Organisations and the ECDC staff and Governance Bodies members;
- a large-scale questionnaire-based survey addressing ECDC direct stakeholders, decision-makers and risk managers, and the relevant external scientific community (705 valid questionnaires received);
- a desk research on all relevant documentary sources (legal and procedural documents, partnership agreements, technical and reporting documents, strategies and work plan, financial reports, relevant MS-level documents etc.), for an overall 121 titles;
- a bibliometric analysis of scientific impact of a selection of 20 ECDC technical documents;
- a comparative assessment (benchmarking) of relevant information from other selected EU agencies.

As agreed with the Steering Committee, the evaluation covered in particular three disease-areas, namely: Influenza, Salmonella, and HIV/AIDS. The rationale for this selection is that each of these

diseases has different ways of transmissions and patterns of emergence, which call upon different ECDC capacities. The three case-studies have been especially used as concrete examples for a cross-cutting assessment of the various Centres' public health functions. Other noteworthy analytical instruments used include a SWOT analysis, whose main outcome is reported in the last paragraph.

Main Findings, Conclusions and Recommendations

The conclusions and recommendations presented here are grouped along three main core themes: 1) the perceived added value of ECDC activities; 2) the usefulness of ECDC outputs and possible ways to improve them; 3) management and governance issues, including processes and procedures.

I. ADDED VALUE

ECDC is generally perceived as a source of European added value in its activities, although with notable geographical disparities across Europe and among different lines of activity. There is strong consensus that added value has been on an increasing trend and, on average, more than outweighs the burden for Member States - although again disparities of views across countries exist.

Communication and support to laboratory activities are the activities for which the cost / added value ratio is less convincing or at any rate considered more controversial by stakeholders, for different reasons. It is therefore generally recommended here that both areas are closely monitored and possibly evaluated in the next mid-term evaluation.

The low score attributed to the added value of laboratory support activities partly depends on the pilot and often explorative nature of ECDC activities themselves, and the lack of a clear consensus on the broader issue of creating a European Network of Reference Laboratories. However, a clear quantification of the objectives to be achieved through ECDC support is missing and this appears at odds with the considerable expenditure made in this area. Therefore, the first very obvious recommendation is that ECDC should be more explicit in the quantification of the concrete objectives it wants to achieve in this area, that go beyond the generic maintenance of existing laboratory capacity. To this aim, better monitoring systems should be in place to report on the progress achieved in microbiology laboratory capacity Europe-wide, including first and foremost among the laboratories supported to judge on the added value of the activity.

At a more strategic level, it is observed that in order to steer activities and be in a position to judge on added value ECDC staff skills in this area should be strengthened, especially in the light of the fast technological progress. So any future continuation of ECDC activities in this area appears likely to greatly benefit from a carefully designed staff development strategy.

ECDC now has a strong communication capacity, which has translated in high quality outputs and in particular in a well appreciated website. However, there remains the widespread feedback that too many resources have been invested in this line of activity and deliverables are not always relevant to the specific Country needs.

Conversely, an unmet demand for further ECDC support can be found in the provision of technical advice on new approaches to risk communication together and in the provision of more practical examples of what works and what does not, including a facilitator role in sharing actual practice among Member States. To increase its added value ECDC can either more clearly focus on activities with a European dimension, and invest more in synergies with the existing campaign events, or

endeavour into a more differentiated and country-tailored strategy. Additionally, it is recommended that ECDC should further focus in assessing the impact of health communication techniques and tools and in following the latest technical developments in the field.

II. USEFULNESS

ECDC activities have generally resulted in good quality outputs appreciated by different professional communities. Their immediate usefulness for policymakers could, however, be further improved. First of all, one of the clearest need stemming out from this evaluation exercise is that, in order to increase the usefulness of deliverables and their impact on policymaking, ECDC should substantially strengthen its knowledge of local conditions together with the Country partnership component. This can be achieved through various direct and indirect means: a broadening of the expert basis that can be mobilized through outsourcing, a more intensive programme of Country visits and related support activities, a strengthening of the AF role in debriefing about local developments, mechanisms to allow staff to better share their knowledge about MS. Also internal repositories of MS systems, programmes and procedures could help in this respect. Then, to better steer activities to local needs MS could be encouraged to much more proactive approach to the use of mandates with a clear indication of the type of support needed, including, in the identification of possible responses.

Finally at the level of specific activities, ECDC should be encouraged to strengthen the provision of scientific evidence from surveillance data (reinforce the ‘evidence-based’ approach) by better highlighting the policy-relevant information that can be drawn from them in dedicated sections/chapters of their epidemiological reports and move away from a too descriptive approach. The overall usefulness of scientific advice can be enhanced by focusing more in the provision of new evidence from studies and broaden the issues covered to include more in-depth considerations on cost and cost-effectiveness. There also appears to be consensus on the fact that there is room to further expand the usefulness of the RRA instrument that is already perceived as fundamental. Also the ESCAIDE Conference enjoys a very positive reputation in the scientific and PHI peer community. However, its possible impact on policy-makers appears as comparatively more limited.

Increased responsiveness to policymakers’ needs can be achieved also by widening the range of sources used from peer-reviewed literature to include policy-relevant communications or grey literature coming from MS themselves and reviewing the concrete lessons learnt from past experiences. To this aim, it is worth considering the establishment of a sort of repository where all those concerned at the MS level can share documents, analyses, etc. to allow a smoother exchange of information between countries. A monitoring of client satisfaction on the conclusions of RRA could help highlighting potentially contentious issues or cases of perceived exceedingly generic conclusions and help align expectations with practice.

III. MANAGEMENT AND GOVERNANCE

Although it is widely acknowledged that ECDC management and governance have improved in the period considered there remains three main areas deserving further attention: 1) overall transparency of the organisation to outsiders; 2) cumbersome and poorly formalised procedures and processes often resulting in very slow reaction times; 3) better operational efficiency through increased inclusiveness and user-friendliness. More in particular there appears to be a key need to improve the intelligibility of the organization and key decisions to outsiders as stakeholders often report difficulties and uncertainties in understanding internal allocation of responsibilities, division of labour across units

and sections and related coordination mechanisms. Moreover, there are aspects of the decision-making process that remain somewhat obscure to stakeholders. This includes better clarity and transparency in the selection of priorities proposed to the AF for scoring and the overall readability of the budget. This can be addressed through very simple means such as enhanced use of directories and better explanative organigrams. The practice of rotating staff responsible for the same project that was sometimes reported by interviewees as an inconvenience and a cause of disruption of activities should be minimized and kept monitored. The rationale behind inclusion of an item in the prioritization process should be better explained in a background document. A budget organized along a matrix structure should be replaced by a more intelligible budget highlighting resources allocated to key missions and to the achievements of the MAP /sectoral strategy objectives.

Coordination mechanisms to improve cooperation between agencies (notably WHO/Europe) are often in place but appear as poorly participative for those stakeholders at the MS level that would like to provide their input on areas where activities can be streamlined and duplication of efforts avoided. So public consultations or restricted public consultations could be held on draft programmes of cooperation to allow for comments and make the process more participative. Reports published on the progress achieved to give a feedback and inform about developments in the making could also be welcome.

There is converging evidence from several sides that ECDC has long relied on informal procedures and centralised decision-making and this has negatively impacted on operational and budgetary performance and internal information flows. It appears that the Centre has already taken steps to redress these weaknesses although it is too early to see results. The process of creating internal procedures should be encouraged and adequately monitored through appropriate mechanisms to control compliance. Also the current process of administrative decentralisation of decisions is worth encouraging. Indicators to monitor possible problems in processing contracts, disbursing funds and ensuring compliance with procedures should be developed and routinely reported to the Management Board.

Most importantly there is a clear need to refine the staff and outsourcing policy to address several aspects of staff management that appear suboptimal to stakeholders. Such a strategy could help provide a clearer vision of the tasks to be developed in-house and those to be contracted out. In fact, there appears to be at the same time excessive recourse to outsourcing and underutilisation of outsourcing as a tool to build more inclusive networks and enhance cooperation and partnership with the MS. Within the room of manoeuvre allowed by the current financial regulation, ECDC should explore all the possible contractual means to make outsourcing more inclusive and broaden the range of expertise available.

Governance Bodies are generally satisfied with the way they can fulfil their mandate as defined by the ECDC Founding Regulation. Limited complementarity between the Advisory Forum and the Management Board can be considered as the most important problem area and a cause of delays in decision-making. Several proposals formulated in the past to improve complementarity have hardly materialized. These include sharing their agenda setting process, joint sessions, mutual access to the intranets. Both bodies should identify those more feasible and try to explore them on a pilot basis. In the evaluation of the different areas of ECDC activity a number of suggestions on how to improve user-friendliness of certain systems were formulated also as a way to save time and increase operational efficiency. For instance, in the field of surveillance the user-friendliness of the system could also be improved by better machine-to-machine interaction (ongoing); enhanced data access and analysis by external users; and rationalisation and better timeliness of reports and other outputs. There is also room for better integrating the EPIS and EWRS systems by establishing appropriate

linkages between events, which may then facilitate the rapid sharing of materials across platforms. The ECDC management of EWRS could better distinguish the information therein that is really confidential from the information that is publicly available from other sources and introduce procedures to avoid that EPIS information not validated yet escalates to the EWRS.

SWOT Analysis

<p style="text-align: center;">STRENGTHS</p> <ul style="list-style-type: none"> • Good reputation and scientific credibility among peers in core activities. • Products of good professional quality in all areas. • A learning-oriented organization very active in addressing shortcomings and improving performance. • Already quite Internet-oriented and open to the information society. • Good capacity of quickly reacting to health threats and performing in crisis conditions. • Good human capital potential and capacity to deliver. • Good visibility among peers. • Strong attention to inclusiveness and networking aspects. • Clear focus on system rationalization and sustainability. • Successful ‘catalyst’ role in supporting MS surveillance systems overhaul • Fairly recognized independence. 	<p style="text-align: center;">WEAKNESSES</p> <ul style="list-style-type: none"> • Lack of a clear strategic focus with shifting priorities over time. • Complex governance structure poorly conducive to strategic focus • Not fully recognized as a credible or legitimate player in the fields of microbiology and risk communication. • Extremely slow and burdensome management of ordinary activities. • Excessive reliance on informal processes. • Limited overall transparency of functioning, and intelligibility to outsiders. • Poor translation of the appreciation voiced by decision-makers into tangible change. • Limited first-hand intelligence of MS conditions and needs. • Underutilisation of internal expertise. • Uneven recruitment of available expertise across Europe.
<p style="text-align: center;">OPPORTUNITIES</p> <ul style="list-style-type: none"> • Strong demand for networking and partnership at the national level. • Growing need for evidence-based sources for policymaking and policy implementation. • Room to strengthen synergies with European and International organizations. • Demand for more interactive and internet-oriented deliverables. • Strong demand for technical assistance, capacity building and training activities. • Increased capability of staff to play a more direct role in the production of knowledge. 	<p style="text-align: center;">THREATS</p> <ul style="list-style-type: none"> • Fast technological change hard to cope with. • Risk that ECDC deliverables are used in conflicts on agenda setting at the national level. • Poorly defined boundaries with neighbouring International and European organizations. • Imbalances in the support to policymaking activities, too much driven by Commission needs and too little by MS needs. • Little MS willingness to invest in improving and harmonizing surveillance systems and conducting campaigns. • Increasing budgetary pressures.

INTRODUCTION

Nature of the Report. This Report is the final deliverable to be submitted by *Economisti Associati* (the “Consultant”) as part of the assignment titled “*The second independent external evaluation of ECDC in accordance with its Founding Regulation (European Parliament and Council Regulation (EC) no 851/2004)*” (the “Assignment” or the “Study”), undertaken on behalf of the European Centre for Disease prevention and Control (ECDC).

Structure of the Report. This draft final report is structured into twelve main chapters, namely:

- **Section 1** – describing the *purpose and the methodology* of the Study;
- **Section 2** – on ECDC *surveillance* activities and the integration of the former DSNs;
- **Section 3** – on the *scientific advice* provided by ECDC;
- **Section 4** – on *early warning, preparedness and response* activities;
- **Section 5** – on trainings and other *capacity building* activities;
- **Section 6** – on *health communication* activities;
- **Section 7** – on the *partnership* established with WHO, other EU agencies and national PHI;
- **Section 8** – on *organizational, administrative and legal* aspects;
- **Section 9** – on ECDC’s *governance* mechanism and procedures;
- **Section 10** – on the *disease programmes* and their networks (case-studies);
- **Section 11** – on the overall added-value of ECDC, its *mission, mandate and tasks*;
- **Section 12** – providing a set of *conclusions and recommendations*.

The Report includes also a series of *Annexes* containing additional information, methodological documents and supporting evidence. The Annexes are submitted in a separate *Volume 2*. In particular:

- **Annex A** – List of key-informants interviewed at MS and international levels.
- **Annex B** – Checklists used for interviews with key-informants.
- **Annex C** – The survey questionnaire.
- **Annex D** – Bibliometric analysis of selected publications.
- **Annex E** - Bibliography.
- **Annex F** – Survey results dataset (provided as a separated Excel file).

1. PURPOSE AND METHODOLOGY OF THE STUDY

1.1 Purpose and Scope of the Assignment.

Purpose. This is the second mandatory external evaluation of the ECDC since its establishment. According to the Centre's Founding Regulation¹ an external evaluation has to be carried out once every five years. The evaluation is to assess in general terms how well the ECDC has carried out its mission and performed the tasks assigned to it by the Regulation. More specifically, the objective of this assignment is three-fold:

1. to respond to the legal obligation to have an external independent view informing EU policy makers of the benefits and impacts of their past decisions, and to highlight future options regarding key questions on the ECDC's role and functioning (a transparency and accountability requirement);
2. to inform the ECDC and its Management Board on any lessons to be learned from the Centre's processes and activities (a formative evaluation); and
3. to assess the ECDC's performance in respect to intended effects, results and impacts and how their implementation has impacted on both the ECDC and their partners results over the past few years (a summative evaluation).

The results of the evaluation will provide insights on how the ECDC's activities can be improved, delivered more efficiently, or, if necessary, reprioritised; and will ultimately serve as an input for implementing the *Strategic Multi-Annual Programme* (SMAP) for the period 2014-2020² that had already been approved before this evaluation was launched.

Scope. The Study covers a period of five years from 2008 (when implementation of ECDC's Strategic Multi-annual Programme 2007-2013 started) until the end of 2012. As much as possible, the evaluation is therefore limited to the activities carried out in the target period, however, in order to provide a complete picture to readers, major developments occurred in 2013 or in the first half of 2014 are taken into account (although not 'assessed' in proper sense). Furthermore, the feedback collected from experts and stakeholders even when expressly referring to the 2008-2012 period appears inevitably influenced by their up-to-date perceptions. To minimize such influence and keep the focus on the target period, rather than general opinions on the current situation, the discussions with stakeholders largely concentrated on specific items (projects, publications etc.) or events (outbreaks, etc.) that took place in the period under analysis.

The Study addresses ECDC's core institutional activities impacting on the MS and the EEA countries. It does not include what the ECDC separately does as part of development or external cooperation projects in its relations with candidate or neighbouring countries. As clarified by the Steering Group in the inception phase, the evaluation is not aimed at assessing any specific ECDC department or project but on how ECDC is performing as a whole. In accordance with ToR requirements and with the Steering Group instructions, the evaluation focusses on a set of main ECDC's tasks and do not cover all the statutory activities of the Centre, since this would have inevitably implied a dilution in the depth of analysis. In the same vein – given the unfeasibility of covering all thematic areas - three 'disease case-studies' were identified with the support of the Steering Group, for in-depth analysis, namely:

¹ Regulation (EC) No 851/ 2004 of the European Parliament and of the Council of 21 April 2004 establishing a European centre for Disease Prevention and control.

² European Centre for Disease Prevention and Control, "*ECDC strategic multi-annual programme 2014 – 2020*." Stockholm, 2014.

- *Influenza*,
- *Salmonella*, and
- *HIV/AIDS*.

The rationale for this selection is that each of these diseases has different ways of transmissions and patterns of emergence, which call upon different ECDC capacities and the development and implementation of different measures and tools. The purpose of the three case-studies is however not only to assess ECDC performance in these areas *per se*, but to extrapolate from its performance in such very different cases indications on its overall performance and to confirm more general findings. The three case-studies have therefore not been used so much to assess the corresponding disease programme, but rather they ‘cross-cut’ – as concrete examples - all the various public health functions analysed in this Study.

The evaluation questions. As described in Table 1.1 below, the evaluation mandate is articulated into twelve evaluation questions (EQ), of which: seven specifically attaining the performance of the various Centre’ PH core functions, one dealing with disease-related work, and the remaining concerning more general and horizontal aspects of ECDC’s activities and mandate. Task-specific questions generally address issues of usefulness, European added value, effectiveness and impact, while the horizontal questions mainly concern operational efficiency and coherence aspects. The main EQ were complemented by a *set of 63 detailed subquestions* (or ‘judgment criteria’) laid down in the ToRs and further elaborated by the Consultant in the *Inception Report*. Table 1.1 below includes also additional notes, further specifying the focus of EQ as laid down in the ToR and/or clarified by the Steering Group.

Table 1.1 – Core evaluation tasks and questions

Core evaluation task	Core evaluation question	Notes
PUBLIC HEALTH CORE FUNCTIONS		
A. Surveillance	1. To what extent does the ECDC integration of the former Disease Surveillance Networks bring added value? 2. To what extent have the Centre’s ongoing activities improved the quality, collection and analysis of surveillance data to produce better information for action?	With the focus on: <ul style="list-style-type: none"> • Integration and operation of DSN (and burden thereof) • Quality, collection and analysis of surveillance data It is important to consider the usefulness of data for public health purposes and not (only) for scientific research purposes.
B. Scientific Advice	3. To what extent has the ECDC issued risk assessments, scientific advice and opinions that are relevant, credible, reliable and useful for its key partners (Commission, the European Parliament and/or the Member States) and other stakeholders, in a timely and efficient manner?	With the focus on: <ul style="list-style-type: none"> • Risk assessments • Scientific and technical advice • Contribution to prevention and control Added-value of scientific advice involves reducing duplication with PHI activities, and a balanced geographic distribution of advice. Also timeliness is to be considered.
C. Preparedness and Response	4. To what extent does the Centre manage effective integrated early warning mechanisms and systems for emerging threats in Europe that adequately support the Member States and the Commission in the detection, risk assessment, investigation and	With the focus on: <ul style="list-style-type: none"> • Rapid risk assessments • Early warning systems • EU-wide technical coordination during public health emergencies

	coordinated response to threats from communicable diseases?	Other priorities: direct support to MS on specific events, and the overall efficiency of the notification chain.
D. Capacity Building	5. To what extent is ECDC considered to be a key support centre for strengthening and building capacity through training for the prevention and control of communicable diseases?	With the focus on: <ul style="list-style-type: none"> • Training and public health capacity reinforcement (but not repeating the EPIET evaluation) This includes also ESCAIDE, the external quality assurance (EQA) schemes. It is important to consider not only benefits for direct participants / trainees but also systemic effects for MS and the EU on the whole.
E. Health Communication	6. To what extent does the ECDC communicate its scientific and technical output effectively and efficiently to professional audiences, policy makers, the media and to the European public?	With the focus on: <ul style="list-style-type: none"> • Stakeholder proximity The main purpose is to assess whether the scientific and technical output from ECDC is disseminated to and implemented by the relevant target population, and the efficiency of the dissemination mechanism in place.
F. Partnerships	7. To what extent is the ECDC cooperating appropriately and effectively with all the Member States, the Commission and other relevant European Union agencies, as well as third countries and international agencies (including especially WHO) and other important partners at regional and global levels?	The focus is on how far ECDC brings added value to EU knowledge and if partners do work in synergy with ECDC or there is still room for improvements.
DISEASE RELATED WORK		
G. Diseases Programmes and their networks	8. To what extent do Disease Programmes and their networks provide support and evidence for policy makers and enhance the EU and national responses to the relevant diseases?	With focus on three selected disease case-studies: <ul style="list-style-type: none"> • Influenza • HIV/AIDS • Salmonella Other priorities: integration of microbiologist and epidemiologist and the price and added-value of this integration.
HORIZONTAL ISSUES		
H. Organizational, administrative and legal framework	9. To what extent are ECDC's organisational functioning, management systems and processes appropriate to ensure the effective and efficient execution of its mission and core tasks?	The aspects already being covered by another parallel evaluation should not be covered here. Main focus is on team, project and programme management.
I. Governance	10. To what extent are the ECDC Management Board, Competent Bodies and the Advisory Forum working in a coherent and appropriate manner?	With the focus on: <ul style="list-style-type: none"> • Operation and relations between the Management Board, Competent Bodies and Advisory Forum. Emphasis on whether different actors have the same understanding and agreement on their roles.
J. Mission and Tasks	11. What would be the elements to reconsider, amend or expand in the ECDC's mission and tasks?	The option of expanding of the mandate should be explored even if it is unrealistic under the

		current budgetary constraints, with a view to identify gaps and priorities.
K. Follow up of the first independent external evaluation	12. To what extent have the recommendations from the first external evaluation of ECDC been implemented?	

1.2 Methodology and Tools

1.2.1 In-depth Interview Programme

Overview. The in-depth interview programme addressed 112 key-informants from national and international institutions and agencies who have some structured or otherwise significant interaction with ECDC in various fields and capacities, as well as the ECDC staff responsible for the various tasks under analysis. Interviews were carried out over the phone or in person, by the team leader or by other senior members of the team. On average, in-depth interviews lasted about 60 minutes each.

Sample description. The composition of the sample of interviewees followed the methodological indications laid down in the *Inception Report*. In particular, with respect to national counterparts, the interviews addressed experts from both public health institutions (PHI) and central authorities (typically Ministry of Health), who are either member of ECDC governance bodies (Management Board, Advisory Forum) or National Focal Point (various areas), or National Coordinator / Coordinating Competent Body Director, or country representative within the Health Security Committee (HSC) or other DG SANCO relevant committees. As regards other organizations, the interviews involved key informants from the European Commission – DG SANCO, the WHO Regional Office for Europe (WHO/Europe), the European Food Safety Authority (EFSA), and the European Monitoring Centre for Drugs and Drug Addiction (EMCDDA), the European Medicines Agency (EMA) and Public Health Canada. In addition, some 29 interviews with ECDC staff were conducted during the inception phase.

The sample was built in three steps: (1) at first we have ‘clustered’ stakeholders based on their ‘profiles’, (ii) secondly we sampled them partly randomly and partly giving precedence to those who have longer or otherwise greater experience of collaboration with ECDC (e.g. member of the former network’s ‘coordination group’); (iii) finally, we set up a list of 150 potential interviewees divided into a ‘primary’ and a ‘reserve’ list taking into account geographical balance. For international organisations the selection was less structured and essentially dictated by the role interviewees play in some ECDC governance body or by their being identified as the primary ‘counterpart’ by the relevant ECDC responsible persons.

All in all, 112 interviews were conducted, well in excess of the established target. The summary breakdown of respondents by profile and country is provided in Table 1.2 and 1.3 below. Respondents’ details are provided in Annex A. As regards profiles, it is important to highlight that several interviewees had more than one ‘link’ to ECDC, e.g. membership of ECDC governance bodies and appointment as NFP in various fields. This was especially the case with small Countries. In such instances, interviews covered a selection of maximum three ‘roles’.

Table 1.2 – Interviewees, Breakdown by Country/Affiliation

AT	BE	BG	HR	CY	CZ	DK	EE	FI	FR	DE	GR	HU	IS	IE
1	3	1	1	1	1	2	2	3	4	4	2	2	2	4

IT	LV	LT	LU	MT	NL	NO	PL	PT	RO	SK	SI	ES	SE	UK
1	1	3	1	1	2	2	1	2	1	2	5	3	2	5

EFSA	EMCDDA	EMA	WHO/ Europe	DG SANCO	Third- country agencies	ECDC Staff
2	2	2	2	9	1	29

Table 1.3 – Interviewees, Breakdown by profile (only national-level informants)

Profiles	#	Profiles	#
Management Board	10	NFP Scientific Advice	17
Advisory Forum	14	NFP Microbiology	3
National Coordinator/ CCB Director	22	NFP Surveillance	11
Health Security Committee	11	NFP Preparedness and Response	10
Health Security Committee Communicators	6	NFP Threat Detection, EWRS and IHR	14
Influenza Health Security Committee	14	NFP Public Health Training	11
Early Warning Response System	15	NFP Communication	11
Network Committee 2119	6	NFP Food- and Waterborne diseases	4
HIV Think Tank	3	NFP HIV/AIDS, STI and hepatitis B/C	4
Others (networks)	5	NFP Influenza	7

Note: Multiple appointments. Total headcount=65.

Themes discussed. Interviews were duly prepared by sending in advance to respondents an indicative ‘checklist’ with the themes for discussion. These themes essentially reproduced the interview questions laid down in the *Inception Report*. The selection of questions was tailored on respondent’s profile on the basis of 13 standard thematic checklists (provided in Annex B). In other words, in the event of multiple ‘roles’ of the interviewee in the ECDC system, an *ad hoc* combination of the relevant checklists was prepared and send out. The approach was semi-structured and interviews were conducted taking into account the true knowledge and experience of respondents. A final section was left open and interviewees could discuss and raise issues of special interest.

Timeframe. The interview programme had three steps. The first step was during the inception phase and focused essentially on the ECDC management responsible for the various areas at stake. The second step (the bulk of the programme) was carried out during the data gathering phase and addressed stakeholders within national and international organisations, including EU bodies and institutions (see Tables 1.2 and 1.3). It started around mid-February 2014 and lasted approximately ten weeks, i.e. until the end of April. These interviews addressed essentially national counterparts. The third step was carried out in the final phase of the Study and encompassed additional interviews with MS representatives – aiming at filling information ‘gaps’ – as well as other interviews with international organization and EU agencies representatives, including for ‘benchmarking’ purposes.

1.2.2 Survey of Stakeholders

Overview. The second main source of evidence for the Study was a large-scale survey of stakeholders. The survey addressed respondents with different background and profiles having in common the fact of being (potential) users / beneficiaries of ECDC work. The questionnaire was drafted in the inception phase and largely reworked on the basis of the feedback received from the abovementioned interviewees, who gave the Consultant useful indications on: perceived added-value and expectations, aspects to be investigated in greater details, issues and contentious points..

The Sample. The target group included three main categories: (1) *ECDC ‘direct’ stakeholders*, which include – in addition to the categories identified for the in-depth interviews (see 1.2.1) – all members of ECDC networks, EPIS and TESSy users, EPIET/EUPHEM fellows and supervisors, ESCAIDE conference participants, EQA-participating laboratory staff and other experts otherwise involved in any ECDC activities; (2) *policy-makers, risk managers, communicators* and other experts of the MS (including – when relevant – at subnational level) - not already included in the first category; (3) the relevant *‘external’ scientific community* (epidemiologist, public health experts, microbiologist etc.) not directly involved in ECDC activities. The sample *did not include ECDC staff*.

The list of potential respondents was built through various sources:

- For Category 1, the main source was ECDC itself and its CRM system. This was integrated with the list of EPIET / EUPHEM fellows and supervisors (when not already recorded), and by ESCAIDE participants³. The exercise proved not trivial since the same experts appeared in different lists, sometimes with minor differences in the spelling of the name or with different email addresses. After due ‘cleaning’ a list of 1,954 ‘unique’ potential respondents have been set up.
- Policy-makers and experts not already engaged in ECDC activities (Category 2) have been the most difficult to identify. For this category the Consultant had to entirely rely on the indications provided by National Coordinators (especially for policy-makers at subnational level) and Management Board members. Overall, ten MS replied to this request for information providing names and email addresses of decision-makers potentially interested to respond. Additional names were also retrieved through survey respondents by means of the ‘snowball’ technique.
- For the scientific community not directly addressed by ECDC activities (Category 3), the potential respondents have been identified through the Elsevier’s SCOPUS database, filtering by authors of scientific publications appeared between 2010 and 2012, affiliated to an institution based in EU28 plus Norway or Iceland, and whose publications are classified in one of the following thematic field: (i) infectious disease; (ii) epidemiology; (iii) microbiology; and (iv) public health. The potential respondents identified amounted to some 70,000. Among them, a random sample of 10,000 was invited to participate in the survey.

The Questionnaire. The preparation of the questionnaire was quite laborious as it had to respond to three main and partly conflicting necessities: (1) to collect a great amount of indicators, as required to address the numerous (63) judgment criteria laid down in the Study ToR; (2) to cope with respondents (part of the ECDC system) with varying and multiple roles and appointments; (3) to maintain the questionnaire as short and manageable as possible. For this reason, the following methodology was adopted:

- At first, we have identified and listed all the relevant variables characterizing respondent’s profile on the basis of his/her affiliations/memberships/participation to ECDC activity. This led to the identification of 25 different profile’s ‘characters’.
- Secondly, we have developed a series of standalone ‘modules’ (group of questions addressing the same theme). Modules were developed with a view to strike a balance between length and depth (i.e. limited number or no open questions, request to provide feedback on specific ECDC output etc.). Overall, 32 different modules have been developed, grouped in nine sections (including a preliminary and a concluding section).

³ Only from 2011, 2012 and 2013 editions. Since email addresses were not available through ECDC, they have been retrieved manually.

- Additional ‘filter’ questions were added at the beginning of the questionnaire, and at the beginning of various modules with a view to (i) determine the response path for not previously ‘profiled’ respondents (i.e. respondents not recorded in the CRM system), and (ii) avoid posing too detailed questions to respondents not very familiar with a given subject. This way, some 10 more ‘ex post’ profiles of respondents with customised response path were designed.
- Finally, the above filters (both ‘ex ante’ – i.e. for profiled respondents – and ‘ex post’ – i.e. for non-profiled ones) have been matched with the modules to determine which respondents should answer to what. This allowed building appropriately balanced and *ad hoc* questionnaires. Since some hundreds potential respondent from the CRM list appeared to have several profile’s ‘characters’ – which would have led to an excessive number of modules to answer – a threshold of max 4 ‘characters’ per respondent was set.

The final questionnaire was duly tested and commented by the public health experts in the team, and proof-read by a English-native team member. The complete version of the questionnaire (i.e. with all modules), as well as the description of filters applied and the applicable modules by profile is provided in Volume 2 - Annex C.

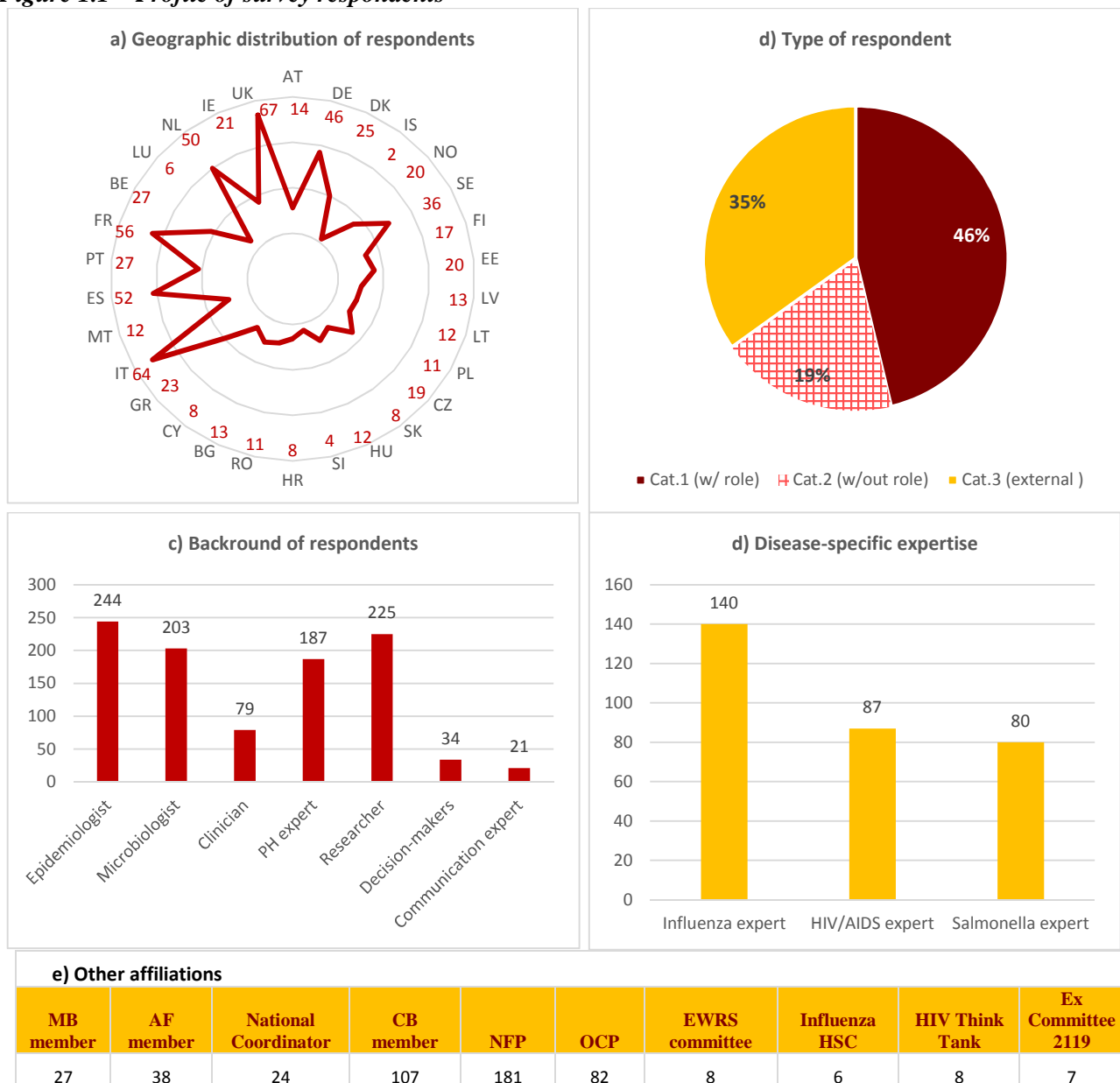
Survey recruitment and management. The online survey tool has been developed through the MySQL-based *LimeSurvey* application. Once the questionnaire and the (profiled) respondent lists were finalized, we attributed to each potential respondent a unique ‘token’ and a personal weblink through which he/she could access his/her ‘customised’ version of the questionnaire. The weblink was sent via email along with a brief description of the purpose of the survey and the salient administration features (e.g. confidentiality of data). To enhance user-friendliness some functionalities were added: (1) it was possible to complete the survey in one or several sessions. Completed parts of the survey were automatically saved, allowing respondent to resume and complete his/her full response at a later time (this also proved helpful as a ‘back up system’ in case of momentary interruption of the internet connection); (2) it was possible to print or save in *pdf* the questionnaire after its completion, and further modify it.

Timeframe. The abovementioned technical and methodological complexity caused an extension in the survey preparation time from the two weeks originally planned to nearly four weeks. The questionnaire was finally uploaded in testing modality on May 16, 2014. Then, a few days were needed to fix some bugs and improve the layout. The soft launch (100 names) eventually occurred on May 28, and since no major issues emerged a first mass launch (nearly 1900 names) followed on June 3. The first mass-launch addressed experts falling under Category 1 above, i.e. who are to some extent involved in any ECDC activity. Further large-scale launches followed on June 12 and June 17 addressing some 10,000 potential respondents from Category 3. Other 67 stakeholders from the Category 2 group have been added later on as soon as they were identified by MS counterparts and/or through snowballing. On June 18, a gentle reminder was sent to those who have not replied yet or had not finished to complete the questionnaire. The minimum quantitative target of 400 responses were achieved on June 20, 2014. As agreed with the Steering Group the survey remained however open until July 4, 2014 in order to give sufficient time to reply to all interested parties recruited later.

Response rate. Overall, 13,050 stakeholders were invited to take part in the survey. The number of ‘valid’ questionnaires received - i.e. excluding respondents who were erroneously invited, those who declared totally unfamiliar with ECDC work, and those who filled in only the preliminary questions of the survey, for an overall 202 respondents – ***amounts to 705***, of which 524 complete and 181

incomplete but ‘admissible’.⁴ The salient features of the survey sample are illustrated in Figure 1.1 below.

Figure 1.1 – Profile of survey respondents



Note: (b) Cat.1 = ‘direct’ ECDC stakeholders with or without roles or functions within the ECDC system. Cat.3 = external stakeholders (i.e. relevant scientific community); (c), (d) and (e) multiple answers are possible; (e) roles and memberships in the ECDC system include ‘alternates’ and positions held in the past.

1.2.3 Other Data Sources and Methodologies

As clarified at the outset, it was neither feasible and nor useful to analyse the entire wealth of documents produced in the monitored period. Instead, the Steering Group has recommended the Consultant to focus on selected issues of primary importance according to the evaluation design. This

⁴ When a respondent completed only a portion of the questionnaire modules relevant for his/her profile, the answers have been included in the analysis for that module, but obviously he/she was not counted to form the total of the modules not responded.

entailed *inter alia* concentrating on the evidence of use / utility of selected ECDC outputs among the relevant target groups. The evidence so collected was triangulated with the result of interviews and the survey for a better understanding of the impact of ECDC output.

More generally, the types of documents covered by the *desk research* included 120 documents, which can be grouped as follows (see Annex E for details):

- (i) legal framework and main corporate publications, e.g. SMAP 2007-2013, SMAP 2014-2020 and sectoral strategies, annual work plans and Director's reports;
- (ii) governance-related documents and in particular minutes of meetings and other documents, useful to respond to EQ# 11 on the work of governance bodies;
- (iii) relevant evaluation reports;
- (iv) Memorandum of Understanding and other agreements established with WHO/Europe and EU agencies;
- (v) selected technical documents and studies related to specific activities under evaluation, e.g. sample RRAs, scientific advice reports, EQA reports, guidance documents, surveillance reports, and the like;
- (vi) summary data on budgetary execution.⁵

With respect to budgetary data, a *benchmarking* exercise has been carried out with the aim of identifying the most relevant budgetary ratios and compare them to the extent possible to those of other European agencies, notably EFSA, EMCDDA and EEA. The ECDC budgets in the 2008-2012 period were first compared with their final versions after amendments were made during the year to identify trends over time. Then to the extent made possible by the different classifications used by the different agencies for Title I, II and III expenditure, comparisons were made of the weight of the most significant items of expenditure on the total level of expenses. Finally the ECDC budgetary information available for 2011 and 2012 was classified by area and type of activity and – for 2012 – procurement-related information extrapolated to better identify typology of Title III expenditure whether laboratory-related, outsourced through framework contracts or openly tendered. The benchmarking was conducted duly taking into account the differences between agencies' structure, mandate and operating environment. As clearly indicated in the report, various methodological limitations and caveats apply to the outcome of the exercise, which should therefore be taken 'with a grain of salt'.

Finally, the qualitative review of technical documents was complemented by a *bibliometric analysis* of such documents' impact on the scientific literature. A sample of 20 ECDC deliverables (including when relevant, the related *Eurosurveillance* articles that sometime followed up on the Centre's publication) was assessed with respect to number and 'weight' of citations obtained in other publications, which may provide a proxy of the influence they might have had on the target audience (essentially scientific community and, indirectly, decision-makers). The data have been collected via *Publish or Perish* - an application that retrieves and analyses academic citations by performing an advanced research on Google Scholar database. Two quantitative indicators have been used, namely: (i) the total number of papers quoting the referred publication; and (ii) the weighted average H-indexes of the authors citing the sample publications.⁶

⁵ Although it has been established that an in-depth budgetary review is outside of the scope of the evaluation, as the focus is on staff's skills, processes and procedures

⁶ By definition an academic has an index h if " h of his/her N_p papers have at least h citations each, and the other (N_p-h) papers have no more than h citations each". Hirsch, J.E. "An index to quantify an individual's scientific research output". [arXiv:physics/0508025](https://arxiv.org/abs/physics/0508025) v5 29 Sep 2005.

1.3 Methodological challenges and limitations

In order to properly understand the significance and the strength of the evaluation findings, it appears important to summarise the main caveats and limitations of the methodology used to collect and represent the information, as well as the measures adopted to tackle challenges and minimise issues.

Subjectivity of views. The main problem with the use of interview and survey data as a source of evidence is the intrinsic bias in respondent's view. This may be 'involuntary' i.e. cause by the fact that respondents have inevitably a partial knowledge and experience of the subject matter, or due to vested interests. Moreover, in the case of survey, there is also a 'self-selection bias', i.e. a distortion of the sample due to the fact that those willing to respond to the survey might not be representative of the population. In order to mitigate the risk of 'biased' evidence we have adopted various countermeasures:

- The ECDC staff was interviewed only at the beginning of the exercise and with the precise aim of gathering factual evidence (rather than opinions) on the Centre's activities and performance. The ECDC staff did not take part in the survey and did not discuss with the Consultant the results of the analysis before the publication of the report.
- As much as possible, all aspects were investigated through a 'triangulation' of sources involving primary (interviews, survey) as well as secondary sources (documentary sources). As a rule of thumb, interviewees' opinions were tested through the survey in order to determine the degree of consensus on a larger scale, and verified through factual data in order to detect possible bias. This sometimes led to the identification of clear disparities of views across different groups, which were reported and commented.

To a certain degree, the subjectivity is however inevitable, due to the lack of 'hard data' on certain matters. For instance, the extent to which ECDC output can influence policies at country level, was often measured mainly through key informants' feedback, given the absence of documents showing the decision-making process. On the other hand, subjective information is also important for analytical purposes, as it indicates how certain aspects of ECDC work are perceived by its target stakeholders and how perceptions may differ from (or align with) facts.

Representativity of data. The use of survey data as a source of evidence poses inevitably questions on their statistical representativity. In the present Study this issue is particularly complex due to both (i) the variability of what can be considered as the relevant population across the survey themes, and (ii) the heterogeneity of the target groups under various respects.

- To have a picture of the *variability of the relevant population* it is sufficient to consider, for instance, the difference between the target population of (a) questions on awareness about ECDC website - relevant to potentially all experts and policy makers concerned by infectious diseases, (b) questions on HIV/AIDS programme - relevant for those who have an expertise in this area, or are otherwise responsible for sectoral policies and actions, and (c) questions on the functioning of the Centre's Management Board – relevant to its members and to a restricted group of other representatives. Furthermore, in many instances, the 'boundaries' of groups are not clear-cut.
- As concerns the *heterogeneity of target groups* it is worth mentioning: (a) 'proximity' to ECDC – ranging from members of ECDC governance system to infectious diseases researchers poorly familiar with ECDC work; (b) differences in the profile and/or background, i.e. target groups may include epidemiologists, microbiologists, risk managers, researchers, clinical experts, risk communicators etc., as well as thematic experts of the various diseases;

(c) sectoral ‘affiliation’, i.e. affiliation to PHI, Ministries and/or State authorities, laboratories, universities, NGOs etc.; (d) geographical differences, particularly relevant in the case of countries with different level of capacities; and (e) level of experiences (years of professional experience).

The number of valid responses to the survey obtained (705) is well above the target of 400 and this ensures a general reliability of the exercise. However, this not always translates into statistical significance of results in a strict sense, especially at the sub-group level. Concretely, the following limitations and caveats apply:

- The ultimate composition of the relevant population cannot be determined. In fact, relevance does not have clear-cut boundaries but rather appears as a continuum reaching wider circles of potentially interested researchers and clinical experts. For this reason, it was not possible to determine to what extent our sample corresponded to the entire universe, and by consequence to apply appropriate ‘weights’ to enhance the representativity of answers.
- The number of answers to survey questions varies with the size of the applicable population, which in some cases can be small (for extremely focussed questions). Obviously the smaller the sample the less representative the results are, although this primarily depends on the actual distribution of data: i.e. if there is limited or no variance in the responses also data based on small sample may be statistically robust. The matter has been dealt with on a case-by-case basis.
- Connected with the above, the amount of responses available typically does not allow to draw solid comparison across countries. The ‘geographic’ variable has been used here and there in the report only for descriptive purposes, since there is no sufficient evidence (and is by the way not a Study’s aim) to establish causal links between some country’s features and the corresponding response patterns. When the number of responses available was high enough, country-based frequency distributions have been provided in order to show the variability or to highlight similarities and disparities.⁷ More often the number of observations available for certain small countries was instead too limited and it was not displayed.
- The same considerations apply to any classification and comparison among sub-groups carried out in the report. These are intended to show trends and to highlight differences that may have analytical implications. Since in many instances the subgroups are too small to allow statistically strong evidence, the significance of such comparisons emerges in the report from their triangulation with qualitative evidence.

Validity of findings. The two abovementioned issues may affect to varying degree the validity of findings, and therefore of conclusions and recommendations. In particular, the more a finding is based on purely subjective views and from a small sample of key informants, the greater is its uncertainty. In order to preserve the Consultant’s independence of judgement no feedback was solicited from the Centre prior to the submission of the report. Therefore, the factual accuracy of the evidence collected was entirely left to the means of verification available to the Consultant and small inaccuracies are possible. In some cases, when the evidence available was limited and/or controversial, in order to avoid endorsing one-sided views, we opted to present our findings in an interlocutory rather than conclusive form. Additionally, all conclusions are accompanied by a description of the supporting

⁷ Some ‘clusters’ of countries with often similar patterns of response have been observed, for instance: (i) the German-speaking countries (DE and AT); (ii) the UK and Ireland; (iii) the Baltic countries (EE, LT, LV); (iv) the Benelux region (BE, NL, LU); (v) Sweden and Denmark; (vi) the Mediterranean countries – although sometimes difference between west (IT, ES, PT) and east (GR, CY) were observed. Also New MS often provided coherent feedbacks, but sometimes sub-clusters were observed involving some Balkan countries (especially RO, BG, and HU) or northern countries (especially PL and CZ).

evidence in a clear and transparent manner, as well as with a judgment on its strength, so that the reader can put the Study's results in the appropriate perspective.

1.4 Structure of the analytical sections

The following Sections 2 through 11 provide an in-depth assessment of the Centre's performance in the various areas touched upon by the evaluation questions and related sub-questions. Some general principles have been taken into account in the analysis of the data collected and the presentation of results:

- **Validation of evidence** through 'triangulation' of sources. Typically, the process involved five steps: (i) the collection of factual information from ECDC on the activities carried out in a given area and the output available; (ii) the in-depth considerations of key informants on perceived strength and weaknesses; (iii) the review of output produced (documents etc.); (iv) the gathering of large amounts of feedback on selected relevant aspects through the survey of stakeholders; (v) the cross-check and comparison of the abovementioned information in order to establish factual evidence.
- **Definition of findings** on the basis of available evidence. Study's findings stem from a critical review of the evidence collected. Expert's assessment was particularly important in the various instances where the information gathered appeared conflicting. In such cases, the analysis required a proper granularity, so as to differentiate views and positions of the various subgroups of stakeholders, in connection with their interests and ambitions. In this sense, findings do not simply emerge from the 'aggregation' of evidence, but very often reproduce the complexity and the dynamics that exist in the ECDC work environment (e.g. across countries with different capacities, across experts with different backgrounds and responsibilities etc.).
- Findings largely addressing the stated '**judgement criteria**'. The ToR spelled out a series of specific aspects – or sub-questions - to be investigated with respect to each EQ. Such aspects represent the judgement criteria that have been used to respond to EQ. Such criteria have been elaborated in the inception phase and proper indicators have been identified.
- **Conclusions and recommendations** based on findings. The third step of the analysis consisted of consolidating the findings into a set of conclusions and a list of recommendations for the way forward. Conclusions are not just a mere summary of findings but should be interpreted as the succinct response to EQ. Recommendations mostly relate to the ECDC's performance in the 2008-2012 period. In some cases, measures going in the same directions have been already adopted by ECDC in more recent times. Where the information was available, this have been shortly reported in the Study. In such cases, the proposed recommendation should not be considered as void, on the contrary the recommendation is valid and its validity is reinforced by the already planned / ongoing action, and it will be responsibilities of the next statutory evaluation to determine to what extent it has been implemented and with which results.

The following analytical sections have a tripartite structure. The first part provides an overview of the activities carried out in a given area of work, the related milestones (e.g. key strategic documents), the chronology – when relevant – and the key factual information. The second part illustrate the evidence collected and provides the main findings for each of the judgment criterion identified (some judgment criteria were aggregated for better readability and to avoid excessive repetitions). The third part summarises the results of the evaluation in tabular form. The final evaluation matrix includes: (i) the summary of key findings for each judgment criterion considered; (ii) the succinct evidence

supporting findings (in the form of quantitative or qualitative indicators); and (iii) the overall conclusions and recommendations related to the EQ at stake. Such conclusions and recommendations are then reproduced and integrated in the final Section of this report.

Needless to say, evaluating the activities of an agency that has adopted a matrix structure implies that certain items or procedures are sometimes repeatedly addressed in the text under different angles. Attention has been paid to minimize such cases when not strictly required. This also entails that some cross-cutting themes, which in principle could fit in a number of sections, have been developed in only one section in order to enhance the readability of the report.

2. SURVEILLANCE

2.1 Overview

The ECDC action in the field of CD surveillance has been informed and guided by the 2008-2013 long-term strategy, which followed the 2006-2008 one and the related 2005 Commission Communication.⁸ The strategy marked the switchover from the prior project-based approach to an integrated and coordinated EU-wide system, under the aegis of ECDC. In summary, the general objective of ECDC action has been “*to contribute to reducing the incidence and prevalence of communicable diseases in Europe by providing relevant public health data, information and reports to decision makers, professionals and healthcare workers in an effort to promote actions that will result in the timely prevention and control of communicable diseases in Europe*”.⁹ The main expected results of this process can be summarized as: (i) more efficient and sustainable surveillance through better synergies, less duplications, and simplification of processes; (ii) better quality and reliability of data, as well as cross-country comparability, for a more effective use of indicator-based data; (iii) increased MS capacity and strengthened national surveillance systems for an enhanced detection and monitoring of outbreaks. At the end of 2011, the strategy was complemented with a specific strategy and action plan on public health microbiology.¹⁰ Eventually, a new multiannual strategy covering 2014-2020 has been published.¹¹ The priorities of the new strategy include *inter alia*: (i) the need to strengthen EU surveillance guidance, tools and standards with a view to further improve data quality, comparability and timeliness; (ii) streamline and reduce the burden for data reporting as well as for the accessibility and use of ECDC outputs; (iii) further the integration of molecular surveillance data (also boosting genomic epidemiology), and (iv) more integration between event-based and indicator-based surveillance.

The support to the development of European surveillance system has been a top priority for ECDC during the entire monitored period. In the first phase, efforts concentrated on integrating the pre-existing EU-funded *Disease Surveillance Networks (DSN)* under ECDC management and control.¹² The process involved, in the 2006-2008 period, the evaluation of DSN and their progressive integration under ECDC’s supervision, which terminated at end 2011.¹³ Eventually, 15 DSNs were transferred to ECDC, one (on norovirus) was discontinued and another one (on imported viral infections) outsourced to outbreak-assistance laboratories.¹⁴ The process involved the transfer of

⁸ ECDC, “Surveillance of communicable diseases in the European Union. A long-term strategy: 2008-2013.

⁹ *Ibidem*, p.2.

¹⁰ ECDC, “Updated public health microbiology strategy and work plan 2012-2016”, adopted by the Management Board in Nov. 2011.

¹¹ ECDC, “Long-term surveillance strategy 2014-2020”.

¹² All surveillance reporting at the EU level is now centralized at the ECDC in Stockholm who acts as a clearinghouse for requests from other international organizations – notably the WHO –, thereby avoiding duplication of requests at the MS level. Measles still represents an exception and double reporting to ECDC and WHO is still in place as different standards are used by the two organizations. The timing of double reporting discontinuation does not necessarily coincide with the timing of DSNs incorporation into ECDC and some delays were experienced. At present, however double reporting is reportedly there only for measles, mumps and rubella although there remains the possibility that data is asked on a spot basis by other international organizations other than the WHO.

¹³ Some delays on the integration schedule were registered, reportedly due to the 2009-2010 H1N1 public health emergency.

¹⁴ These included BSN, Enter Net for FWD, EU-IBIS for meningococcal and haemophilus influenzae infections, EuroHIV for HIV and AIDS, EuroTB for tuberculosis, IPSE for HAI, EISS for influenza, ESSTI for STD, EARSS for antimicrobial resistance, DIPNET for diphtheria, EWGLINET for travel-associated legionnaire disease, EUVACNET for measles, rubella, mumps, pertussis and varicella, ESAC for antimicrobial consumption, EUCAST for harmonization of antimicrobial susceptibility testing, EuroCID for the variant Creutzfeld-Jakob disease, DIVINE (discontinued) for norovirus, and ENIVD for imported viral infections.

databases, historical data and website contents to a common European surveillance system. The integration entailed some re-design of network's scope of activities and operation modalities (as well as its renaming), but generally preserved the specificities of each DSN through *ad hoc* transition plans. Some of the specific activities of networks had to be outsourced due to lack of internal capacity or infrastructure (ECDC cannot carry out laboratory work).

In connection with the management of the legacy of pre-existing networks and surveillance systems, a major task carried out by ECDC during the period under evaluation was the establishment of *The European Surveillance System (TESSy)* – which was launched in 2008 - and the continuous enhancing of its applications and functionalities. TESSy has been designed as an integrated system covering collection, analysis and reporting of surveillance data for 52 communicable diseases and health conditions indicated in the European Regulation.¹⁵ As of beginning of 2014, some 83 different experts from all the EU28 and 3 EEA countries had the credentials to access TESSy. All pre-existing datasets created by specific DSN were progressively transferred under TESSy. Its metadata are revised on an annual basis following specific procedures drafted in 2011, and further updated in 2012 and 2013.¹⁶ Between 2008 and 2012, the TESSy metadata-set was updated 26 times for an overall 80 different changes.¹⁷ Other standard operating procedures (SOP) and guidelines were set up over the years, covering aspects such as data validation and analysis (i.e. the *Technical Analysis Plans*¹⁸), data call schedules, data access rules for third parties and conditions for use,¹⁹ report production and quality assurance²⁰, etc. Outside of the monitored period, there are various projects in the pipeline to further develop the technical functionality of TESSy. In this respect it is worth to mention (i) the 'dashboard', already finalized in pilot form, which consists of an online interactive interface that facilitate users' exploration and analysis of TESSy data; and (ii) the plans to implement a machine-to-machine system that would streamline the data collection process. A detailed evaluation of TESSy performance is planned for 2014.

Closely linked to the need for improving national surveillance systems (infrastructures and capacity), the period covered by the evaluation was characterised by the need for strengthening the *microbiology* component of CD surveillance and control. The needs for convergence of microbiology data and increasing of laboratory capacity were outlined in several subsequent strategic documents, including the *General Strategy and Framework of Actions (2007-2013) for ECDC Cooperation with Microbiology Laboratories and Research Institutes*,²¹ the *ECDC Public Health Microbiology Strategy (2011–2015)* and the *Updated Public Health Microbiology Strategy & Work Plan 2012-2016*.²² More recently, the focus of PH microbiology strategy has been placed more clearly on the integration of molecular typing into EU-level surveillance²³ and on the development of a *Microbiology Capability Monitoring System for the EU*.²⁴ Until 2009, the activities in this field were mostly limited to coordination of the national microbiology focal points, the mapping of resources, and the identification of needs. In 2009-2010 the first pilot projects for the creation of molecular

¹⁵ Decision No 2119/98/EC.

¹⁶ ECDC, "Metadata implementation procedure", (internal document).

¹⁷ Source: Metadata-set ver. 2014-01-03.

¹⁸ The Technical Analysis Plan (TAP) describes the individual analyses to be carried out for surveillance reporting and the detailed processes and methods. As regards the three disease case-studies covered here, TAPs were published (latest versions) in 2011 for HIV/AIDS and in 2012 for Zoonosis. TAPs are ECDC's internal documents.

¹⁹ ECDC, "Policy on data submission, access, and use of data within TESSy – 2011 revision", (internal document).

²⁰ ECDC, "Disease specific surveillance report production", August 2012 (internal document).

²¹ http://ecdc.europa.eu/en/activities/microbiology/microbiology%20documents/0711_mic_generalstrategy_ecdc_cooperation_with_lab.pdf

²² http://www.ecdc.europa.eu/en/activities/microbiology/documents/1203_updated-ecdc-public-health-microbiology-strategy-work-plan-2012-2016.pdf

²³ Thirty-third meeting of the ECDC Advisory Forum, Stockholm, 20-21 February 2013.

²⁴ Eleventh meeting of the NFP for microbiology, Stockholm, 7-8 November 2013.

surveillance systems were set up, in the fields of tuberculosis and FWD. The first instances of 'structured' integration of labs in threat investigation and response to outbreaks also started in 2010.²⁵ In 2011, the development of a module to include molecular typing data into TESSy was initiated. This went live in November 2012, with coverage of *Salmonella*, *Listeria*, *E. coli* and *Mycobacterium tuberculosis*. Other key activities not covered in this Section that form part of the PH microbiology programme include trainings (the EUPHEM programme) and external quality assurance (EQA) schemes for microbiology laboratories (see Section 5.2.3).

The main stakeholders in this line of work are the networks that have replaced the former DSNs. The surveillance function itself is to be articulated on a network of focal points and three layers of operational contact points (OCP) on general surveillance, data management and IT surveillance respectively. A fairly complex situation is found in the PHM field, where activities have been generally outsourced to consortia providing support to network members. The various networks differ as to the range of activities implemented²⁶ and involvement of ECDC in their coordination. On top of that, there is a network of national microbiology focal points that were initially appointed for strategy definition purposes.

Surveillance data and analyses are reported and disseminated mostly through periodical and *ad hoc* publications. The main cross-cutting publication is the *Annual Epidemiological Report* (AER), which summarises and analyses the surveillance data gathered by ECDC through MS for more than 50 diseases and health issues. The AER is being published since 2007 and, since 2011, includes also a summary of the epidemic intelligence outcomes for the previous year. Other disease-specific periodical reports for the three disease case-studies covered in this evaluation include (1) the "European Union Summary Report on Trends and Sources of Zoonoses, Zoonotic Agents and Food-borne Outbreaks", which is published in collaboration with EFSA since 2005 and, since 2009, replaced *de facto* the various *Enter-net* quarterly disease reports; (2) the "HIV/AIDS Surveillance in Europe" published since 2008 in collaboration with WHO/Europe; and (3) the "Weekly Influenza Surveillance Overview" (WISO), published since September 2009 (with lower frequency outside of influenza peak season). *Ad hoc* publications are normally issued as either thematic surveillance reports, or special monographic editions of the *Eurosurveillance* journal, or *Epidemiological Updates* (short updates on the state of progress of certain outbreaks, released since 2011). Finally, epidemiological data circulate also through the weekly *Communicable Disease Threat Report* (CDTR) - possibly the main 'product' of event-based surveillance. Since this tool is pertinent also for epidemic intelligence and threat detection, it is reviewed also in Section 4.2.1.

Financing allocated to surveillance has remained in the € 4-5 million range, until being halved to € 2.5 million in 2011-12 after all the DSN were incorporated. In 2012, it accounted for 8% of total ECDC expenditure including 23 FTE staff. Most of this financing is directly allocated to the disease programmes and - with notable variations from one year to another - also addressed various laboratory activities (or in the case of AMR, the point prevalence survey). Some 90% of procurement in 2012

²⁵ See for instance the involvement of the ENIVD-CLRN (the lab network on imported viral diseases) in the coordinated response to West Nile outbreak in Europe.

²⁶ These might variously include on a case by case basis: coordination of network activities, provision of external quality assurance, provision of training, strain collection, supranational reference services also implementing testing on behalf of MS that do not have sufficient capacity to do so, laboratory support to outbreak preparedness and response, typing, production of advice and guidance, and assessments of laboratory capacity and microbiology technology available. In the field of influenza, the Community Network of Reference Laboratories for human influenza in Europe do not carry out external quality assurance and perform strain collection but are involved in all other activities. Conversely, the food and water borne diseases and zoonoses network performs external quality assurance but does not carry out assessments. Finally, an epidemiological framework for HIV incidence studies is under consideration, and activities have materialized so far just in a microbiology technology assessment.

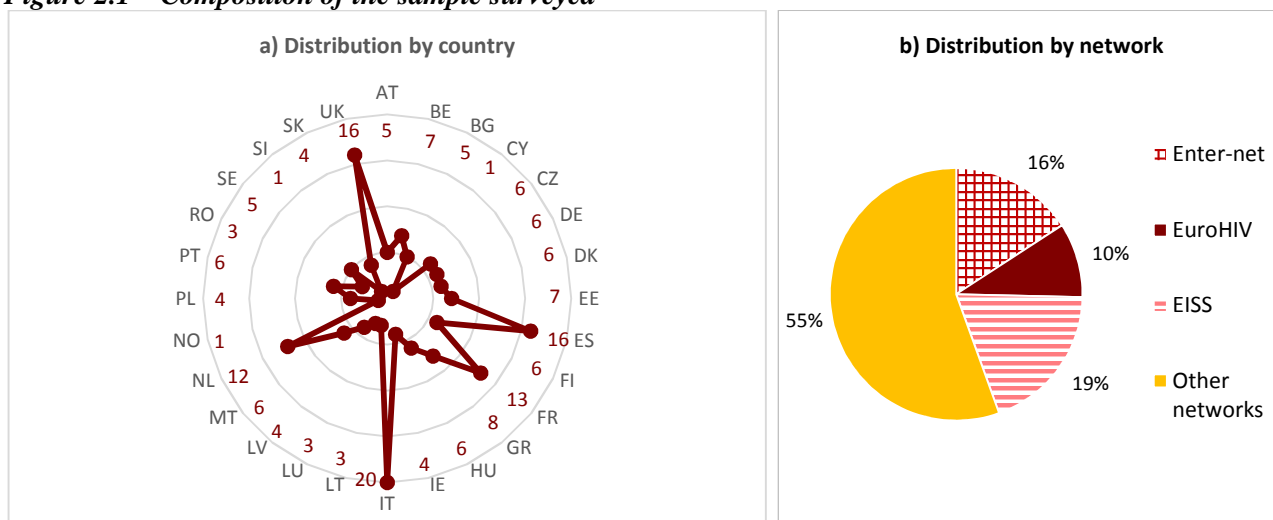
was under a framework contract. Surveillance has been one of the main responsible for delayed budgetary execution, but the share of funds disbursed on the total allocated has steadily increased from 15% to some 50% in the period considered.

2.2 Main Findings

2.2.1 Integration of former DSN.

The benefits and shortcomings of DSNs integration under ECDC have been assessed by triangulating the in-depth feedbacks collected through interviews with key informants and the results of the large-scale survey of current and former network members. The sample surveyed includes an overall 184 network members (30% of the total stakeholders surveyed), from all EU28 MS except Croatia and with the addition of Norway (Figure 2.1.a). Special focus has been placed on the networks corresponding to the three disease case studies selected for this evaluation, namely *Enter-Net* (for salmonella), *EuroHIV* (for HIV/AIDS), and *EISS* (for influenza). As illustrated in Figure 2.1.b, these network's members account respectively for 16%, 10% and 19% of the total experts surveyed.

Figure 2.1 – Composition of the sample surveyed



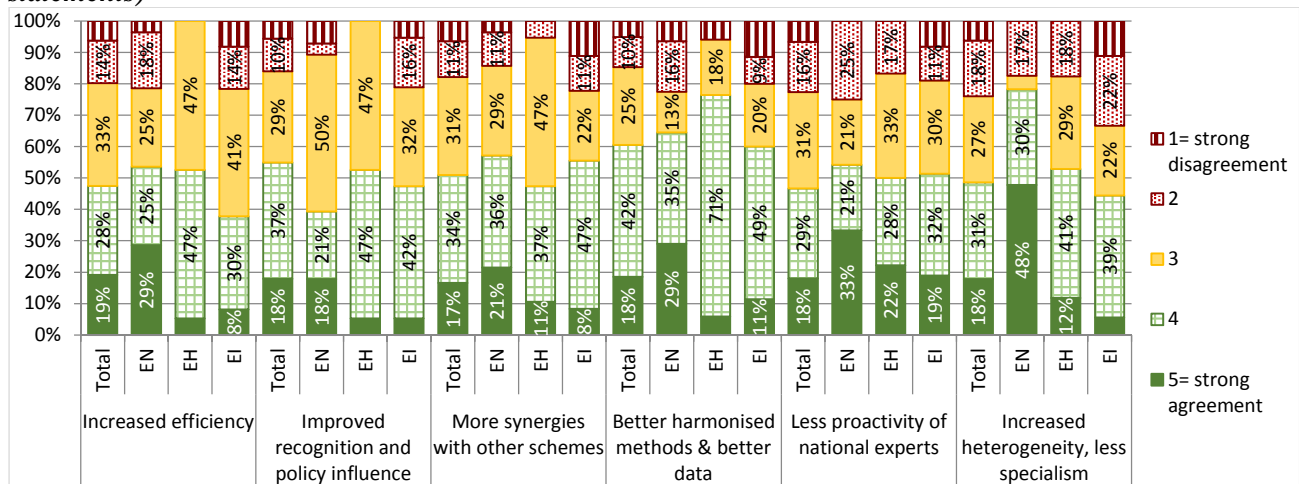
Note: Total headcount: 184. Figure (b): multiple memberships are possible.

The evidence collected on pros and cons of DSN integration returns a quite mixed picture, with perceptions that vary across networks, experts' profile, and nationality. The discontinuation of seventeen different hubs and their centralization into the ECDC responded to a logic of 'optimization' that seemingly none of stakeholders would challenge. The efficiency advantages of reporting all data to one single place are obvious, for both the reporting end (the MS sending surveillance data) and the receiving end (ECDC), although – as discussed further below – data submission and access still present numerous shortcomings. Significant advantages were perceived in terms of improved coordination with national surveillance systems as well as with WHO. However, for some respondents, the institutionalization of networks has inevitably increased 'bureaucracy' and "action appears limited to 'standard operating procedures'". The persistence of disparities in the working methods and rules followed by the various networks seemingly adds unnecessary complexity for participant bodies and moderates the advantages of integration. On the other hand, the transition under ECDC positively resolved the issue of financial long-term sustainability for networks.

Some issues were voiced with respect to the new networks' membership. First of all, it was reported that the enlargement to all MS – including 'low-capacity' ones - inevitably 'slowed down' the progress of work. Similarly, the exclusion of non-EU previous participants was seen in some cases as inappropriate. In some respondents' experiences, there have been drawbacks also due to changes in the participants' profiles, as well as to their reduction in numbers. Particularly, some believe that the unique mix of epidemiologists, microbiologists, clinicians and researchers characterising (some) previous DSN disappeared or was severely jeopardized, with ensuing detrimental effects to the quality of discussion. On the other hand, more than half respondents confirm that the systematisation of DSN improved their ability of making disease experts' voices heard by risk managers and policy-makers. This seems especially the case with the *EuroHIV* network.

The switchover to a centralised system entailed the 'merging' of separated networks into more comprehensive Disease Programmes (DP – see Section 10), with the ensuing reduction in specificity of participants, and a possible 'dilution' of competence. This issue appears particularly acute with the former *Enter-Net*, where it is reported by about eight in ten respondents. Dilution of competence is paired with the fact that, in some instances, members did not feel that the ECDC staff taking over the network coordination role had enough scientific competence and experience on the technicalities of subject matter, particularly on microbiological issues. So, on the basis of former DSN members feedbacks, it can be inferred that integration did not necessarily increase the scientific quality of discussion within the networks, and in some instances may conversely have negatively affected it. Finally, mixed views were registered also with respect to the operational management of networks by ECDC. While there is a widespread appreciation of the tools and procedures put in place to make the work more effective, some interviewees lamented a *de facto* take-over of priorities selection and agenda setting by ECDC, with network members ending up relegated to a more passive role (although this might vary from network to network). Again, more problematic in this respect appeared the transition from *Enter-net* to the FWD programme.

Figure 2.2 –Pros and cons of DSN integration (former participants' agreement / disagreement with selected statements)



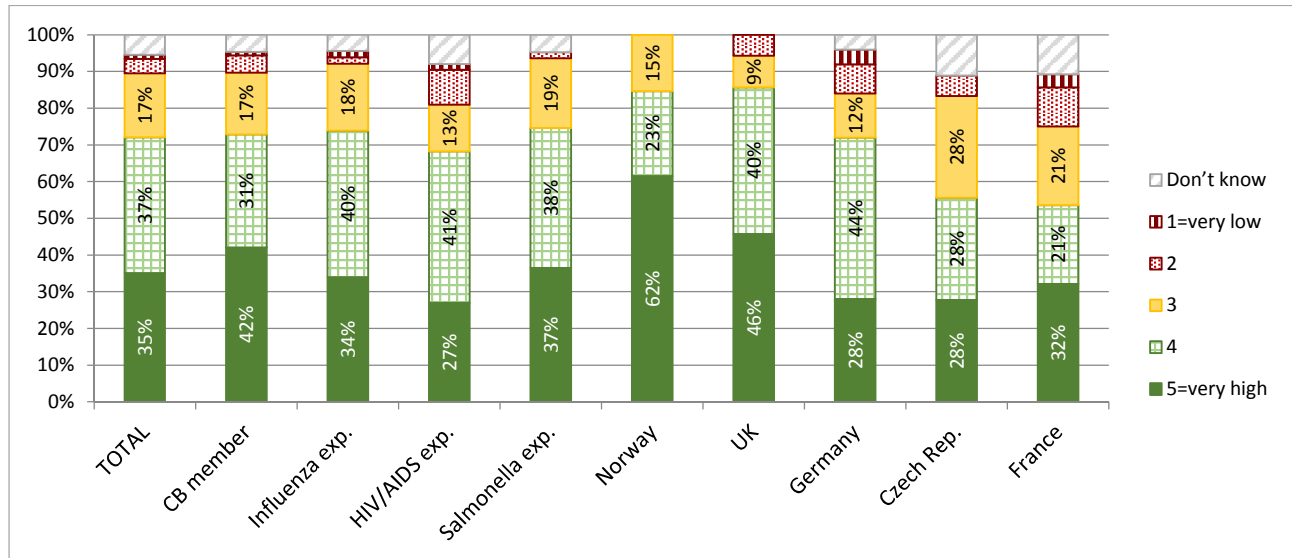
Note: EN=EnterNet; EH=EuroHIV; EI=European Influenza Surveillance Scheme (EISS)

2.2.2. Network operation, platforms and databases.

The work area that received the most positive ratings by stakeholders in terms of added-value is ECDC's support to networking and cross-country collaboration in the field of surveillance. According to 72% of the 459 stakeholders surveyed on this point, the added-value in this field is 'high' or 'very high' (Figure 2.3). Limited differences were observed across sub-groups, e.g.: (i) CB members'

ratings appear slightly higher than the average; (ii) salmonella and influenza experts expressed a somewhat higher feedback than HIV/AIDS experts; and (iii) positive rates are more frequent in countries like Norway and the UK, as well as in the Baltic region, while negative or ‘tepid’ feedbacks are comparatively more frequent in Germany, France, and the Czech Republic.

Figure 2.3 – Added-value of ECDC support to networking and cross-country collaboration in the field of surveillance.



Note: Total headcount: 459.

A more detailed assessment of the functioning of networks and the performance of ECDC in this area is provided in Section 10 below (for the three DP case-studies selected). The main focus of this section is instead on **TESSy** and the stakeholders’ appreciation of its performance and the various operational aspects concerning datasets’ collection, storage and analysis. Since an in-depth evaluation of **TESSy** is in the pipeline, in this report only the key findings about user’s satisfaction are discussed.

The coverage of **TESSy** and the comprehensiveness of its datasets have grown overtime, along with the DSN integration process and the general uptake of the system in the MS. The number of **TESSy**’s unique records has increased tenfold between 2008 (1.3 millions) and 2013 (11.4 millions). In the same period, geographic coverage has grown from 29 countries to 57, mostly because HIV surveillance for the European Region is now jointly conducted by ECDC and WHO/EUROPE, with **TESSy** as the database of reference. The statistics on numbers of users reported in the ECDC Director’s annual reports show an increase from 115 to 1,492 for the 2008-2013 period, but these figures do not seemingly take into account that very often the same national experts operate on **TESSy** for several diseases/topics. A different count based on ECDC’s CRM system indicates that ‘unique’ operators of **TESSy** (from EU and EEA countries) are much less, i.e. some 84 as of January 2014.

The establishment of **TESSy** system has undoubtedly rationalised surveillance data collection and treatment, offering experts a ‘one-stop-shop’ for data on a number of diseases. Seven in ten stakeholders rate positively the utility of ECDC support to EU-wide data integration through **TESSy**. However, responding to data request for **TESSy** is by far the most burdensome task required by ECDC to its MS partners. Some 70% of respondents surveyed consider such burden ‘high’ or ‘very high’, with no significant differences across sub-groups. Most of the burden evidently concerns data collection and the treatments required to comply with metadata definitions. Also, uploading data on **TESSy** requires some efforts since it is not (yet) a machine-to-machine system; moreover it entails a duplication of work (inserting data both in the national system and in **TESSy**) and therefore a greater

probability of errors. Some also reported avoidable duplications due to lack of coordination with WHO/EURO, resulting in multiple requests for the same or slightly different data. Other relevant problems voiced include *inter alia* the sheer amount of indicators to be collected, which for some stakeholders is excessive (but no clear indication emerged on datasets or variables considered irrelevant or with little value-for-money), and the possible mismatch between TESSy and the domestic definition of certain variable with respect to regional breakdown, which requires burdensome re-classification work. On the other hand, it is worth highlighting that in some instances TESSy had a ‘demonstration effect’, and its metadata and variables have been adopted for domestic-level surveillance by countries that did not use them before. Obviously, the relevance and utility of specific datasets vary across countries according to the different public health priorities. In general, the NFPs for surveillance seem satisfied with the discussion and the mechanisms for selection of priorities. More problematic in this respect are the quite frequent modifications of the variables’ ‘catalogue’ – as seen, an average of 16 changes per year - that cause extra efforts to MS for updating their data collection and classification systems.

Technically speaking, the design of the system does not pose significant problems to users. Only few complaints were voiced about the complexity of the uploading procedures, the need for more training (due to frequent changes of metadata) and some delays in following up to requests for assistance. More significant have been TESSy’s gaps on the side of ‘restitution’. As noted by various users, the system is conceived to exchange information between MS and ECDC, but for most of the period covered by the evaluation the flow was essentially ‘one-way’ from MS to ECDC. Many stakeholders expressed the need to have more and better access to TESSy data and better functionalities to support analyses.²⁷ As seen above, over the years ECDC has adopted specific SOP to manage and streamline access to data. The positive effects are seemingly being felt and in 2013 the amount of requests for information exceeded 90 in a year.²⁸

To sum up, stakeholders tend to consider the burden imposed by TESSy as sizeable and partly inevitable, and its ‘acceptability’ as conditioned to the magnitude of benefits it may bring, which in the period under analysis was limited, due to issues with data quality and comparability described in the next section. However, the improvements that occurred overtime were perceived and acknowledged by stakeholders. Moreover, strategic indications towards a possible simplification have already been included in the newly approved Long-term Surveillance Strategy 2014-2020. These take into account the increasing resource constraints faced by network partners.²⁹

2.2.3 Quality of surveillance data.

The availability of good quality and reliable surveillance data supporting decision-making (‘information for action’) is the main goal of the surveillance system put in place by ECDC and the ultimate justification for its burden on MS. Overall, there is no hesitation among stakeholders in recognising *a priori* the importance and added-value of having access to EU-wide surveillance datasets. The potential uses of such data are manifold and are not limited to monitoring but encompasses also the assessment of policy outcome and more generally the support to evidence-based

²⁷ As shown during Contractor’s meetings at ECDC premises, an online dashboard with several functionalities is being developed and will reportedly be implemented soon (some are already accessible at the time of writing)

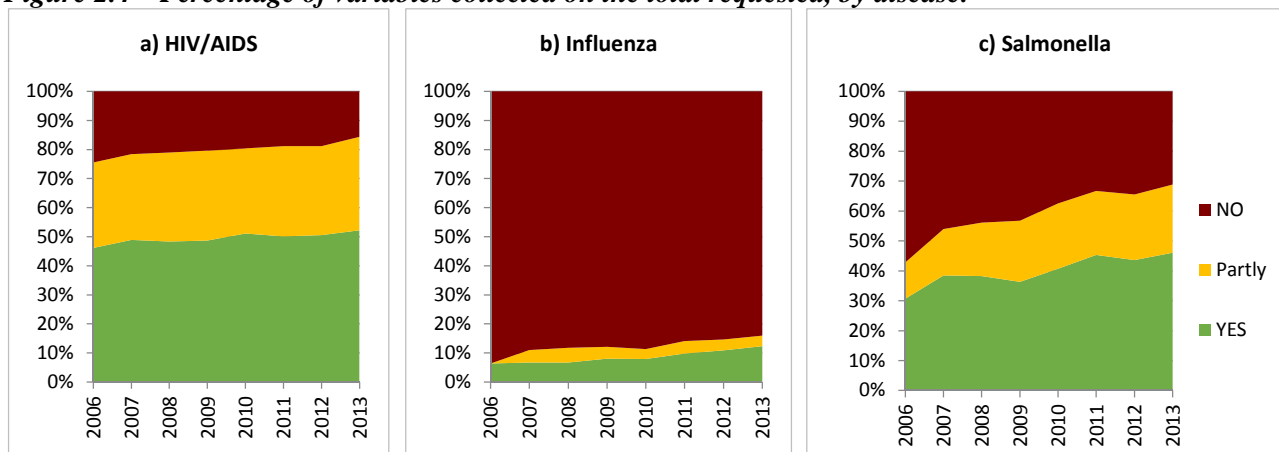
²⁸ Data on the request for information received in the past years were not available.

²⁹ “In these times of economic pressure, many Member States are facing cuts in vital resources such that they are no longer able to carry out more than the minimum surveillance. It is therefore of paramount importance that plans for any further development of EU surveillance activities over the next few years are kept realistic and do not add any burden to already stretched country resources”. <http://www.ecdc.europa.eu/en/publications/publications/long-term-surveillance-strategy-2014-2020.pdf>

public health. To these ends, data evidently need to be comprehensive, standardised and reliable, and this is where problems lie. Over the 2008 – 2012 period, there have been improvements in the quality of data stored in TESSy and published by ECDC³⁰ but more needs to be done by all parties (ECDC, MS and the EU policy-makers) to make the system fully exploitable. A set of criteria has been used here to analyse the matter.

- **Completeness.** Despite improvements, there persists gaps in datasets due to some countries not submitting or submitting incomplete data. This seems mostly due to budgetary constraints and/or low capacity of the national surveillance system. In this sense, data completeness falls outside of the direct responsibilities of ECDC, whose possible contribution is limited to further streamlining data submission procedures through TESSy. Incomplete national data obviously may jeopardise the utility of the overall datasets for aggregated analysis purposes. However, positive trends have been registered: as shown in Figure 2.4, in the areas of the three disease case-studies there has been a steady increase in the share of variables reported by MS on the total requested.³¹ As it can be seen, there have been improvements in all fields although in the case of influenza full reporting is far from being achieved.³²

Figure 2.4 – Percentage of variables collected on the total requested, by disease.



Note: “Yes” indicates that 100% of cases for a given variable in a given MS were reported; “No” indicates that there is no reporting on a given variable in a given MS; “Partly” indicates that only a percentage of cases for a given variables in a given MS were reported. Source: ECDC *Completeness Report* (not published).

- **Internal quality assurance.** Once surveillance data are submitted by MS through TESSy, they undergo a ‘cleaning’ and internal validation process. The procedure consists of two main steps. The first step is a (automated) check intervening during the upload process able to detect errors and inconsistencies before data are inserted in the database. Since data are still uploaded manually, material errors are frequent. The TESSy meta-dataset defines the validation rules for all variables, i.e. the format and the consistency checks that data need to comply with. The validation rules have been updated on a quasi-yearly basis in the period concerned. Once submitted, the system sends back the uploaded data to MS for review and – in case - corrections. This mechanism was introduced in 2009 and helped greatly improve the quality and streamline the review process. The second step consists of an expert validation of uploaded data prior to and

³⁰ Interviewees with longer historical recollection reported that at the beginning there were often ‘macroscopic’ issues with the consistency of data collected as well as with the statistical treatment and analyses published by ECDC, which made them almost useless.

³¹ Source: ECDC completeness reports.

³² The analysis uses the number of variables actually reported as a proxy for the overall completeness. This indicator obviously does not take into account the varying importance of the variables measured and/or the actual accurateness of the data reported.

with a view to support analysis and reporting. The scope and extent of expert validation has enlarged overtime, in order to cope with more structural incoherencies in the data reported by the different MS, which hampered their aggregated analysis. Expert validation criteria are disease-specific and are laid down in the corresponding *Technical Analysis Plans*. The SOP for surveillance report production adopted in 2012 further elaborates on data cleaning for analysis and reporting purposes, distinguishing two steps: (i) the data validation according to validation checklist (defined in the Reporting protocol and Analysis plan); and the (ii) data validation by running analysis scripts.

- **Quality at MS level.** Another relevant dimension of data quality assurance is the external one. In this area, it is worth signalling the project run by ECDC since 2009 devoted to improving the quality of data collected by the MS domestic surveillance systems. The project consisted of a mapping of national systems for data monitoring and Quality Assurance (QA), and the development of a toolset (e-library) and a manual intended to guide national experts through these processes³³. The project – originally set to end in 2011 – is still ongoing. A first version of the manual was released in November 2013 and is expected to be published in the near future. The third and last phase of the project consists in conducting a pilot study to evaluate the use of the manual in three Member States. The final aim is to promote a common approach to monitoring the quality of surveillance data ‘at the source’, so as to have better and more comparable data downstream in TESSy. There has been one country (LV) that reportedly used the ECDC’s tool to improve its capacity in surveillance and response activities. Such country was also the subject of a ‘country assessment visit’ carried out in 2011 upon request from the local authorities, with the aim of reviewing the domestic general surveillance and early warning system.³⁴

As concerns the possible effects of the support provided by ECDC to the improvement of national system, a before / after analysis has been conducted to compare the changes occurred in the MS surveillance systems between 2008 and 2011, with reference to selected diseases.³⁵ In the case of HIV/AIDS, two MS moved from a voluntary-reporting system to a compulsory one, one country switched from aggregated reporting to case-based reporting and one more country started submitting laboratory data. As concerns salmonella, one country passed from comprehensive coverage to sentinel-based reporting simultaneously switching from passive to active surveillance. Moreover, one country added hospitals to reporting entities and another one added physicians.³⁶

- **Comparability.** In connection with the two points above, the data quality and the different methods and systems in place in the various MS to define, organise, collect and check surveillance data ultimately affect cross-country comparability and pose serious obstacles to data aggregation and the significance of analyses. For instance, the completeness and reliability of MS indicators vary immensely whether data are collected and reported mandatorily or voluntarily, or whether the source is population surveys or laboratory data. It took several years to come to agreed case-definitions for all diseases covered by the European surveillance system. Such definitions are laid down in the EU regulation by means of subsequent EC Decisions.³⁷ This is expected to solve the

³³ ECDC, “Manual for monitoring data quality and evaluation of surveillance systems Working group surveillance systems quality”, November 2013

³⁴ ECDC, “Surveillance and early detection and response systems in Latvia. Mission Report. 26–30 September 2011”.

³⁵ More recent data are not available at the time of writing.

³⁶ Sources: Annual Epidemiological Report (AER) 2010 (reporting on 2008 data) and 2013 (reporting on 2011 data).

³⁷ See: Commission Decision of 28 April 2008 amending Decision 2002/253/EC laying down case definitions for reporting communicable diseases to the Community network under Decision No 2119/98/EC of the European Parliament and of the Council, as well as the latest updates laid down in EC Implementing Decision 2012/506/EU.

major issue, which in one respondent's words consists of “*what is 'positive' in a country, may be 'negative' in another*”. However, the degree of implementation of harmonised case-definitions is reportedly still incomplete. On the top – as seen in the previous section – there persist significant differences in the data collection and quality assurance systems of MS, which various stakeholders complain are not sufficiently explained and elaborated upon in the TESSy datasets and in the related outputs. Unless sources and methods are properly documented, the aggregation and comparison between countries based on sheer ‘number of cases’ can lead to serious errors. ECDC may also facilitate TESSy users not only by describing in greater detail the characteristics of the data reported, but also actively signalling cross-country comparability or lack thereof.

In this respect, it is worth to mention the high appreciation received by the point prevalence surveys (PPS) for healthcare associated infections and antimicrobial resistance rolled out by ECDC in 2011-2012³⁸. This results are viewed as very useful for the immediate comparability of data, and the survey is regarded by many as an example of added-value activity that ECDC should replicate.

- **Timeliness.** As discussed further below with respect to reports, another major factor that severely hampers the utility of ECDC datasets and statistical analyses, is the delay that occurs in the publication of reports or in making datasets available to stakeholders. For instance, the *Annual Epidemiological Report* (AER) provides indicators dating back of two years, but also online data publication is not timely. More timely data publication was the issue most frequently voiced by survey respondents when asked about needs and priorities for improving the surveillance system in place (mentioned by more than one in ten respondents). In particular, it emerged that experts from ‘high capacity’ countries (e.g. UK, DE, FR) tend to be more concerned than others with the delays in data publication.
- **Usefulness.** The various issues mentioned above inevitably affect the usefulness of the overall surveillance system put in place by ECDC. While integration and centralisation of DSNs under ECDC has stimulated the convergence and the adoption of common quality standards, the concrete use of TESSy data for benchmarking, analysis of trends and the like has still to face serious limitations. On this point, it is however worth mentioning that there have been improvements in the explanation of countries’ specificities (and corresponding limitations in the use of data), which allow to deal more consistently with data aggregation and comparison (which would not be the case if users had to directly access the databases of national PHIs in local languages). Secondly, some experts pointed out the added-value of the system in the field of rare diseases, where EU-level aggregation helps creating richer databases of cases to be used for investigation and research purposes.

Future perspectives appear mixed. Some stakeholders maintain that, since comparability is set to remain a complex issue - irrespectively of ECDC efforts - ECDC should refrain to set ambitious goal and invest excessive resources in sophisticated data collection and analysis tools. On the other hand, others believe that ECDC should further encourage harmonisation across MS, by putting more effort in developing an evidence-based approach on the matter, i.e. demonstrating the scientific and practical benefits of harmonisation, while carefully assessing the burden for MS of the proposed methods and solutions.

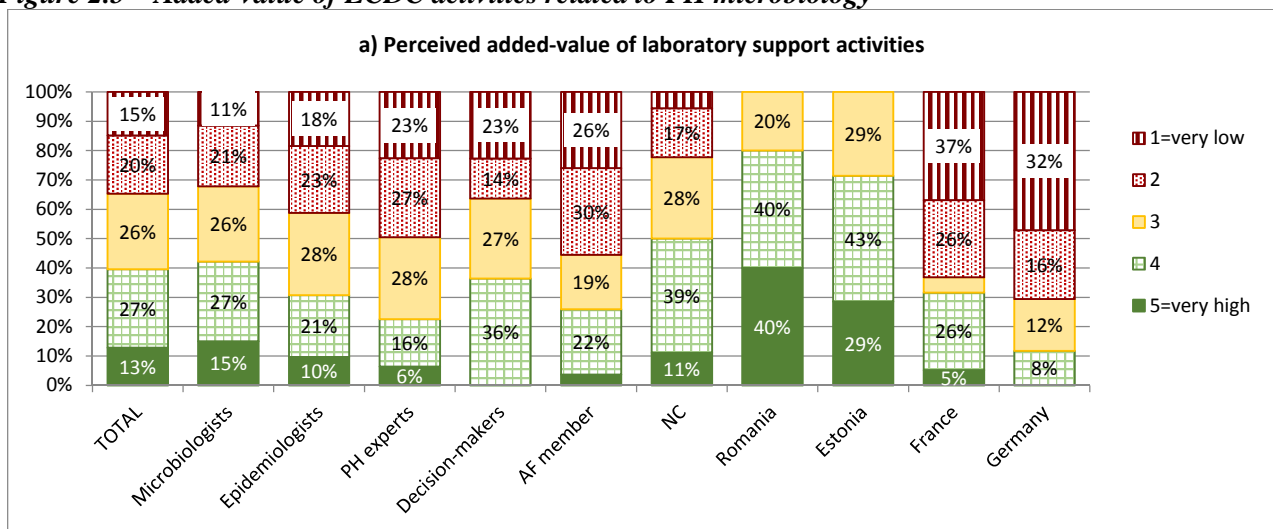
³⁸ http://www.ecdc.europa.eu/en/publications/_layouts/forms/Publication_DispForm.aspx?List=4f55ad51-4aed-4d32-b960-af70113dbb90&ID=865

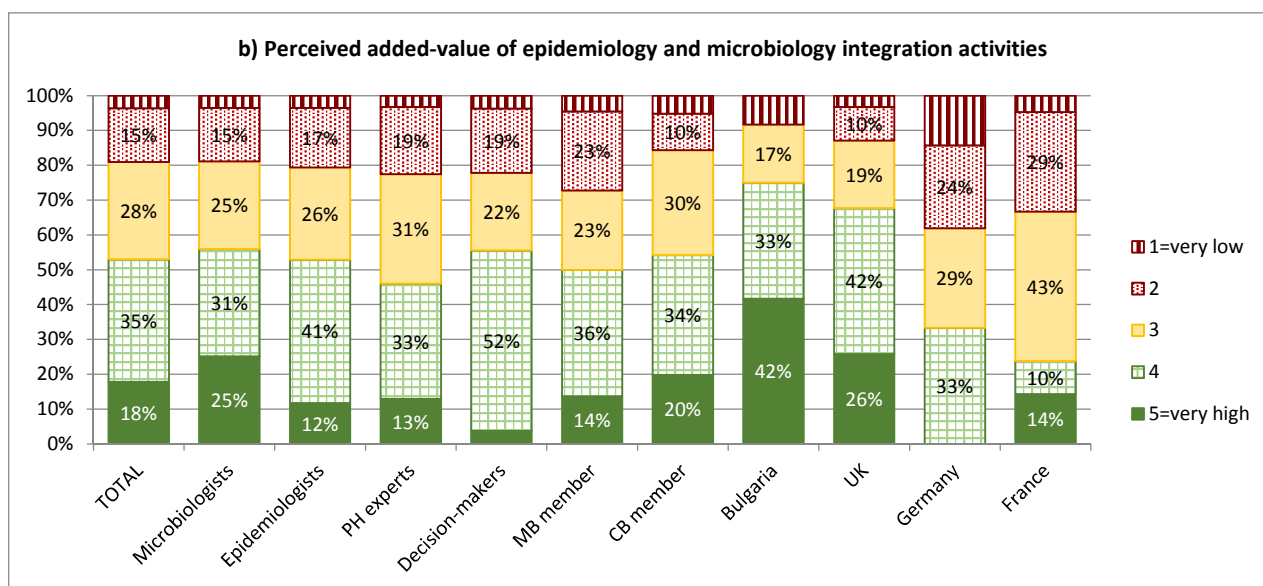
2.2.4 Public Health Microbiology

Until 2012, ECDC did not have a fully-fledged and well-structured strategy for PH microbiology. The activities carried out in the 2008-2012 period in this field were mostly of exploratory and preparatory nature, and oriented at both building the Centre’s internal expertise and ‘mission’ (considering that ECDC does not have laboratory capacity) and supporting outsourced pilot projects involving laboratory networks. The extent of ECDC budget spent in this area is however significant, for instance lab-related activities in 2012 amounted to the bulk of expenditure for procurement under the Influenza, FWD, and EVD programmes and in excess of one-third for the VPD programme and the overall scientific advice activities. This does not compare too favourably with the perceived added-value of such activities by stakeholders, and in particular with the perceived added-value of laboratory support (Figure 2.5.a). As further discussed in Section 11, in comparative terms this is the least-appreciated area of ECDC work. However, two caveats apply: (i) it is also the least known area: some 32% of stakeholders declared to be not sufficiently familiar with these activities to express a judgment (while ‘don’t know’ answers in the other work areas amounted to some 13% on average); so, there appears to be a clear need to better communicate the purpose, the modality and the outcome of lab support; (ii) the feedbacks on lab support appear highly ‘polarised’, with views that vary significantly across respondents’ profile, position and nationality. Microbiologists are – quite unsurprisingly – the most positive about the utility of supporting laboratories, while the majority of PH experts are negative in this respect. Significant differences have been registered also between the positions of AF members – who are very critical on lab support activities – and national coordinators – who instead attribute high added-value to such activities. Geographic differences are also marked, possibly reflecting the disparity of capacity and hence the different degree of benefits that national systems may receive from ECDC support.

On average, the added-value attributed to activities facilitating the collaboration between epidemiologists and microbiologists is higher, but still on the ‘low-end’ as compared to other work areas. The share of positive feedback in this area is 44% - much smaller than the 72% of positive feedback on the overall Centre’s added-value. In this case, awareness levels are in line with other ECDC’s activities and the variations across subgroups are smaller (Figure 2.5.b). Again, microbiologists are the most encouraging, but also the majority of decision-makers at various levels consider such integration and collaboration as particularly useful.

Figure 2.5 – Added-value of ECDC activities related to PH microbiology





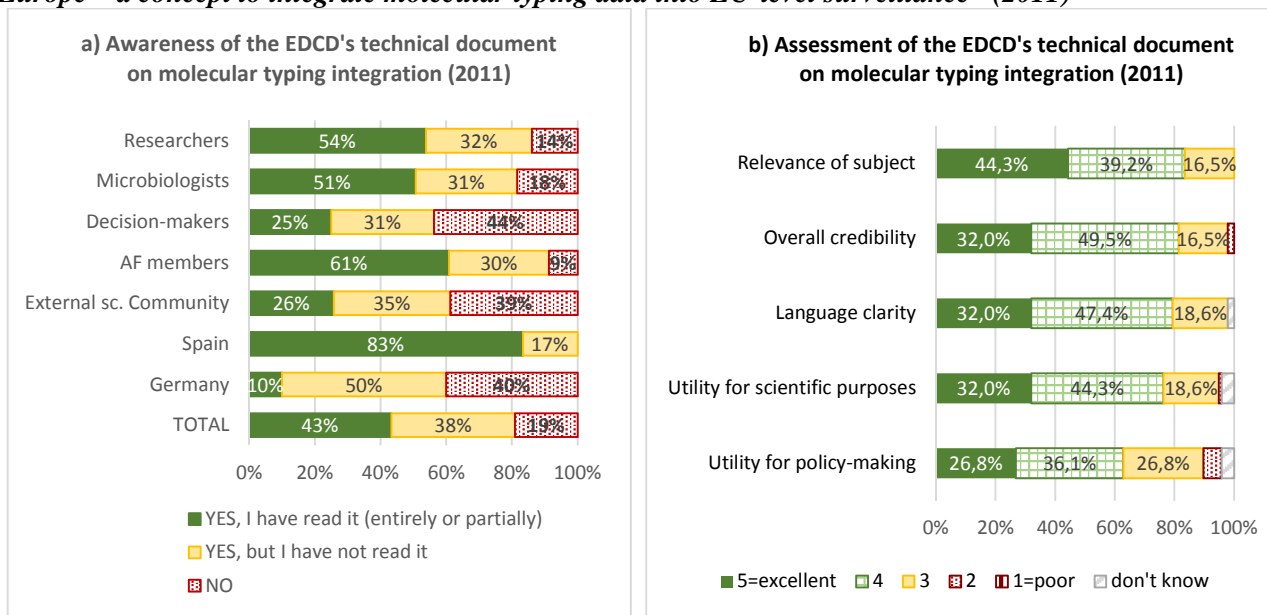
Note: Total headcount: 459. ‘Don’t know’ answers are not displayed (respectively 148 for (a) and 76 for (b)).

The support to molecular typing and the corresponding data integration into surveillance datasets have been a key priority for ECDC in the concerned period. A concept document was prepared in 2011³⁹ and a proper ‘road map’ was later released setting out a comprehensive 5-years strategy for molecular surveillance implementation.⁴⁰ The concept document on molecular typing integration has been selected in this evaluation to test stakeholders’ awareness and appreciation of concrete outputs of ECDC work. The test involved only potentially ‘acknowledgeable’ stakeholders, i.e. microbiologists and/or experts holding relevant positions as NFP, OCP, or AF members. The results, summarised in Figure 2.6.a below, show that such document was read by less than half potentially interested targets (43%). In particular, it raised the interest of researchers, while decision-makers resulted largely unaware of its existence. The document was particularly read by experts from the Mediterranean area (Spain, and to a smaller extent Greece, Cyprus and Portugal) and went largely unnoticed in German-speaking countries and France. Readers’ feedback on the document seems largely positive (Figure 2.6.b). This regards especially the relevance of the subject, which is ‘high’ or ‘very high’ for more than 83% of experts surveyed. Also the credibility of the contents of the publication and its clarity are considered very positive. Instead, the actual usefulness is rated comparatively lower, and especially as far as policy-making is concerned (63% of positive ratings).

³⁹ ECDC, “Surveillance of communicable diseases in Europe – a concept to integrate molecular typing data into EU-level surveillance”, 2011.

⁴⁰ ECDC, “Road Map for molecular surveillance implementation (2012-2016)”.

Figure 2.6 – Stakeholders’ review of the Technical Document “Surveillance of communicable diseases in Europe – a concept to integrate molecular typing data into EU-level surveillance” (2011)



Note: (a) headcount=226. (b) Questions posed only to those who have read the document (headcount= 97)

The implementation of activities was generally outsourced to consortia supporting network members, not without some complexity.⁴¹ The various networks differ as to the range of activities implemented⁴² and the involvement of ECDC in their coordination. On top of that, there is a network of national microbiology focal points who were initially appointed for strategy definition purposes. The work on the quality and comparability of microbiological data was mainly carried out by means of guidance, technical assistance and the voluntary external quality assurance (EQA) exercises. It is

⁴¹ The ECDC MAP, 2007-2013 envisages the integration of laboratory data into TESSy including data derived from molecular typing and the strengthening of microbiological support. This was to be done through a series of approaches, ranging from networking with professional organisations and national laboratories to developing core competencies and unified molecular typing schemes, developing directories of national reference laboratories mapping capacities, developing training schemes, promoting EU-wide quality assurance systems for microbiological laboratories, analysing the needs for improved diagnostic technologies and reinforcing links between human and veterinary laboratories. Over the past 5 years, all these approaches have been implemented to different degrees. In 2008, ECDC first started with a 2-year fellowship for training in Public Health Microbiology, strongly linked to the established EPIET training network. The General Strategy and Framework of Actions for ECDC Cooperation with Microbiology Laboratories and Research Institutes in the EU (2007-2013) was then established by a forum of National Microbiology Focal Points. The EU situation was analysed and the NRL systems for CD in the MS were mapped. Stakeholders were consulted on laboratory quality systems, biosafety and biosecurity and efforts were joined with professional organizations to promote good practice in this area across the EU. A consensus definition of public health microbiology and core public health functions of national reference laboratories was published. Based on a mid-2011 survey of ECDC microbiology activities, 13 DSNs supported by ECDC currently have a microbiology component, comprising 21 ECDC-funded projects on 22 diseases outsourced to the MS. Of these, 11 projects integrate molecular typing data for surveillance on 16 pathogens. In addition, there are 12 ongoing external quality assessment schemes including 23 pathogens and 14 laboratory training projects on diagnostic testing, antimicrobial susceptibility testing and molecular typing.

⁴² These might variously include on a case by case basis: coordination of network activities, provision of external quality assurance, provision of training, strain collection, supranational reference services also implementing testing on behalf of MS that do not have sufficient capacity to do so, laboratory support to outbreak preparedness and response, typing, production of advice and guidance, and assessments of laboratory capacity and microbiology technology available. In the field of influenza, the Community Network of Reference Laboratories for human influenza in Europe do not carry out external quality assurance and perform strain collection but are involved in all other activities. Conversely, the food and water borne diseases and zoonoses network performs external quality assurance but does not carry out assessments. Finally, an epidemiological framework for HIV incidence studies is under consideration, and activities have materialized so far just in a microbiology technology assessment.

generally considered that these exercises have contributed to reassure about the quality and comparability of data and improve reporting standards (see Section 5.2.3). The various sets of EU case definitions adopted so far and in particular the 2008 one - relevant for this evaluation - have generally included laboratory criteria to confirm a case, although there are different trends in confirmed cases among diseases and countries.⁴³ Just in the case of avian influenza, confirmation is officially required from a laboratory participating in the EU Community Network of Reference Laboratories for human influenza (CNRL). In other cases this is not mandatory, and there are actually very few diseases and countries reporting data confirmed by ECDC National Reference Laboratories only (e.g. tuberculosis).

The integration of microbiological laboratory data into surveillance data has therefore been limited by the following factors: (i) most but not all MS have made reference to the EU 2008 case definition for their reporting purposes, and most importantly in the interviewees' judgment, (ii) there are MS where laboratory-confirmed cases with unknown clinical criteria, or without clinical criteria, are not reported because the legislation allows certain forms of notification only - typically from clinicians or hospitals - and does not envisage that laboratories may directly report cases for epidemiological purposes. In other words, there are situations where cases are well known by the local scientific community and sometimes even by the ECDC, but such cases are not included in the official records.

Since the contribution of microbiological laboratory data for routine surveillance has been so far limited by the legal factors above, such data have sometimes been used for so-called enhanced surveillance (FWD diseases, TB). In particular, laboratory-based enhanced surveillance has been introduced in the 2008-2012 period to better monitor the trends in invasive pneumococcal disease⁴⁴ (IPD) serotypes, especially in those not covered by the vaccine, together with data collection for enhanced surveillance of other invasive bacterial diseases, haemophilus influenza and meningococcal disease⁴⁵.

Other experts reported that earlier / better detection of threat was spurred by integration of microbiological data with epidemiological ones in various other cases, such as: (i) Salmonella Stanley (2012) and (ii) the AH1N1 influenza pandemic (2009). Some noted that ECDC could have played an even stronger advocacy role, although by far the outstanding issue remains the uncertainties and conflicting views related to the establishment of a European Networks of Reference Laboratories. A need for stronger ECDC coordination and greater involvement of its microbiological unit for the harmonisation of laboratory support activities has also been reported.

All in all, according to the experts surveyed the impact of ECDC activities in the field of microbiological surveillance have been felt especially in terms of better harmonisation and standardisation of methods and data, allowing more cross-country comparability (Figure 2.7). This

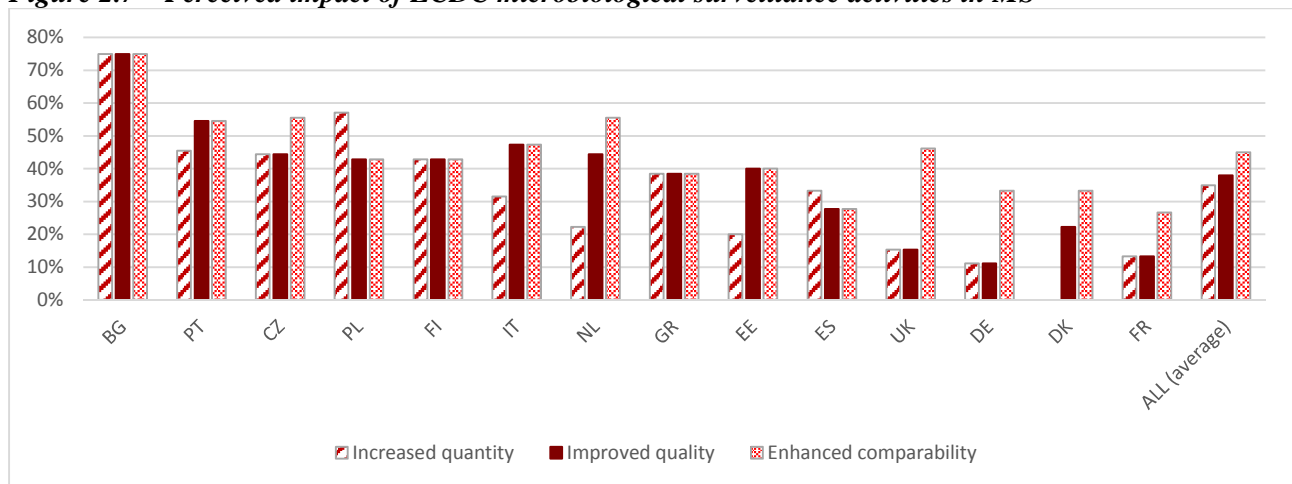
⁴³ For instance in the field of tuberculosis the overall trend in case confirmation by culture, nucleic acid detection and sputum smear has steadily increased since 1995

⁴⁴ There is a wide heterogeneity of IPD surveillance systems in the EU, particularly in the type of surveillance systems in place, their coverage and the case definition used; while in some countries there are no surveillance systems in place

⁴⁵ The current situation is as follows: influenza sentinel virological surveillance is routinely implemented by all MS, together with data on antiviral resistance (see case study above); salmonella serotypes are now routinely reported by all MS and comparable although with limitations as to the granularity of coverage and its significance (see case study above); almost all MS but two report Escherichia Coli STEC/VTEC serotype data; multidrug resistant and extensive drug resistant tuberculosis, although with patchy and often inconclusive reporting patterns; haemophilus influenzae serotypes are reported by 24 countries, while another four recur to sentinel surveillance which is not strictly comparable. This was started in 2010; invasive meningococcal disease serogroups are reported by almost all MS. This was also started in 2010; invasive pneumococcal serotypes are reported for 74% of all confirmed cases by 23 MS. Data on antimicrobial susceptibility testing are submitted by 18 countries. This was started in 2010

seems largely the outcome of the various projects promoted and of the other forms of support to networks. Improvements in the quality of data were also registered especially in countries of Eastern and Southern Europe. This appears also connected with the positive reviews received by EQAs and other training activities. The area where impact still lags behind regards the sheer amount of microbiological data available. Given the often ‘pilot’ nature of the initiatives supported, little improvements were registered as regards the quantity of molecular surveillance data collected and submitted, and – again – especially in Southern and Eastern Europe.

Figure 2.7 – Perceived impact of ECDC microbiological surveillance activities in MS



Note: The figure displays the percentage of respondents reporting a ‘high’ or ‘very high’ impact in a given area. Total headcount: 220. Data are shown only for countries accounting for more than 3% of total headcount.

In various instances, ECDC operated to facilitate interaction and exchange of information between epidemiologists and microbiologists by organising joint sessions of the respective network meetings or in the framework of training activities. This reportedly was at the beginning of the period considered, and going through some ebbs and flows, it gained further momentum in the last few years. The effort is generally appreciated as particularly appropriate and it is only regretted that budgetary constraints have limited its implementation to a restricted number of sessions. However, this has mainly remained limited to the public sphere. At a strategic level, it is recognised that little could be done to address the decreased interaction between microbiologists and epidemiologists following consolidation of microbiology services into large private laboratories and new fresh thoughts would be needed to approach this growing trend. More generally, some considers this as an internal issue for MS, where ECDC has limited power to act.

In perspective, there seems to be the need to better demonstrate the usefulness or results in this area and the efficiency of the work. There is general consensus on the fact that laboratory techniques and protocols will change radically in the coming years and inevitably new molecular characterisation methods will gain momentum⁴⁶. On the one hand, this process is set to dramatically change surveillance systems (at least for certain diseases), on the other hand the uncertainties and the costs

⁴⁶ Microbiological and drug resistance screening tools are a fast-moving field and new products are now even reaching the point-of-care diagnostic market. It is anticipated that whole genome analysis has the potential to uncover novel markers of virulence and drug resistance. This will pose a challenge to national reference laboratories in terms of access to training and external quality assurance schemes for novel microbiological technologies to ensure comparability of data used for EU surveillance and MS access to routine and emergency diagnostic and reference laboratory services to detect, identify, characterize and subtype human pathogens of public health significance, either locally or through cooperative agreement. Several EU exercises of national public health microbiology capacities particularly the EURLOP project have already mapped a diversity of models for reference laboratory service provision and identified areas for improvement, but this faces financial constraints in health services, shortage of trained medical specialists.

of innovation are always significant, so resistances and disparities are anticipated. In this area there is potential added-value for ECDC to closely support this process, by conducting scientific assessment of new methodologies, analysing costs and benefits, contributing to their uptake e.g. by disseminating evidence, developing guidelines, implementing pilot projects etc. At the same time, it is important that in the field of molecular surveillance ECDC advances on a 'double track', i.e. investing on state-of-the-art technologies, but without neglecting 'basic' laboratory capacity issues that affect various MS. Overall, various stakeholders consider the financial burden of the ECDC microbiology activities in a period of shrinking PH budgets as not sustainable, even for affluent countries. Reducing the overall expenditure (and in broad sense the commitment) under the microbiology programme seems an option to be considered.

2.2.5 Reporting and dissemination.

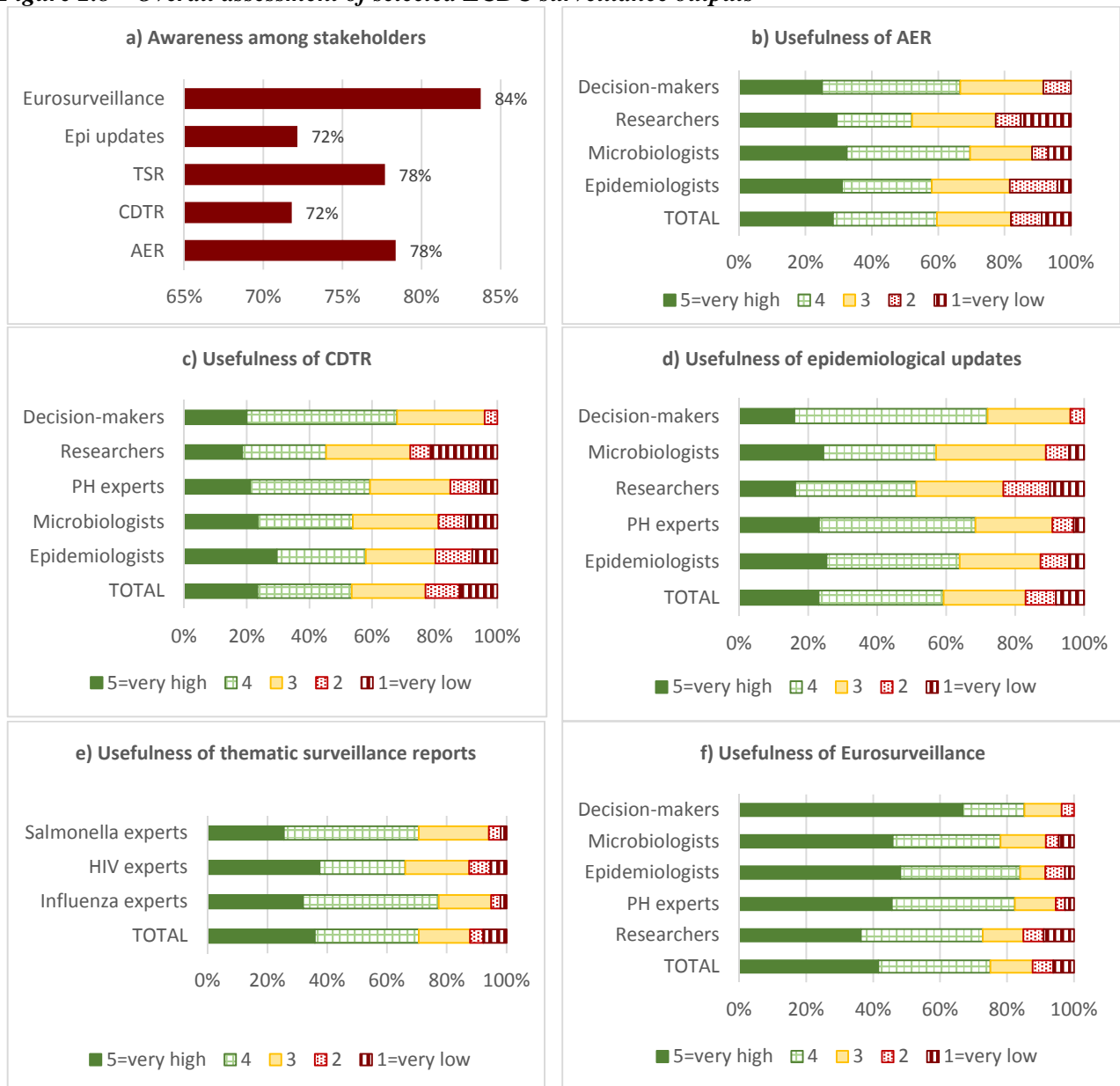
The question on whether ECDC effectively communicates the output of surveillance activities to stakeholders raised mixed and sometimes conflicting views. Obviously, since the range of different surveillance products is vast a 'catch-all' judgment is of limited significance. The answer to this question is therefore provided in this section in two main parts: (i) the first part analyses a selection of the main 'types' of report produced by ECDC with special focus on awareness and usefulness for readers; (ii) the second part focuses more closely on the main periodic output published by ECDC for the three disease case-studies selected for this evaluation. With respect to the first part, the results of the survey are provided in Figure 2.8 below and can be summarised as follows:

- The *Eurosurveillance* publications are possibly the most popular ECDC outputs in the field of surveillance. They are known by nearly 84% of stakeholders, and the awareness rate is high also among the external scientific community, where it reaches 65%. With nearly 73% of positive or very positive feedback, Eurosurveillance emerged also as the most useful product. Despite being mainly a scientific publication, its utility is rated more positively by decision-makers (62% of 'very high' ratings) than researchers ('only' 26% of 'very high' ratings).
- The *Communicable Disease Threat Report* (CDTR) appears instead the least known and used by this sub-set of respondents, but it is important to keep in mind that CDTR is more an epidemic intelligence product than a surveillance product and it is more popular and appreciated by risk managers and in general by stakeholders more directly involved in preparedness and response activities.
- The periodic '*Thematic Surveillance Reports*' related to the various diseases are quite popular (78% of awareness) and appreciated (70% of positive ratings). Appreciation seems, unsurprisingly, somewhat higher among epidemiologists and decision-makers. However, in the case of TSR, judgments need to differentiate between diseases and products. In this respect, the results for the three disease case-studies considered indicate that influenza reports are the most known (90% of aware respondents) and appreciated (77% of positive ratings on usefulness); while HIV/AIDS report are both the least known (79%) and appreciated (65%).
- The *Annual Epidemiological Report* (AER) is - after some *Eurosurveillance* special issues - the ECDC's product distributed in the greatest number of copies (ranging from 2,500 to 3,000 per edition). It is also the most comprehensive output of surveillance activities. It is therefore not surprising that AER is quite well known among stakeholders, but awareness level is skewed, with ECDC partners and direct stakeholders very much aware of AER, while the external scientific community far less so (43% of this sub-group is not aware of AER). The perceived usefulness is positive but comparatively lower than for other products. This appears largely a consequence of delays in the publication. The AER for a given year N contains data referring to year N-2, and is

sometimes published in year N+1. Irrespectively of any consideration on quality, this makes the information provided in AER poorly usable.

- The *epidemiological update* is an output published since 2011 that provides a quick update on the progress of outbreaks that ECDC is monitoring. Epidemiological updates are in general among the less popular documents, appreciated especially by decision-makers and PH experts who are responsible for outbreak control. Their utility also varies greatly across countries.

Figure 2.8 – Overall assessment of selected ECDC surveillance outputs

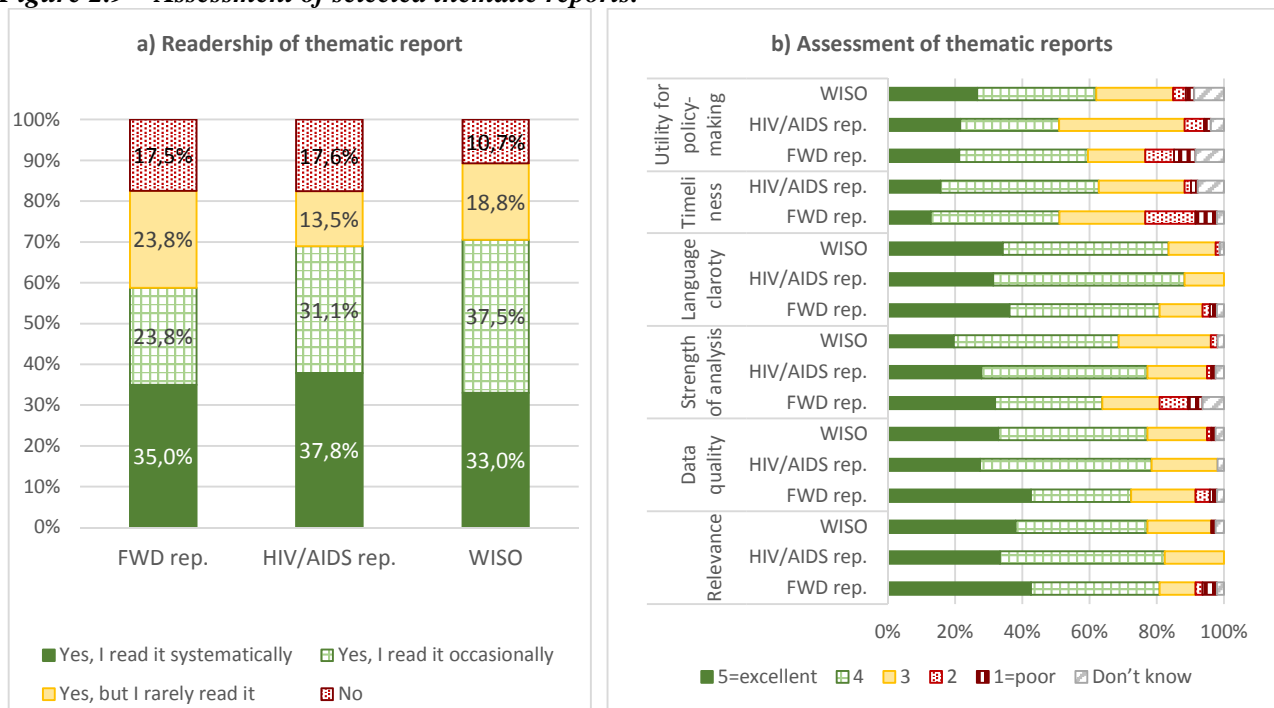


Notes: Respondents headcount: 578 (a), 453 (b), 415 (c), 417 (d), 449 (e), 484 (f). In figures (b) through (f) ‘don’t know’ answers are not displayed. Figure (a): TSR: thematic surveillance reports.

A closer look at three main periodic outputs related to the three disease case-studies provides additional evidence on ECDC publications’ popularity and appreciation among target groups, i.e. the disease experts to whom the reports are mostly addressed. The three documents selected here are: (i) the “*EU summary report on trends and sources of zoonoses, zoonotic agents and food-borne outbreaks*”, for Salmonella experts; (ii) the “*HIV/AIDS Surveillance in Europe*”, for HIV/AIDS experts; and (iii) the “*Weekly influenza surveillance overview - WISO*”, for influenza experts. The

results indicate that WISO is the most known with nearly 90% of respondents aware of it and more than 70% regular or occasional readers (Figure 2.9.a below). The FWD report is instead the comparatively least read with ‘only’ 59% of occasional or regular reader among salmonella experts. As concerns appreciation, the relevance of the information provided for epidemiological purposes as well as language clarity appears the best reports’ features (Figure 2.9.b). Data quality also received a quite positive feedback, especially in the case of the FWD report. The strength of the analysis in the report is rated positively but less than other factors. The same applies with utility for policy-making, which is comparatively lower for the HIV/AIDS report. Finally, timeliness emerges again as the worst constraint of ECDC publications. In the case of the FWD report timeliness was rated positively only by 50% of respondents.

Figure 2.9 – Assessment of selected thematic reports.



Note: FWD rep.: “EU summary report on trends and sources of zoonoses, zoonotic agents and food-borne outbreaks”; HIV/AIDS rep.: “HIV/AIDS Surveillance in Europe”; WISO: “Weekly influenza surveillance overview”. Questions posed only to disease experts and relevant partner within the ECDC system. Total respondents headcount: FWD rep. (80), HIV/AIDS rep. (74), WISO (112).

In conclusion, while the efforts deployed by ECDC to communicate the results of its surveillance work seem generally well received, there appears to be room to improve the added-value of products at the different stages. At the data analysis stage there seems to be an unmet demand for more reliable, deep and sophisticated analysis of data, which obviously need to take into account the limitations imposed by data of poor quality or not standardised and comparable. As put down by one respondent: “Too much emphasis is put on the collection of data, maintenance and improvement of TESSy and too little on the interpretation of the data collected”. Although timely detection of threats is nowadays mainly based on early warning and epidemic intelligence tools, the indicator-based systems can still play a role in the timely detection of new trends in diseases or risk factors. This requires adequate analyses of data, based *inter alia* on algorithms for the automated identification of unusual clusters and other quantitative analytical approaches, including for modelling and forecasting of trends⁴⁷. The

⁴⁷ For instance, when the 2008 pandemic happened, ECDC caught a signal from Epidemic Intelligence, which was considered quite unusual, and they started collecting more structured information. Then, when they realized there was a bigger threat, they moved all the info to TESSy.

challenge here is to further develop analytical instruments and move from an essentially descriptive analysis of data to a clearer ‘information for action’ approach. This may include also a better analysis and interpretation of the reasons of cross-country variability for certain indicators.

As concerns reporting, and in connection with the above, there is an expectation for reports more concise and better focussed on data interpretation rather than simply descriptive documents (in which respect it would be more efficient to facilitate access to data online rather than preparing long compilation of merely descriptive data). Better analysis and interpretation may also entail the production of ‘regional’ reports covering a group of homogeneous MS, thus overcoming data comparability constraints. Reports may also be reduced in number, since they have proliferated over the years. In this sense, there might be scope for further consolidation with WHO/EURO and other agencies’ reports. Another reiterated factor that would enhance the added-value of reports would be a more timely publication. Finally, there seems to be an excessive recourse to hard copies, which is seen as an overly expensive and inefficient format, instead of electronic dissemination and web-based navigable tools.⁴⁸ A standard operating procedure for disease-specific surveillance report production was internally released in 2012, which is expected to further improve the quality of these reports.

The last point touches upon the issue of dissemination to the different stakeholders and audiences (MS, EU bodies, international agencies and NGOs). Overall, the level of visibility of ECDC surveillance products seems not optimal. As discussed in greater detail in Section 6, large shares of relevant audience seem poorly informed about ECDC work or are unaware of the materials published. Overall, there is the need for more awareness-raising activities, which should involve also the responsible MS counterparts (NC and NFP in the first place), and perhaps a larger recourse to other communication tools such as new (social) media.

2.3 Conclusions and Recommendations

Evidence	Findings
<p>Integration of DSN</p> <ul style="list-style-type: none"> • Perceived optimisation of surveillance work and reduction of duplication; • Increased coordination globally; • Improved long-term sustainability of networks; • More heterogeneous participants with more mixed background and areas of competence; • Increased participation from ‘low capacity’ countries; • Perceived less participation, with ECDC taking the leading role. 	<p>The integration of former DSN under ECDC is largely perceived as an inevitable and potentially very useful step. Some initial positive effects are already felt, e.g. as concerns coordination with national and international entities and the rationalisation of data collection. Also, the institutionalisation of DSNs under permanent ECDC programmes make their voices more easily heard by policy makers and ensure a longer-term sustainability.</p> <p>On the other hand, a large share of the expected benefits still has to materialize, and drawbacks has also appeared: (i) scientific ‘slow-down’ and partial loss / dilution of scientific competences within networks; (ii) less proactivity from the side of MS; (iii) more bureaucracy and rigid procedures.</p>
<p>Network operation, Platforms and databases (TESSy)</p> <ul style="list-style-type: none"> • With 72% of positive feedback, support to networking and cross-country collaboration is the Centre’s work area with the highest perceived added-value; 	<p>The support to cross-country networking, joint projects, coordinated surveillance etc. is largely perceived as the core of a EU-wide surveillance system. In this context, TESSy is perceived as a necessary step toward the rationalisation and integration. While the technical and</p>

⁴⁸ According to ECDC data, the total number of copies of reports and publications distributed were some 58,000 in 2011 and some 43,600 in 2012.

<ul style="list-style-type: none"> • TESSy’s unique records grew tenfold between 2008 and 2013 (11.4 million record); • Seven in ten respondents consider data integration and rationalisation through TESSy as useful; • Response to ECDC data call is among the most burdensome activity for MS (including the manual uploading); • Heavy burden due to the high number of variables collected and the frequent change of TESSy metadata (26 times for an overall 80 changes); • TESSy has <i>de facto</i> been a one-way system so far, with limited restitution (but changes are underway). 	<p>management aspect of TESSy do not pose significant problems, there is a wide perception of the whole data collection system as too onerous for MS. For a number of reason: (i) the sheer amount of the information to be collected; (ii) the frequent modifications of metadata; (iii) the lack of a machine-to-machine interface, etc. On the top of that, until recently the system did not return sufficient information to MS to compensate the effort.</p> <p>Simplification of the system and improved access to data have been already identified as priorities and have been inserted in the new long-term surveillance strategy.</p>
<p>Quality of surveillance data</p> <ul style="list-style-type: none"> • Datasets collected are still largely incomplete although positive trends are registered; • Two-steps data validation and QA mechanism introduced since 2009 and upgraded later on (automated check and expert controls); • Some delays and (thus far) limited impact of ECDC activities to support the improvement of national surveillance system and data quality; • Case-definitions are standardised by regulation, but still persists implementation gap and substantial disparities in the way data are collected and classified; • Significant delays in the publication of reports; • Issues with data quality affects the overall perceived usefulness of the system. 	<p>Progresses were made in improving the quality and the availability of surveillance data in furthering cross-country harmonisation. But many problems persist, which makes the utility of ECDC surveillance data very limited and subject to a number of caveats. Obstacles are at various levels: incomplete datasets, diverging reporting systems (leading to severe underreporting in some instances), delays in submission and reporting. For this reason, the potential of the EU-wide surveillance system is still largely untapped and benefits hardly balance burdens. ECDC may increase its effort, but the bulk of the responsibility in this case mostly lays on MS, which are the collectors and the suppliers of data.</p>
<p>Public Health Microbiology</p> <ul style="list-style-type: none"> • There is quite limited awareness of ECDC PH microbiology activities; • Laboratory support and activities for the integration of epidemiology and microbiology are perceived as bringing limited added-value. But judgements appear polarised; • The drafting of a definitive PH microbiology work plan is quite recent (2012) the same apply to the roadmap for molecular typing integration (2013); • Concrete projects on molecular surveillance have been implemented so far only at the pilot stage, but with encouraging results (e.g. on salmonella typing); • The overall burden for furthering molecular surveillance seems beyond what MS are willing to invest; • Benefits have been registered especially in terms of harmonisation and to some extent on data quality (thanks to EQA). But distribution of benefits across EU seems uneven; • Support to collaboration between epidemiologists and microbiologists is perceived as important and in need for expansion. 	<p>The activities carried out by ECDC in the field of PH microbiology in the 2008-2012 period were primarily of exploratory and preparatory nature. The level of financial investment was high and does not compare very well with the current perceived added-value of such activities by stakeholders. However, it is important to stress that there is a widespread lack of awareness on what the Centre has done precisely in this field. Secondly, the matter is at the cross-roads of conflicting interests and therefore attracts very ‘polarised’ feedbacks (positive or not positive depending on respondent’s profile, position and nationality).</p> <p>The state of relationships between PHI and laboratories differ across MS and significantly affect the perception of the usefulness of ECDC efforts for better collaboration between epidemiologists and microbiologists.</p>
<p>Reporting and dissemination</p> <ul style="list-style-type: none"> • Eurosurveillance is the most popular and appreciated ECDC output in the field of surveillance; • Thematic surveillance reports are better appreciated than AER in terms of usefulness, and also for the timeliness problems of AER; • Periodic disease reports are generally read by their direct stakeholders (readership > 59%); 	<p>Judgements on reporting and dissemination obviously vary across products, but some general findings emerged. First, there seems to be an unmet demand for more reliable, deep and sophisticated analysis of data. Long compilation of merely aggregated data are of limited added-value, while what is needed is ‘information for action’. Second, the number of reports</p>

<ul style="list-style-type: none"> • Periodic disease reports are mostly appreciated for their relevance and the data quality, much less for their utility for decision-making; • Guidelines to improve the quality of reports have been issued in 2012. 	<p>have mushroomed and is hard for interested experts to cope with the numerous and 'heavy' documents published. More concise reports and appropriate summaries would be appreciated. Also, greater recourse to electronic rather than hard-copy dissemination would prove efficient. Third, visibility and dissemination of ECDC surveillance outputs has been so far suboptimal. More collaboration from MS responsible counterparts should be sought.</p>
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Conclusions and Recommendations

The discontinuation of seventeen different hubs and their centralization into the ECDC responded to a logic of 'optimization' that seemingly none of stakeholders would challenge. The efficiency advantages of reporting all data to one single place are obvious, for both the reporting end (the MS sending surveillance data) and the receiving end (ECDC). Integration brought with it the setting up of a single surveillance system (TESSy) harmonising data collection procedure and centralising data storage, also facilitating surveillance reporting activities. The 'centralisation' also stimulated a better definition of surveillance metadata and variables to be collected, as well as of more rigorous data validation rules. It provided a clear and predictable 'data call' structure and a central support service. In some areas there have been important policy convergence processes among MS, which was certainly facilitated by ECDC work (e.g. on influenza and influenza-vaccine coverage). On the other hand, there is a widespread consensus on the fact that the above benefits remain largely untapped, and the integration process is far from being concluded. The process of establishing a fully-fledge and perfectly functioning surveillance system at EU level is obviously long and onerous. The potential benefits are clear to all, but until an appropriate level of quality and comparability of data is reached, the added-value of most surveillance network remains limited to that of a sunk investment to be mobilised in case of urgent need if a sudden threat appears, rather than as an ordinary source of 'information for action', i.e. to support policy analysis and change, especially when compared to the burden imposed on MS by the system. Also the user-friendliness of the system can be improved in certain respects. (*Evidence strong, priority high*)

Recommendations. ECDC should be encouraged to strengthen the provision of scientific evidence from surveillance data (reinforce the 'evidence-based' approach) rather than via political agreements or 'top-down' approaches. This is not only coherent with the design of ECDC as a network-of-networks but may also prove effective in winning the 'resistances to change' that ECDC has sometimes encountered at the national level as regards the uptake of common metadata and case-definitions. The argument is to some extent 'circular', as demonstration of the usefulness of improving data quality presupposes that data quality is improved - which falls entirely under the responsibility of MS. There are requests from several sides to demonstrate the added value of the analysis that can be made through the already available harmonised data, including enhanced surveillance data. There seems to be also a request to phase in the integration of molecular typing into EU wide surveillance. But this requires giving consideration first of all to the synergistic use of the data for joint analysis within the TESSy framework and to avoid 'leaps forward' to keep abreast of the technological frontier. On the other hand, the financial burden of molecular surveillance should be kept into account since many MS seem unwilling to continue invest significant resources in this area.

The user-friendliness of the system can also be improved through: (i) the technical upgrade of TESSy, to become a machine-to-machine system (ongoing); (ii) the improvement of functionalities for data access and analysis by external users; and (iii) the rationalisation and better timeliness of reports and other outputs.

3. SCIENTIFIC ADVICE

3.1 Overview

ECDC is statutorily required to provide *independent scientific opinions and expert advice* and, where independent scientific expertise is not available in its dedicated surveillance networks, to set up independent *ad hoc* scientific panels for that purpose. This can be both upon request and a self-mandated task. In fact, the Centre may promote and initiate scientific studies necessary for the performance of its mission and the feasibility, development and preparation of its activities, but in doing so, it should avoid duplication with Member States' or Community research programmes. Up until recently, there was a certain terminological confusion as to the typology of possible outputs in which this scientific advice could materialize.

First of all, there are the so-called *risk assessments* (RA) that differentiate from the parallel rapid risk assessment (RRA) inasmuch the latter focus on immediate threats and should be produced at a very short notice, while the first refer to more chronic and long-term conditions. Then, there are a number of policy-support documents of various type generally based on *review of scientific literature*. These have been recently categorized⁴⁹ as (i) scientific opinions, that literally represent the opinion of the author(s), because there is little or no literature available on the subject, (ii) technical reports, in which ECDC carries out systematic reviews of the literature available, and (iii) guidance documents, in which results are discussed and validated with a panel of experts broadly representative of the different MS. These panels are generally selected in agreement with the relevant MS before conclusions are drawn and recommendations formulated, but MS retain no formal power of veto on their composition. Finally, there are studies to gather new evidence and improve the informational basis.

The distinction between scientific advice delivered as risk assessment and early warning delivered as RRA is sometimes blurred and mainly relates to the urgency of the request and the Centre's unit responsible for delivering the output that in the case of scientific advice is generally a disease programme or another unit under the responsibility of the Chief Scientist. *Requests for scientific advice* classified as such have increased over time from eight in 2008 to 34 in 2012, but peaked in 2009 because of the H1N1 pandemics. Not all of them have been published. The ECDC SARMS (Scientific Advice Repository and Management System) - which is roughly the equivalent of the EFSA's Register of Questions - keeps track of the requests and, since 2012⁵⁰, also of compliance with timeliness requirements. However, the system not necessarily includes data on the originator of the request, which therefore must be inquired on a case-by-case basis. This is not considered as a major issue, as almost all requests (95%) reportedly come from the Commission, even when they originated from the needs of a given MS.⁵¹ In the past, the mechanism for formulating a request for scientific advice was poorly formalized and only recently the practice of issuing mandates detailing the terms of reference of the request was introduced. Self-mandated tasks originate from within the organization and its various networks and are then validated at the AF level through the IRIS scoring mechanism. This creates a double mechanism for agenda setting: one based on requests from policymakers (mainly the Commission, but in theory also the MS) and one justified by the needs voiced at the NFP/AF level where mainly public health institutes are represented.

⁴⁹ This terminology has been only recently introduced and was borrowed from EFSA practice. In the past the title of the document was not necessarily related to its contents.

⁵⁰ Starting with 2012, the SARMS system also monitors requests for RRA.

⁵¹ For instance, the request for a risk assessment about an epidemic of HIV in Greece discussed above formally came from the Commission after a discussion with the Greek minister of health, but did not originate from Greece.

It is worth noting that carrying out risk assessments and serving as the prime source of scientific advice on communicable diseases for the European Parliament and the European Commission represent only two of the five original objectives (or ‘strategies’ in the ECDC document terminology) included in the 2007-2013 SMAP. These also included various horizon-scanning activities: i) identifying and prioritizing gaps in European public health scientific knowledge (particularly as far as the public health dimension and research into determinants e.g. climate and socio-economic factors, as well as the burden of infectious diseases are concerned); ii) identifying possible future threats; and iii) initiating and/or undertaking horizontal studies on key determinants of communicable diseases in Europe like demography, migration, climate change and health inequality⁵². Apart from health inequality that has recently been proposed for upgrading to the status of a disease programme, all the remaining horizontal aspects are presently being dealt with in the core coordination of scientific advice section of the ECDC, that also serves as an advisor and a provider of support on scientific methodology for the disease programmes.

The title III *budget allocated for scientific advice* long kept increasing well above the original budgetary provisions and ranged from some € 2 mn in 2008, to almost € 5mn in 2011, until decreasing to some € 4mn in 2012. In 2012, scientific advice accounted for some 10% of total ECDC expenditure including the costs of some 28 full time equivalent (FTE) staff. Roughly, one-fourth of it was managed as core scientific advice, while the remaining part was distributed to the disease programmes and the other units. With the only exception of disbursements in 2009, the amounts annually committed and disbursed for scientific opinions over the period have remained above the ECDC average. In 2011-2012 they were roughly equal respectively to some 98-99% and 60% of funds. So, scientific opinions as a whole have positively contributed to the principle of annual budgetary execution.

3.2 Main findings

3.2.1 Reputation and Independence

Although a relatively young organisation, ECDC scientific reputation has constantly been increasing over time and has now consolidated at quite high levels in the peer community of public health officers across Europe and among public health experts in general. ECDC is generally reported as a well-known institution also because of the massive visibility of the *Eurosurveillance* bulletin in the public health expert community⁵³. Key informants at the MS level generally agree (over 80% of respondents, see Figure 3.1.a below) that ECDC has managed to become a centre of scientific excellence and technical leadership and a prime repository for scientific advice on infectious diseases. As can be seen, ECDC reputation as a repository of advice is higher than its reputation as a promoter of studies (45% of respondents give a clearly positive score, but some 16% voice some open dissatisfaction in this respect), and much higher than its reputation as a catalyst of research in the public health field - a role less than 30% of respondents are fully persuaded ECDC has convincingly

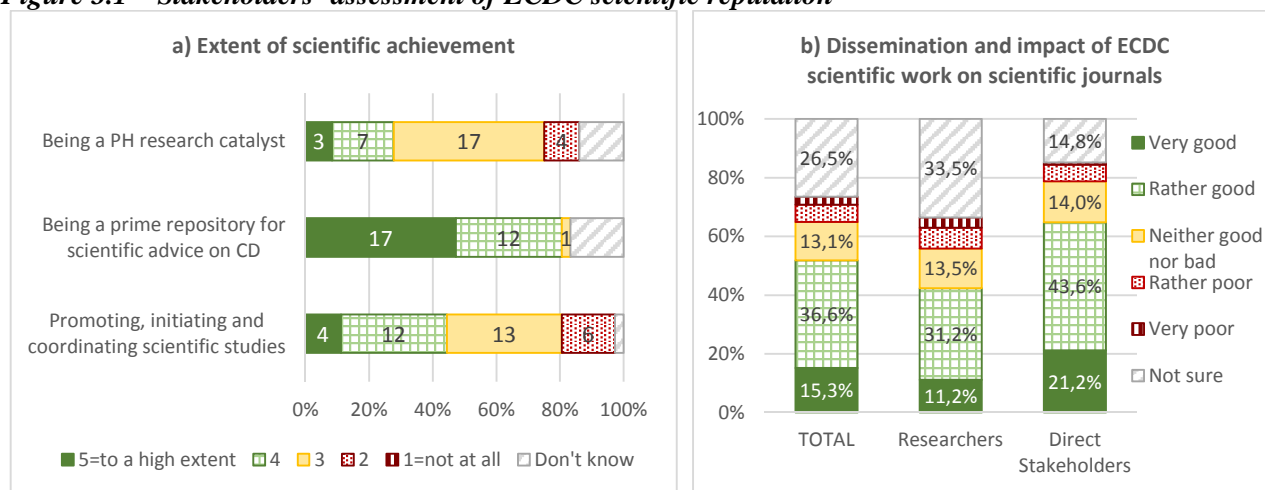
⁵² This includes studies on climate change and communicable diseases managed in cooperation with the European Environment and Epidemiology Network and an initiative on calculating the present and future burden of communicable disease in Europe, which is managed by a consortium of PHI and has already delivered a tool kit. It is understood that these horizontal activities fall outside the scope of the evaluation question.

⁵³ As a matter of fact, instances could be found of ECDC deliverables that are better known as *Eurosurveillance* articles than as ECDC reports (see tab. 3.6)

played. This is also indirectly confirmed by the results of the case studies where contribution to DG Research agenda appears to be sporadic and unsystematic at best⁵⁴.

ECDC visibility and scientific standing in the expert community is further confirmed by the results of a question on the *dissemination and impact of ECDC scientific work* on scientific journals which is scored by over 50% of respondents (and 65% of ECDC partners and direct stakeholders see Figure 3.1.b below) as either good or very good. Peers in other PHIs have also acknowledged that some of these RAs can even be considered among examples of absolute international best practice in the field. This indirectly confirms the evidence from the *Eurosurveillance* bulletin impact factor, that is reported by ECDC as fairly high among those of scientific journals in the field.

Figure 3.1 – Stakeholders’ assessment of ECDC scientific reputation



Note: Headcount (a)=36; (b)=544

Generally speaking, ECDC scientific opinions are considered independent from industry interests and the ECDC policy on the subject – which also involves staff declarations - adequate to needs⁵⁵. The latter has however materialized only at the end of 2012, after a preparation period that appears exceedingly long to some interviewees. Since ECDC remains one of the most heavily scrutinized institutions in Europe by the Commission, the EU Parliament and other national and international agencies, the overall *a priori* likelihood of conflict of interest is considered low whatever procedures are implemented and some maintain the issue of regulatory capture has been probably overstated in response to a single such instance in the past⁵⁶. There is broad consensus among stakeholders on ECDC independence of judgment in the area of scientific advice (more than seven in ten positive or very positive feedback) and no case of open dissatisfaction are reported. Some find ECDC is not

⁵⁴ For instance, in the field of HIV/AIDS it was reported that that so far ECDC has only very informally acted as a catalyst of research priorities for DG Research. Much in the same vein also in the field of influenza it was noted by interviewees that ECDC has limitedly interacted with DG Research despite these are often included in its reports

⁵⁵ The only controversial area is represented by vaccines, although here the real issue is not that much related to ECDC, but on whether there is a need to base policies on studies funded by industry or these have to be independently replicated by public-funded sources of any kind.

⁵⁶ In December 2012, following several months of consultation and discussion and a long preparation period, ECDC’s Management Board agreed a new policy on independence that aligns the Centre with the very best practice within the EU agencies and in particular the EMA model. The new policy extends the requirement to make an annual declaration of interest to all ECDC staff (the Director, Management Board members, Advisory Forum members and members of scientific panels have always been required to make such declarations by ECDC), provides that declarations have to be scrutinized by a Compliance Officer of ECDC and makes provision for potential conflicts to be referred to a Declaration of Interest Review Committee. The ECDC independence policy is in place and implemented since January 2013.

doing enough to highlight industry-financed studies in their reviews of literature, as this could represent a source of potential bias in drawing conclusions.

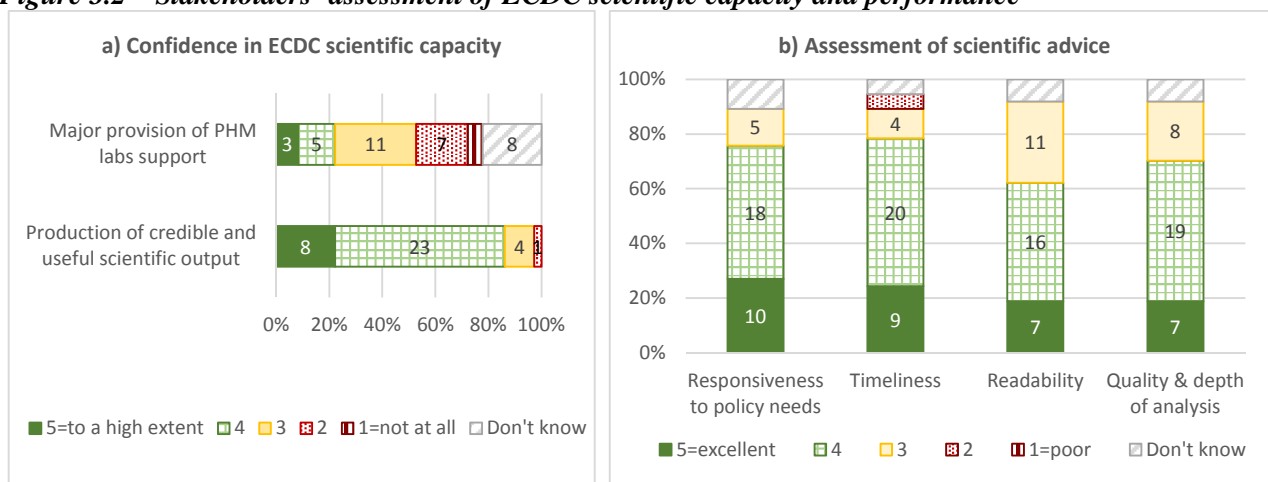
As far as independence from political influence is concerned, some believe that the emphasis on independence of external experts from Government while drafting guidance documents would be fundamentally misplaced. To the extent that most of the added value of guidance documents actually lies in a consensus-building process, this should not be considered as a source of bias, but rather as a factor increasing the likelihood that local conditions (costs and features of the healthcare systems) are properly taken into consideration and guidance eventually implemented. So, in their opinion, procedures to ensure that experts from the Countries most affected by a given health problem are always included in the panels should be established to enhance impact of activities.

3.2.2 Confidence in ECDC Capacity to Perform

Survey results (Figure 3.2.a) show that confidence in ECDC is still differentiated by area of activity. There is among stakeholders a strong *a priori* confidence in ECDC capacity of producing credible and useful guidance, as well as risk assessments and other technical reports in their traditional epidemiology-related fields of expertise. On the contrary, there appears to be much more scepticism on its capacity of becoming a major provider of microbiological laboratory support - a more recently introduced area where ECDC still seems far from enjoying a strong reputation.

At a more granular level of analysis, this level of confidence appears quite high when it comes to responsiveness to policy needs and timeliness (although with some difference by DP as better reported in the box 3.1. below), while there are some more reservations as to certain features of the analysis and, above all, the overall readability of ECDC deliverables as Figure 3.2.b below demonstrates. The comments received in the case studies on the quality and in depth of the analysis make reference to the range of the sources consulted and to a certain neglect of cost-benefit and feasibility aspects that often represent the key barrier to the implementation of guidance at the national level.

Figure 3.2 – Stakeholders’ assessment of ECDC scientific capacity and performance



Note: Headcount (a)=36; (b)=37.

Box 3.1 – The Quality of ECDC Scientific Advice – Evidence from the Case Studies

- ***Influenza.*** There is also a general consensus on the good quality of ECDC deliverables – with the major qualification of the timeliness of seasonal influenza risk assessment report. Many would be happy to trade off a shorter and less descriptive report with a more timely release or to have one preliminary version as soon as possible and another later during the season. Content-wise, some insist that the assessment of vaccine effectiveness should be further strengthened as it represents one of the key pieces of information of the report. In general, an overall need to further simplify report presentation is often highlighted (no need to repeat the analysis each and every time, suffice to update the data). No comments were received on a need for better codification in ECDC guidance reports (e.g. grading of evidence). ECDC scientific advice on seasonal influenza vaccination of children and pregnant women would largely overlap in terms of informational contents with the parallel WHO guidelines. European added value is more perceived as related to the underlying consensus building process, while the existence of European specificities deserving a separate scientific document appears as more controversial to some. The report was to be based on European and other Western countries data in general and on European data only as far as safety, efficacy, effectiveness and cost effectiveness were concerned. However, key evidence came from third countries and European restrictions simply dropped from the report any reference to cost-effectiveness studies.
- ***HIV.*** Overall quality is good but information is not always presented in a format suitable to policymakers and for instance executive summaries are sometimes missing, which is particular cause of concern to those who are more interested in ECDC conveying clear messages from underlying strong analysis than in publishing epidemiological data. It is noted that as ECDC works mainly by means of well-balanced and exhaustive bibliographic searches - in the field of HIV even more than in other areas - there are very limited elements of novelty in their reports and the wealth of information that could be drawn from behavioural surveillance and other forms of enhanced surveillance underexploited. In addition, cost and resource issues would tend to be relatively underweighted in the analysis (with the notable exception of cost-effectiveness of blood screening) as no additional original information is added on the subject if not already reported in the literature.
- ***Salmonella / FWD.*** Generally speaking, ECDC is deemed to provide good scientific advice reports, in a clear and readable format, written in good English, hence accessible to the stakeholders' community. Their quality has improved over time, especially because attention was duly paid to the comments made by the MS and these were usually taken on-board. The main limitation in perceived quality appears to be that the joint report with EFSA would still be based on poorly comparable surveillance data and, above all, provide an insufficient coverage of antimicrobial resistance issues. This would indeed appear among the main current weaknesses, because past ECDC laboratory guidance on the subject would have been only very limitedly implemented on the field. Others also mention a certain neglect of cost issues.

The level of confidence on the overall usefulness of ECDC scientific advice has been reported as increasing over time. For some 54% of experts surveyed such improvement has been 'significant' while another 27% qualified it as 'moderate. Positive feedbacks are obviously more visible among respondents who have a relatively long experience with ECDC than among those who have had a relatively more recent exposure (86% of those with over six years of experience with ECDC perceived an improvement, against 'only' 63% among those with two to six years of experience)

3.2.3 The General Perception of the Quality Features

To assess the quality features of ECDC scientific outputs a sample of ten such products (see Table 3.1 below) in different areas (DP-related, horizontal, etc.) and of different nature (technical reports, guidance documents, evidence-gathering studies, etc.) have been selected and 'tested' among ECDC direct stakeholders as well as a larger group of PH experts and sector specialists.⁵⁷ In particular, respondents were asked about their: 1) awareness of the ECDC deliverable; 2) opinion about the relevance of the subject at the time it was published (a broad proxy of the level of interest in the scientific community); 3) professional assessment of the intrinsic technical quality of the output, 4) subjective expert perception of the potential usefulness of the contents of the deliverable for risk

⁵⁷ Identified among scholars whose publications appear in relevant categories of the SCOPUS database.

management / policymaking purposes. This was complemented by results from a bibliometric search conducted on both the ECDC relevant reports and the *Eurosurveillance* publications drawn from it (Table 3.1).

Table 3.1 – Number of Citations of Selected ECDC Scientific Outputs

#	Year	Title	Type of document	Number of Citations in Scientific Articles
1	2012	Assessing the potential impacts of climate change on food and water-borne diseases in Europe	Horizontal + FWD	4
2	2011	Evidence-based methodologies for public health	Horizontal	10
3	2010	Fostering collaboration in public health microbiology in the EU	Microbiology	0
4	2012	Seasonal influenza vaccination of children and pregnant women	Influenza Report	1
5	2012	Narcolepsy in association with pandemic influenza vaccination – a multicountry epidemiological vaccination	Influenza Study	49
6	2010	The 2009 A(H1N1) pandemic in Europe, a review of the experience	Influenza Pandemic	45+141
7	2011	Joint ECDC/EMCDDA guidance prevention and control of infectious diseases among people who inject drugs	HIV Guidance	33+1
8	2010	HIV testing: Increasing uptake and effectiveness in the EU	HIV T. Report	66+4
9	2012	Point prevalence survey of healthcare-associated infections and antimicrobial use in European acute care hospitals	HAI Study	40+26
10	2011	Current and future burden of communicable diseases of communicable diseases in the EU and EFTA countries – methodological protocol.	Horizontal	6

Note: Number of citations in scientific articles refer to the ECDC publication + the relevant *Eurosurveillance* article (when relevant). The source is Google Scholar, analysed through the *Publish or Perish* data mining software (see Annex D for details).

As can be seen from the figures reported in the Table 3.2 below the level of outreach of ECDC among survey respondents is generally good for both horizontal and disease-programme related publications and the echo in the expert community can reach some one-third of the PH expert community across Europe and as high as 60%-80% of relevant sectoral experts for disease specific publications. The notable exception in our sample is represented by laboratory microbiology, which appears confirmed as an area where ECDC is still relatively poorly accredited and by the report on HIV and intravenous drug users, a subject considered in several Countries more within the scope of social policies than public health, and at any rate more easily associated with the EMCDDA remit⁵⁸. It is worth noting that evidence from the bibliometric search generally represents a very rough proxy of the echo of ECDC scientific advice products in the relevant expert community.

⁵⁸ For instance in the 2011-2012 period EMCDDA reports some 32,826 visits to the webpage of the Joint Guidance Document and 3572 downloads of the related report (which was translated in several languages for accession and neighboring countries in particular, and 24,522 visits to the webpage and 1,799 downloads of the preceding technical report document on the same argument. For comparison purposes the order of magnitude of page views of the HIV/AIDS surveillance report roughly in the same period would lie around some 2,500 hits (see chapter 6 on health communication below). Data on visits and downloads of the ECDC deliverables from its own website are not available.

Tab 3.2 - Share of Respondents Aware of ECDC Publications

#	Title	External	Direct Stakeholders	Sectoral Experts	TOTAL
1	Assessing the potential impacts of climate change on food and water-borne diseases in Europe	28,8%	27,7%	71,9%	27,9%
2	Evidence-based methodologies for public health	40,9%	31,3%	n.d.	33,1%
3	Fostering collaboration in public health microbiology in the EU	7,6%	14,4%	26,3%	13,1%
4	Seasonal influenza vaccination of children and pregnant women	24,2%	33,1%	70,4%	31,4%
5	Narcolepsy in association with pandemic influenza vaccination – a multicountry epidemiological investigation	19,7%	36,3%	62,2%	33,1%
6	The 2009 A(H1N1) pandemic in Europe, a review of the experience	33,3%	42,1%	73,5%	40,4%
7	Joint ECDC/EMCDDA guidance prevention and control of infectious diseases among people who inject drugs	6,1%	17,3%	37,7%	15,1%
8	HIV testing: Increasing uptake and effectiveness in the European Union	9,1%	21,6%	79,2%	19,2%
9	Point prevalence survey of healthcare-associated infections and antimicrobial use in European acute care hospitals	27,3%	34,9%	n.d.	33,4%
10	Current and future burden of communicable diseases in the EU and EFTA countries – methodological protocol.	19,7%	24,1%	n.d.	23,3%

The level of *interest in the subjects* chosen appears always fairly high and, as reported in the Figure 3.3 below, on average between 80% and 90% of survey respondents rate the relevance of the topic as either high or very high. Also in this case, the ratings of microbiology and IDU-related HIV policy is marginally lower. In other cases the relevance of the subject *per se* becomes blurred with considerations on the appropriateness of its inclusion among the ECDC priority items for policy agenda setting purposes. In particular, it is worth noting that the document on HIV testing is deemed of no particular interest by some 20% of respondents. Opinions on the relevance of the study on narcolepsy tend to diverge as also confirmed by the findings of the interview programme. Unsurprisingly, Healthcare Associated Infections stands out as one of the most debated topic these days and over 90% of survey respondents agree on the relevance of the subject, as also confirmed by the number of unsolicited comments received on this study during the interview programme, irrespective of the fact that it was not part of the case studies (see also chapter 2 on Surveillance).

Consensus on the *technical quality* of ECDC deliverables is also very strong and is scored as high or very high typically by some 65% - 80% of survey respondents⁵⁹, a share slightly lower than that found for relevance also because the number of those who maintain to be in no position to judge is on average higher in this case (+5%) and can reach even as high as 10% of total responses for specific products. There are certain deliverables on which opinions about quality notably tend to diverge, as if respondents used different quality criteria for judgment. This is typically the case of the document on seasonal influenza vaccination of children and pregnant women and of the study on healthcare associated infections. This is broadly in line with the findings of the interview programme where both deliverables proved somewhat controversial to some interviewees under certain methodological aspects. In other cases, the share of those who think that the quality is very high simply decreases in favour of a more neutral judgment (neither particularly good nor particularly bad) as is the case, for

⁵⁹ It is worth noting that a methodological document of a horizontal nature in the list: the *Evidence-based methodologies for public health* not only does it appear as even better known in the expert community at large than among ECDC direct stakeholders, but is so strongly appreciated by the first to come out with the highest quality score in the group.

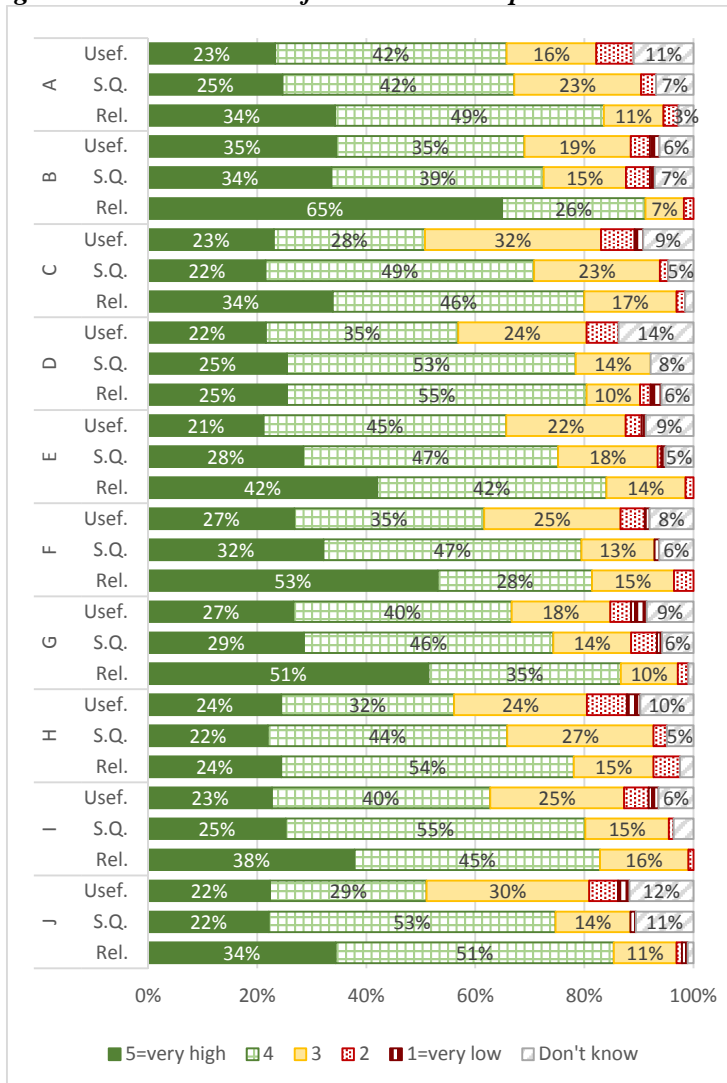
instance, of HIV testing, the document on microbiology and the study on burden of communicable diseases. As mentioned elsewhere in this report (see Section 7.2.5 on Partnership), when the expertise of different EU agencies contributes to the provision of scientific advice and therefore broadens the perspective of the authors, the perception of quality tends to be on the higher range, although this does not necessarily translate in an increased perception of usefulness for the final decision-maker. This is, for instance the case with the *Joint EMCDDA/ECDC Guidance on Infectious Disease Prevention for IDU*.

The single quality feature of ECDC deliverables on which consensus among respondents is less apparent is their *usefulness for decision makers*, which is ranked as high or very high in 50% to 70% of cases, but also low to medium in another 25% -40% as reported in the Figure 3.3 below. This is to some extent expected for methodological documents of a more horizontal nature (although there are exceptions in this respect), but a bit less so for documents of a guidance nature. To this aim it is worth noting that the usefulness of studies providing new evidence and information is also considered slightly higher than that of documents based on lessons learnt or review of literature, which is also in line with the findings from the case studies (see box 3.1 above). To sum up, the quality of ECDC deliverables has generally been reported as good and in line with professional standards in the field. The main comments on how to further improve usefulness for decision makers that currently appears the relatively weakest area can be summarized as follows:

- **Broaden range of sources.** The contents of scientific advice limited to a review of available scientific literature not always meet expectations. Some would like to see more practical information on a) lessons learnt from experiences in other MS, including grey literature and personal communications from colleagues, even if not published in scientific publications and peer-reviewed, b) the pros and cons of concrete practical implementation issues, and c) more analysis on the comparative impact that different responses have had so far in different contexts, so that available options can be better framed. An insufficient attention to cost and ethical aspects as well as – more generally speaking - on quantification is also reported.⁶⁰
- **Increase novelty of information.** ECDC would focus too much on reviewing existing sources and invest too little in providing added value by means of original contents and in exploiting the wealth of information available from surveillance data. However, according to some respondents, ECDC would not have a clear mandate in this field.
- **Improve timeliness requirements.** Reports, particularly when outsourced, would appear sometime with some delay as compared to needs, but this problem is very specific to certain areas of work.
- **Improve language and format used.** Messages would not always be conveyed in a format and language adequate for policymakers, in particular executive summaries sometimes would appear as missing.
- **Improve methodological clarity.** Occasionally scientific assumptions would not have been made clear and explicit to the non-specialist reader.

⁶⁰ Some would like to see more effort devoted to developing methodologies to objectively compare and summarize the pros and cons of the lessons learnt from past experiences (e.g. multilevel analysis and the like), although this would very likely to be considered a risk-management related aspect.

Figure 3.3 – Assessment of selected ECDC publications



- A) Current and future burden of communicable diseases in the European Union and EEA/EFTA countries – Methodology protocol (2011)
- B) Point prevalence survey of healthcare-associated infections and antimicrobial use in European acute care hospitals (2012)
- C) HIV testing: Increasing uptake and effectiveness in the European Union (2010)
- D) Joint ECDC/EMCDDA Guidance: Prevention and control of infectious diseases among people who inject drugs (2011)
- E) The 2009 A(H1N1) pandemic in Europe, a review of the experience (2010)
- F) Narcolepsy in association with pandemic influenza vaccination – a multi-country European epidemiological investigation (2012)
- G) Seasonal influenza vaccination of children and pregnant women (2012)
- H) Fostering collaboration in public health microbiology in the European Union (2010)
- I) Evidence-based methodologies for public health (2011)
- J) Assessing the potential impacts of climate change on food- and waterborne diseases in Europe (2012)

Note: ‘Usef.’: usefulness for risk management / policy-making; ‘S.Q.’: scientific quality; ‘Rel.’: relevance of topic. Total headcount =344

3.2.4 Overall Credibility of ECDC Scientific Advice

In connection with the above, the ECDC appears an institution enjoying on average a fairly high **scientific credibility** in its stakeholders’ community. The survey results show that only one in 37 acknowledgeable respondents have substantial reservations in this regard, while nearly eight in ten deem it already either high or very high. One of the main determinants of credibility remains, however, its track record, that is still too short according to some, to give a more definite judgment and would need further consolidation over time before becoming comparable to that of other better known institutions in the field. In other cases, it is the *a priori* reservations made on the perceived credibility of ECDC as an EU institution as such and the alleged bias these are perceived to have either as politicized bodies or as organizations acting in favour of industry and commercial interests, rather than to specific instances of ECDC behaviours that can be at the basis of a less favourable and more neutral assessment.

Also in the light of these findings, it is important to understand that disagreement on ECDC scientific deliverables is hardly voiced in terms of lack of scientific credibility, but rather phrased in terms

limited *usefulness for policymaking* purposes, or lack of mandate, or overstepping into risk management issues. There appears to be a core group of some 20% MS representatives who still deem that ECDC responsibilities and competences in the field of scientific advice are poorly defined and tend to be critical of any ECDC involvement in policymaking-related issues or in areas they deem outside the strict field of surveillance. This share remains as high as some 15% of respondents even when it comes to the NFPs. Moreover, another 30% believe this mandate is clearly defined only in part.

The blurred *distinction between risk assessment and risk management*⁶¹ remains a fairly frequent possible source of confusion among stakeholders and of conflicting requests upon ECDC itself. The provision of scientific advice becomes therefore practically difficult to enforce, as different stakeholders might have different views and needs on how far ECDC should go in hinting at the possible measures available for response and framing the related options. Moreover, in assessing risks as well as in framing possible options, ECDC would have to make it clear the trade-offs between the different possible policy objectives and enter into cost-effectiveness considerations that may vary a lot from MS to MS based on the local cost structure and the nature of the underlying healthcare systems - an aspect on which its mandate remains unclear also because of subsidiarity considerations.

3.2.5 Evidence of Use for Risk Management or Policy Decisions⁶²

Evidence from the interview programme and the survey have largely confirmed what the SMAP already states, i.e. that the ECDC represents the prime source of advice for the Commission and other European institutions, which do appear as both the main sources of requests for advice and the main users of data for policymaking purposes, while use at the national level is more limited.

The use of scientific advice at the MS level appears more spotty and random depending on local factors. It is also confirmed that there is a certain level of disconnection from policymaking among NFP and network members in a number of Countries to get a well-informed and precise feedback. Lack of stability in setting priorities as Governments come and go further contributes to this disconnection. Only very few instances could be found of interviewees who were able to promote certain activities because they knew these would be needed and used in their own Countries, which can alternatively be seen as evidence of very effective use of resources and link with the underlying

⁶¹ The distinction between risk management and risk assessment was borrowed into ECDC regulation from the food legislation where it has long been codified. The main barrier to mutual understanding is that in the food area risk are assessed before they potentially occur so as to inform risk managers whether it is worth bearing them based on the precautionary principle. It is therefore of a purely preventive nature. Instead, in the field of communicable diseases, risks are assessed after they have occurred or while they are in the process and therefore the assessment actually focuses on the likelihood of their escalation over time, which also depends on the responses taken, which logically ends up in a circular argument on the possible effectiveness of different containment measures in a given situation. So the output is no longer purely preventive strictly speaking, but also a component of response in as much it should ultimately inform and support decision making on whether a risk management decision is appropriate and justified in the light of the current level of threat.

⁶² This Section briefly analyse the influence of ECDC's scientific advice activities – whether risk management or guidance document – on concrete risk management or policy making decision over and above the generic judgment on responsiveness to policy needs analysed above. The key evaluative aspect is whether RAs or guidance documents have been concretely taken into account by risk managers / policymakers and this is discernible in the policymaking process by means of quotations or other references. The matter here is closely connected with the visibility of ECDC deliverables on the one hand and with the polarized debate on the extent to which the Public Health Institutes that are so widely represented in the ECDC governance model are effective “transmission channels” to influence their respective domestic national debates.

policymaking process, or of potential conflict of interest as these also turned out to have been involved as contractors for the project.

Very generally speaking, the level of use of scientific advice for policymaking purposes is *prima facie* often assumed to be the higher the lower the level of national capacity. However, these are also the same low capacity environments in which ECDC advice is also often perceived as not sufficiently strong in terms of wording for advocacy purposes and therefore not sufficiently used as it would be needed. There are some preliminary indications that ECDC scientific advice could be used more intensively at least in certain heavily regionalized Countries to bring some homogeneity to the decision making process at the regional level.

Results from the survey (see Table 3.3 below) cannot be considered as systematic but further confirm this impression. Respondents either cannot recollect any specific impact (or are not informed about it), or frequently mention an advocacy role to put the subject on the Government agenda or a use for technical purposes rather than aimed at informing policy contents. In another more limited number of cases claims are made about the impact on the decision-making process (often as policy indicators), but these cannot always be verified and remain therefore undocumented, and possibly poorly visible in the internal debate. At any rate, impact of RRA and Country visits is much more frequently mentioned. Concrete examples and links to the national-level documents found are provided below. Examples outside the evaluation period have not been removed in order to give the reader the flavour of the feedback received and of the broad areas of perceived impact. Results from the bibliometric exercise (see annex D) can also give some indications on the possible undocumented indirect impact on policymaking process of the different specific deliverables tested in the different MS and upon third countries as well.

Table 3.3 – Reported Instances of Impact of ECDC Scientific Advice on the Decision Making Process

Country	Significant Instances Quoted by Survey Respondents	References
AT	<ul style="list-style-type: none"> Influenza Pandemic, S. Stanley outbreak (RRA) Antimicrobial Resistance and Healthcare Associated Infection Prevention: follow up of a Country visit and of the PPS study 	<ul style="list-style-type: none"> None http://bmg.gv.at/cms/home/attachments/3/2/5/CH1318/CMS1361534036242/nap_amr.pdf
BE	<ul style="list-style-type: none"> Polio RRA (2013) led to additional recommendations on vaccination. Advocacy role on various policies to set the Government agenda Infectious control teams of acute care hospitals involved in the PPS to incorporate results into clinical guidance MERS Rapid Risk Assessment 	<ul style="list-style-type: none"> https://www.wiv-isp.be/pedisurv/Documents/Vaccinatie_Volwassenen_polio_2014_FR.pdf Not visible Not visible None
CZ	<ul style="list-style-type: none"> RRA on poliovirus (2014) Antimicrobial resistance and HAI 	<ul style="list-style-type: none"> None http://apps.szu.cz/earsnet/uvo_d.php, http://www.mzcr.cz/legislativa/dokumenty/vestnik-c8/2012_6865_2510_11.html
DE	<ul style="list-style-type: none"> Document on gonorrhoea resistance RAGIDA is currently used to decide on contact tracing in aircrafts 	<ul style="list-style-type: none"> Technical impact in establishing the surveillance system None
DK	<ul style="list-style-type: none"> Updates during the influenza pandemic (RRA) Influenza vaccination guidelines 	<ul style="list-style-type: none"> None None

Country	Significant Instances Quoted by Survey Respondents	References
	<ul style="list-style-type: none"> Recommendations on polio surveillance 	<ul style="list-style-type: none"> Proposal dismissed because not "recommended" by ECDC
EE	<ul style="list-style-type: none"> General advice on influenza Follow up of the joint ECDC/WHO TB country report 	<ul style="list-style-type: none"> None specific None
ES	<ul style="list-style-type: none"> Framework Action Plan to Fight Tuberculosis in the European Union and Progressing towards TB elimination (uptake of policy indicators) Schistosomiasis outbreak in Corsica (2014) The 2009 A(H1N1) pandemic in Europe, a review of the experience (2010) National Influenza Preparedness Plan⁶³ The 2009 A(H1N1) pandemic in Europe, a review of the experience (2010) Improved indicators of tuberculosis surveillance 	<ul style="list-style-type: none"> http://www.msssi.gob.es/profesionales/saludPublica/prevPromocion/PlanTuberculosis/docs/IndicadoresSeguimiento_VF.pdf None None http://www.msssi.gob.es/ciudadanos/enfLesiones/enfTransmisibles/pandemia/home.htm None but quoted by two different respondents None
FR	<ul style="list-style-type: none"> The first RRA of the MERS - CoV outbreak (2013) contributed to the updated national recommendations on surveillance outbreak In France the "Haut Conseil de la santé publique" uses systematically ECDC scientific advice (mainly RRA) for making recommendations on infectious diseases control and prevention to the Ministry of Health Mainly RRA PPS, agenda setting 	<ul style="list-style-type: none"> http://www.hcsp.fr/explore.cgi/avisrapportsdomaine?clefr=384
GR	<ul style="list-style-type: none"> Guidance on HIV Testing, Joint ECDC/EMCDDA Guidance; Guidance on Chlamidia Control HIV among PWID 	<ul style="list-style-type: none"> None None
HU	<ul style="list-style-type: none"> HPV vaccination 	<ul style="list-style-type: none"> None
IE	<ul style="list-style-type: none"> Risk assessments on MERS (RRA), Guidance on antivirals, Guidance on TB and MDR-TB 	<ul style="list-style-type: none"> None
IT	<ul style="list-style-type: none"> Several documents used to set the MOH agenda Mainly to influence MOH agenda setting and allocation of funds 	<ul style="list-style-type: none"> Not visible Difficult to demonstrate
LT	<ul style="list-style-type: none"> Adapted the surveillance system after the hospital infection pps. Vaccination policy in general 	<ul style="list-style-type: none"> None None
LV	<ul style="list-style-type: none"> ECDC guidance "Public health management of sporadic cases of invasive meningococcal disease and their contacts" was used as a basis for the national guidance document 	<ul style="list-style-type: none"> No No
MT	<ul style="list-style-type: none"> Report on Public Health Actions for Meningococcal disease has contributed to update protocols. Various guidance documents and risk assessments 	<ul style="list-style-type: none"> No Not published
NL	<ul style="list-style-type: none"> None to the best of my knowledge A lot of policy briefs and other policy documents were partly based on ECDC RRA MERS, RRA H7N9 Surveillance guidelines and maps of current spread of vector borne diseases, in particular invasive mosquitoes in Europe Technical discussions on various HIV reports and documents on chlamidia 	<ul style="list-style-type: none"> None None None The reference attached quotes a EURO-WHO document None
NO	<ul style="list-style-type: none"> Treatment of pregnant women from the Q fever risk assessment in the Netherlands 	<ul style="list-style-type: none"> None

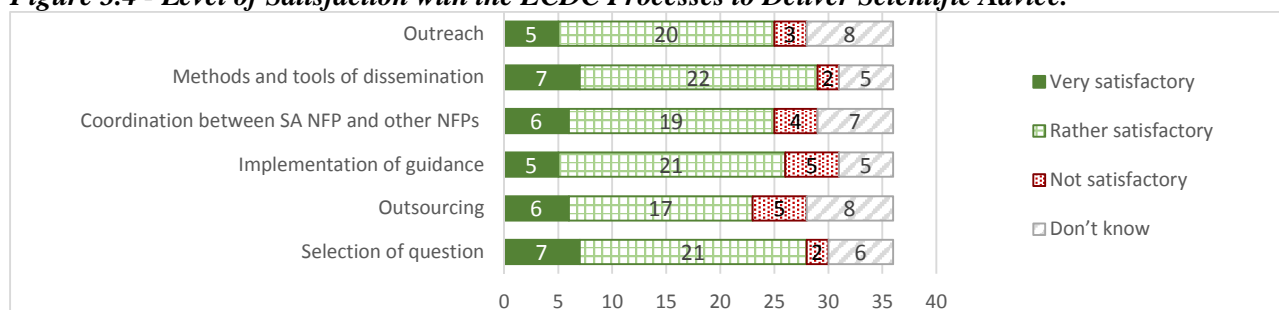
⁶³ The document mentioned in actually dated 2006 and is therefore out of the scope of this exercise. It is reported here for information purposes only.

Country	Significant Instances Quoted by Survey Respondents	References
PL	<ul style="list-style-type: none"> The PPS exercise on HAI 	<ul style="list-style-type: none"> None
RO	<ul style="list-style-type: none"> Surveillance methodologies are up-dated yearly according to ECDC documents. Guidance for influenza pandemic plan revision. Lessons learned from the pandemic (H1N1) 2010 	<ul style="list-style-type: none"> www.insp.gov.ro
UK	<ul style="list-style-type: none"> The PPS 2012 report had a direct impact on investment in IPC indicators being established and further investment in targeted HAI reduction 	<ul style="list-style-type: none"> None

3.2.5 Quality of the Processes

There is a fairly high level of satisfaction among stakeholders about the quality of the processes underlying ECDC scientific advice. The vast majority of respondents declare themselves rather satisfied and sheer dissatisfaction averages in the region from 5% to 15% of replies received, while another 20% decline to respond (Figure 3.4). As reported below the most controversial area appears by far the processes or lack thereof through which ECDC supports the implementation of advice in the specific national contexts. As mentioned elsewhere in this report also the appropriateness of outsourcing practices is likely to appear as a questionable topic. The reasons behind dissatisfaction variously relate to lack of transparency, insufficient recourse to in-house resources, too limited a range of contractors (see Section 8.2.5). What appears important here is on the one hand the demand for a more hands-on approach to implementation of an advice that is otherwise perceived as too formal and theoretical and, on the other hand, the comments on the outreach of dissemination that would not always adequately cover policymakers.

Figure 3.4 - Level of Satisfaction with the ECDC Processes to Deliver Scientific Advice.



Note: Total headcount=36

As far as *safeguards to avoid duplication* with other agencies is concerned, whenever ECDC advice is delivered independently from the work of the networks, there is the risk of duplication of activities between the various actors (e.g. WHO, other EU Agencies, the MS) and the need to reconcile divergent opinions from these various bodies. However, such programming and reconciliation mechanisms mainly exist with the WHO only. Very preliminary attempts have been reportedly made at the level of the AF meetings, in order to coordinate the agendas of the various PHI across Europe and divide the likely issues on the European agenda between them in order to avoid duplications. Because of several concurrent factors, there are notable difficulties in proceeding along these lines. This includes difficulties with joint procurement. Most importantly, there are limited mechanisms in place yet to avoid duplication of calls at the European level. Since the programming timelines of ECDC and the other European Agencies are not aligned the detailed contents of calls are not double-checked there remain risks of overlapping particularly with EAHC tenders and related waste of resources. A cooperation agreement is about to be signed between the two agencies and this is hopefully expected to lead to some improvements in the future.

3.3 Conclusions and Recommendations

Evidence	Findings
<p>Reputation and Independence</p> <ul style="list-style-type: none"> • Reputation as a repository of scientific advice consolidated; among peers (but less so as an initiator of studies or a catalyst for research); • Perception of independence fairly high, however in certain areas possibly counterproductive; • Conflict of interest policy deemed definitely adequate, but requests to increase transparency about possible conflict of interest in sources of data. 	<p>ECDC has developed a reputation as a leading organisation in the provision of scientific advice and as an independent body. It can be considered as a prime source of risk assessments and guidance documents across Europe, but there is still room for improvement as an initiator of studies and a catalyser of external research.</p>
<p>Confidence</p> <ul style="list-style-type: none"> • Confidence in ECDC capacity to produce good scientific advice fairly high, but credibility as a lighthouse for microbiological laboratory support much lower; • A priori confidence in ECDC depth of analysis and readability lower than other quality features; • Overall level of confidence in the quality of ECDC scientific advice steadily increased over time. The Centre therefore enjoys a favourable momentum to further increase its credibility in the future. 	<p>Stakeholders are confident about ECDC capacities, although not necessarily in the field of microbiology and laboratory support. Expectations about readability and depth of analysis are somehow more negatively influenced by some past problems recorded in certain areas.</p>
<p>Technical Quality</p> <ul style="list-style-type: none"> • Visibility of ECDC advice among microbiologists and laboratory experts lower than in the traditional ECDC areas of activities; • Technical quality of ECDC core deliverables generally deemed high; • Usefulness of contents for policymakers considered the weakest area; • Requests to broaden the range of sources considered. 	<p>The overall level of appreciation of the technical quality of ECDC deliverables by peers (both external experts and not) is very high. To please the expert community at large and gain recognition among peers there is possibly an academic bias in the reports and less attention to policymakers needs than would be ideally required.</p>
<p>Credibility</p> <ul style="list-style-type: none"> • Scientific credibility generally reported as high but in core areas of activity only, less so in microbiology; • Disagreement with ECDC scientific advice is generally phrased in terms of unclear mandate rather than contents; • Substantial room for uncertainties and divergences among partners as to ECDC responsibilities and roles in the provision of scientific advice. 	<p>ECDC generally perceived as a credible organisation, although diverging views as to the role it should play in the field of scientific advice.</p>
<p>Use for Risk Management and Policymaking</p> <ul style="list-style-type: none"> • Scientific advice deliverables properly speaking less used for policymaking purposes than other categories of output; • Evidence of a widespread use of ECDC products for agenda setting domestic purposes; • European Commission confirmed as the largest user of ECDC scientific advice products. 	<p>Huge variations in the reported use of ECDC scientific advice deliverables, possibly higher in low capacity and heavily regionalised environments. There is some evidence that ECDC reports are used as tools to influence the agenda setting process rather than informing the contents of policies, which remains a potentially contentious issue and a source of tensions between the PHI and Ministerial bodies when it comes to prioritisation of items.</p>
<p>Adequacy of Processes</p> <ul style="list-style-type: none"> • Processes underlying scientific advice generally deemed adequate; • Requests to have a more direct hands-on approach in implementation of advice in certain Countries; 	<p>Processes can be generally deemed adequate although with room for improvements as far as support to implementation aspects and outreach of dissemination are concerned. There is still room for substantial</p>

<ul style="list-style-type: none"> Limited mechanisms in place to avoid duplication of scientific advice at the national and European level when budgetary constraints and need for savings are more and more apparent. 	improvements when it comes to avoiding duplication of activities at both the MS and European level.
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Conclusions and Recommendations

The right balance between usefulness for policymakers and scientific credibility is difficult to achieve for European agencies and Scientific committees alike. However, there appears to be room for further improving the usefulness of scientific advice for policymakers (*Evidence medium, priority medium*).

Recommendation. ECDC could also consider broadening – at least on a pilot basis - the ranges of sources used from peer-reviewed literature to cover policy-relevant communications or grey literature coming from MS themselves and enter into the concrete lessons learnt from past implementation experiences including better consideration of cost and cost-effectiveness issues. To this aim since some stakeholders voiced the need to complement the scientific information from ECDC with lessons learnt from more practical experiences, it is worth considering the establishment of a sort of repository where all those concerned can share documents, analyses, etc. to allow a smoother exchange of information between countries

ECDC scientific reputation has been steadily growing but certain roles in the ECDC mission have been somehow neglected in the past and there is still room for improvement as an initiator of studies (*evidence medium, priority medium*) and a catalyser of external research (*Evidence weak priority low*)

Recommendation. A possible future strategy on outsourcing policy could include a dimension on balancing the effort between guidance-type documents and evidence-gathering studies by further strengthening the latter and foresee budgetary efforts indicators to this aim. Initiation of studies and catalyst activities could be better reported in dedicated sections of the annual report.

There is evidence of overlapping in the scientific advice projects financed by ECDC and EAHC, and to some minor extent other agencies. (*Evidence medium, priority medium*).

Recommendation. Coordination procedures on tendering by mutual exchange of information are to be established with EAHC, and to a much more limited extent with the other European agencies

Marginal improvements in procedures for involving experts in guidance documents and to improve transparency about conflict of interest in reviewed studies are worth considering (*Evidence weak, priority low*).

The Microbiology function is now attached to the disease programmes to serve as a support to them. Future organisational review of ECDC might consider whether other locations could improve its overall visibility and standing. (*Evidence weak, priority low*)

Following the initiative on joint procurement of vaccines, ECDC could explore whether there is enough consensus to initiate on a pilot basis some experiment with joint procurement of studies and research based on the contractual models that will be developed and promoted in Europe within the framework of the Europe 2020 initiative⁶⁴ (*Evidence weak, priority low*).

⁶⁴ Under the Innovation Union Europe 2020 initiative, the Commission is to offer guidance on implementing joint procurements between contracting entities under the current public procurement directives and use the ongoing general evaluation of the current directives to examine the opportunity to introduce additional rules to make cross border joint procurements easier.

4. EARLY WARNING, PREPAREDNESS AND RESPONSE

4.1 Overview

The activities of ECDC in the field of early warning, preparedness and response (EWPR) basically refer to three main dimensions: (i) detecting and investigating threats; (ii) support to response and technical coordination during public health emergencies (PHE); and (iii) strengthening MS preparedness. In the period covered by this evaluation, the bulk of the activities carried out related to the first two dimensions.

Since 2010, ECDC's *epidemic intelligence (EI)* activities have been supported by a series of dedicated communication platforms – *EPIS* – designed to allow real time discussion among risk assessment bodies. There are currently five active platforms, at different levels of development. Those that have progressed further in the implementation are EPIS FWD (food and waterborne diseases – seemingly the most developed) and EPIS ELDSnet (legionnaires' disease – also well developed, especially because of the legal obligation to report cases). Instead, the other three platforms are still at the general discussion forum stage, i.e. EPIS AMR-HAI (antimicrobial resistance and hospital associated infections), EPIS STI (sexually transmitted infections), and EPIS VPD (vaccine-preventable diseases). There are three main levels of discussion within EPIS: (i) general forums (exchange of information); (ii) "urgent inquiry" forum (when a potential threat is deemed deserving further analysis); (iii) *ad hoc* forum for investigation of threats that are within EU scope. Emerging threats are reviewed on a daily basis at ECDC within the so called roundtable meetings. These consist of expert meetings who assess and in case validate events which require further attention or action from ECDC due to their relevance for public health or the safety of EU citizens. Since 2012, the daily *Roundtable Report* is circulated also among interested parties in the MS (but not publicly available). Since February 2012, the *Communicable Diseases Threats Reports (CDTR)*, a weekly bulletin on emerging public health threats is published on ECDC website. All threats identified through EI activities are documented and monitored by using a dedicated database, called the *Threat Tracking Tool (TTT)*.

Since 2007, ECDC has also been responsible for the management of the EU *Early Warning and Response System (EWRS)*, i.e. the EU legally-established risk manager's communication platform for rapid alerting and response to CD incidents.⁶⁵ The notification of messages on EWRS is typically done by MS risk managers, when an incident meets a series of criteria – first and foremost: a potential cross-country spreading.⁶⁶ Often, this follows a period of threat monitoring and validation by the corresponding EPIS fora. EWRS has undergone a series of restructuring overtime. The last relates to Decision 082/2013 on serious cross-border threats, which envisages *inter alia* an extension of EWRS applicability to all health threats, and not only to those related to CD (i.e. the inclusion of threats

⁶⁵ The EWRS was firstly implemented in 1998, based on Decision 2119/98/EC of the European Parliament and of the Council to set up a network for epidemiological surveillance and control of communicable diseases in the Community.

⁶⁶ Other criteria include: (i) spatial or temporal clustering of cases of a disease of a similar type if pathogenic agents are a possible cause and there is a risk of propagation between Member States within the Community; (ii) spatial or temporal clustering of cases of disease of a similar type outside the Community if pathogenic agents are a possible cause and there is a risk of propagation to the Community; (iii) the appearance or resurgence of a communicable disease or an infectious agent which may require timely coordinated Community action to contain it; (iv) the appearance or resurgence of a communicable disease or an infectious agent which may require timely coordinated Community action to contain it; (v) any IHR notification has to be reported also through EWRS; (vi) any event related to communicable diseases with a potential EU dimension necessitating contact tracing to identify infected persons or persons potentially in danger may involve the exchange of sensitive personal data of confirmed or suspected cases between concerned Member States.

connected to biological or chemical agents or environmental events, including hazards related to climate change, etc.).⁶⁷

The major ECDC output in the EWPR area is the **Rapid Risk Assessment (RRA)**, i.e. the technical report issued by ECDC in the immediate aftermath (usually within 24 to 48 hours) of the detection and validation of an emerging threat.⁶⁸ The main goal of RRA is to understand the magnitude of the health threat and its relevance in terms of extension, ability to spread, and existence of prevention or control measures. In this sense it is aimed at supporting risk managers in adopting an informed and coordinated response, including for risk communication purposes. RRAs can be self-mandated (e.g. following ECDC's 'Round-Table' discussion) or requested by risk managers (e.g. via the EWRS platform) and are prepared by internal staff, often with the support of external experts from national PHIs.⁶⁹ Joint assessments with other agencies (EFSA, EMCDDA) are also prepared for specific cross-cutting topics. RRAs are regularly updated until the threat ceases. In 2011, ECDC published specific guidelines for RRA, applicable to both EU and national-level events.⁷⁰ The guidelines contributed to give a proper structure and procedure to these deliverables.

In the field of **response**, ECDC's responsibilities include *inter alia* the support to MS in the investigation and tackling of outbreak events. In the reference period, three main types of activities have been carried out in this field: (i) development of toolboxes, guidance documents and standard operating procedures for MS to scale up their investigation and response capacity; (ii) deployment of outbreak assistance team on the field, in the event of PH emergencies (this regarded *inter alia* the rapid mobilization of microbiology expertise through the outbreak assistance laboratories network) and (iii) the set-up of the *Emergency Operation Centre (EOC)* facility and procedures to deal with public health events, i.e. extraordinary processes for ECDC's functioning during crises.

Finally, **preparedness**-related activities received comparatively smaller attention in the period considered. In this area, in particular, ECDC (i) participated to projects and joint actions (e.g. SHIPSAN, EUFRAT), (ii) coordinated with WHO/EURO on supporting country's preparation and updating of preparedness plans, (iii) issued guidelines (e.g. RAGIDA) and procedures (e.g. with Europol on bioterrorism), and (iv) organized / took part to simulation exercises of various nature.

The title III budget allocation to preparedness and response remained in the € 1-1.5 million range until dramatically dropping to some € 150 million in the 2011-12 period, where it mainly consisted of 26 FTE staff dedicated to early warning. Vagaries in allocation make it difficult to identify trends in delayed expenditure. Funds disbursed have remained in the 20-30% range of the total allocated, but dropped to 5% in 2012.

⁶⁷ http://ec.europa.eu/health/preparedness_response/docs/decision_serious_crossborder_threats_22102013_en.pdf

⁶⁸ The denomination "Rapid Risk Assessment" is used consistently and systematically since 2011. Previously, documents with the same purpose used to fall in the broader category of 'threat assessments', which includes also 'regular' risk assessments, 'forward look' risk assessments etc. In 2013 the 'threat assessment' denomination was seemingly dropped, and in ECDC reporting documents RRAs are made coinciding with the broader category of 'Risk assessments'.

⁶⁹ The EU Decision on Common Threats (22.10.2013) establishes that ECDC is now responsible for carrying out the risk assessment of the potential severity of the threat to public health, including possible public health measures, for all threats under its remit that are notified through EWRS, while in the past it has increased from some 30% of them in 2009 to some half of them in 2012.

⁷⁰ European Centre for Disease Prevention and Control. "Operational guidance on rapid risk assessment methodology." Stockholm: ECDC; 2011.

4.2 Main Findings

4.2.1 Epidemic intelligence and EPIS

The annual number of threats monitored by ECDC in the 2008-2012 period ranged from 251 in 2008 to only 64 in 2011. The substantial decrease registered since 2008 is reportedly due to various factors, such as a refinement of criteria for monitoring threats “*to focus more on assessment rather than pure monitoring*”⁷¹, fluctuations in the share of threats meeting the criteria to inclusion in EWRS, and most importantly, the progressive implementation of specific modules of the ECDC’s Epidemic Intelligence Information System (EPIS) and the adoption of stricter monitoring criteria (e.g. in the case of legionellosis the decision not to open a threat for every reported travel-associated case but to follow only rapidly evolving clusters, reduced the number of legionellosis threats monitored from 92 in 2009 to eight in 2011). The first version of EPIS was launched in 2010, covering the FWD area (later reviewed in 2013). Other EPIS platforms for disease-specific network were set up later, i.e. STI (2011), ELDSNet (2011), AMR-HAI (2012), and EVD (2012 – partly). ECDC also disseminates EI information through bulletins, i.e. the weekly *Communicable Diseases Threat Report* (CDTR) – publicly available on ECDC website since February 2012 - and the daily *Roundtable Report* whose circulation started in 2012. Plans to make *threat tracking tool (TTT)* – i.e. the repository and archive of the threats monitored by ECDC – accessible to external experts have been delayed.⁷² The variety of early warning methods and systems put in place by ECDC in the evaluated period represents a first and important performance indicator to be considered when analysing the Centre’s progress in the EI field.

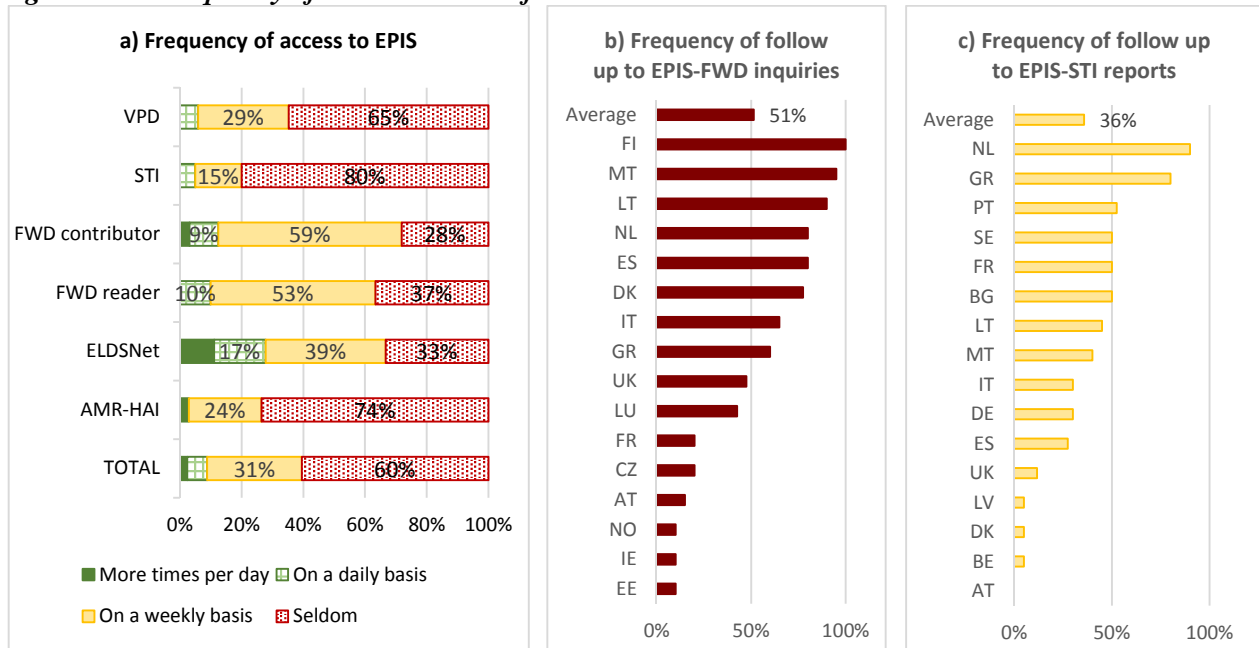
The *Epidemic Intelligence Information System (EPIS)* represents undoubtedly a technical improvement over the previous network-based system. Previously, the exchange of information occurred via functional emails, which made it overly burdensome and made it difficult to retrieve ‘historical’ records. EPIS platforms support the existing collaboration patterns with an efficient IT tool, more functionalities and a user-friendly interface. EPIS platforms are recently established and have undergone repeated revisions in the past years, therefore an in-depth assessment of their functionality seems premature. The same holds true for utilisation statistics, which are available only for EPIS-FWD, which is possibly the most ‘mature’ platform. According to such data, EPIS is still far from becoming a major source of ‘first notification’ of emerging threats. In the 2010-2012 period only 7 out of nearly 50 new FWD threats monitored by ECDC were first detected through EPIS.

The survey statistics on usage of EPIS by the experts who have access to it (129 in our sample) confirm that for many of them the use of EPIS is still sporadic. Only 31% access EPIS on a weekly basis and less than 10% on a daily basis. Patterns of use vary greatly across platforms also in line with the respective different functionalities and frequency of updates. Unsurprisingly, the STI platform, which basically works through periodical reports, is the least-frequently accessed, whereas due the intrinsic nature of the disease and its spreading patterns, the ELDSNet for Legionellosis and the FWD are the most frequently used (Figure 4.1.a). The analysis of frequency of follow-up to EPIS ‘notifications’ (inquiries, reports etc.) shows the existence of some difference across countries in the use of EPIS (Figure 4.1.b and 4.1.c). First of all, it shows once again the disparity in the level of participation between the FWD platform, which cover potentially fast-spreading disease, and the STI platform where incidence rates are typically smaller and outbreaks are normally slower. Secondly, it shows that MS behaviours are far from uniform across Europe, with follow-up frequency rates ranging from nil to 100%

⁷¹ ECDC, Annual Epidemiological Report, 2012.

⁷² Source: ECDC, Annual Report of the Director, 2013.

Figure 4.1 – Frequency of access and use of EPIS

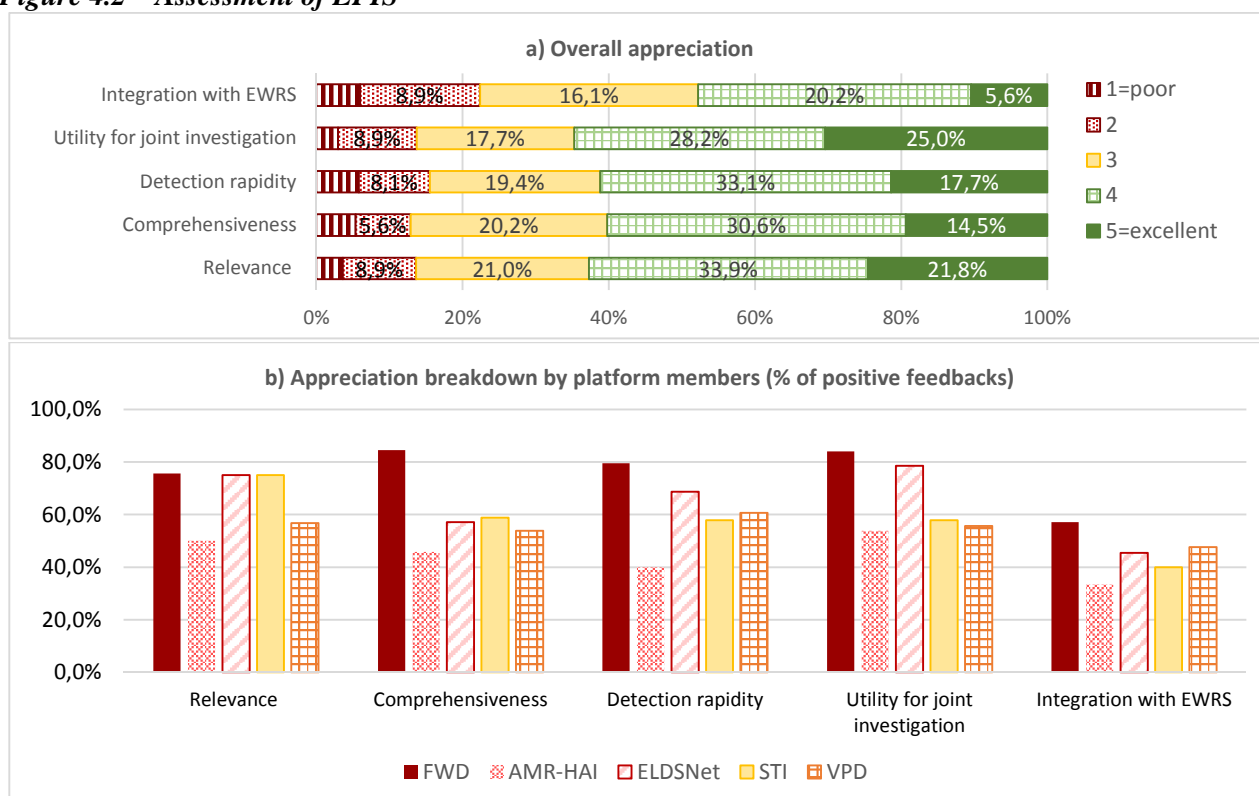


Note: Total headcount= 129 (a); 32 (b); 20 (c).

EPIS is generally perceived as a high added-value tool (see Figure 4.2 below), in particular:

- It is considered a very practical tool as compared to the previous system and it is particularly useful for joint and coordinated identification and investigation of alerts. Utility is obviously correlated to actual use (e.g. for characterisation of ‘clusters’) and in this sense it appears higher in the case of more mature platforms such as FWD and ELDSNet. This suggests that the utility of the other platforms is set to improve proportionally with their future developments.
- The ‘low threshold’ design has been maintained in the transition from the old system to EPIS. This is a largely appreciated feature by users, who normally recognise that, although the importance of individual alerts vary across countries, the overall relevance of information exchanged through EPIS is high.
- Some believes (but there is no hard data to corroborate this perception) that EPIS – where fully implemented - might have shortened threat detection time. Again, this seems to hold true in particular for the most widely used EPIS platforms.
- The integration of EPIS with the EU Risk Management system, and the EWRS platform, in particular, is the more problematic area of EPIS. While on paper the two systems have clearly different goals and targets, some EPIS users lament that sometimes there is confusion of roles. For instance, it may happen that alerts still at the informal level of discussion on EPIS are prematurely taken up by risk managers who have access to EPIS, before they are properly validated by disease experts, thus causing an unduly alarm and reaction.
- The comprehensiveness of EPIS coverage has grown overtime, but there exists a significant difference between the quite advanced FWD platform and the others, which are still at the early stage. Connected to this, it is remarkable that three-quarters of the EPIS users do not regularly use any other EI information sources beside it. This is particularly the case with various Eastern Europe countries’ and German experts, while it is far less true with French and British respondents, who instead greatly rely on their national systems. The main ‘competitor’ of EPIS as an epidemic intelligence tool is ProMED-mail, which is mentioned by one in four respondents as an alternative source to EPIS. Various WHO systems are also popular (e.g. *Infosan*, *GOARN*), as well as the EU early warning system EWRS and RASFF.

Figure 4.2 – Assessment of EPIS



Note: Based on a total of 124 EPIS participants. ‘Don’t know’ answers not included. Respondents’ headcount for individual platforms range from 18 (EDSLNet) to 48 (FWD).

MS experts have mentioned various examples where EPIS demonstrated added-value in facilitating networking and/or helped a quick detection and/or assessment of a threat. In most of cases, these relate to very recent event (2013-2014), which fall outside of the scope of this evaluation. This reflects the fact that – as discussed – EPIS only recently and in few cases has reached an appropriate level of maturity. The most frequently-mentioned examples concern Salmonella, and in particular the following outbreaks: *Salmonella Poona* (2010), *Salmonella Newport* (2011)⁷³, *Salmonella Stanley* (2012) and *Salmonella Mikawasima* (2013)⁷⁴. Other popular examples include (i) the meningococcal disease in men who have sex with men (2013), mentioned by three MS; (ii) various instances of Hepatitis A events, also reported by three different countries⁷⁵; and (iii) the support in general provided during several international incident/outbreak investigations of legionellosis, where the exchange of data between microbiologists and epidemiologists reportedly proved crucial for clustering.

⁷³ On this case an EPIS member reported that: “Germany quickly reacted [to our inquiry] that they also had an ongoing outbreak. Together, we found the source (sprouts). Without EPIS, we probably had not detected that it was an international outbreak or only afterwards via published articles.” <http://www.eurosurveillance.org/ViewArticle.aspx?ArticleId=20665>”

⁷⁴ On S. Mikawasima one respondent reported that: “The best example of successful detection and threat assessment recently would be the outbreak and EU state increase in S.Mikawasima in late 2013 through which EPIS provided the platform for collaborative action between England and Denmark (particularly). The event was a temporal increase in S Mikawasima first detected in Denmark, followed by UK which resulted in a wider investigation in all countries including comparisons and sharing of Gene sequence data.”

⁷⁵ For instance in tourists returning from Egypt. See: http://www.salute.gov.it/portale/news/p3_2_1_1_1.jsp?lingua=italiano&menu=notizie&p=dalministero&id=1065

Beside technical aspects of the EPIS interface – which do not pose particular problems to users⁷⁶ - ECDC has also undertaken the role of facilitating/coordinating exchanges and inquiries among participating organisations, as well as providing technical support and assistance. Additionally, ECDC sometimes contributes to EPIS by signalling relevant events (e.g. taken from other systems such as RASFF), or by preparing and publishing summaries and consolidated overviews on specific events. Overall, the way EPIS is managed by ECDC is considered satisfactory by the interviewees, for the rapidity to follow up to questions and the non-invasiveness in the investigations. According to some stakeholders, the transition to EPIS had instead some drawbacks on the efficacy of epidemic intelligence activities. In particular, as compared to the previous system the proactivity and the reactivity of some participants are reportedly lessened. First, there appears to be greater reliance on ECDC instead of MS themselves in detecting and signalling potential threats; second, EPIS is not an ‘active coordination’ system, i.e. in case of threat does not actively ‘chase’ for information from network members as it usually happened before. This finding seems partly confirmed by survey results, where the ‘responsiveness of partners to inquiries’ received comparatively lower appreciation scores than other operational aspects. This holds true in particular for the AMR-HAI and the STI platforms, while for the others the feedback was generally positive.

Other ECDC’s products for early warning are the daily *Round Table report* (RTR) and the weekly *Communicable Disease Threats Report* (CDTR). The RTR is a recent instrument (2012) addressing specifically risk managers of the MS. The circulation is quite limited. The study’s sample includes only 21 risk managers having access to the RTR and therefore cannot be considered as statistically representative. However, trends suggest that RTR is useful especially for updating on already known threats, and in few cases to inform about threats that were not known yet to recipients – especially with respect to disease outbreaks in overseas countries rather than in Europe, for which other rapid information channels already exist. For one in three respondents the fact that the information contained in RTR cannot be publicly disclosed represents a limitation to its usefulness.

Unlike RTR, the CDTR is publicly available online (since 2012) and is reportedly one of the most visited pages on the ECDC website (i.e. in excess of 8,000 visits in 2013).⁷⁷ Prior to 2012, it was directly sent to a list of 300-400 recipients. CDTR seems as a sort of ‘hybrid’ product, halfway between early warning, event-based surveillance and communication. In fact, since it is publicly available, its contents can be freely used by stakeholders for their communication needs. The consolidation of the information on different threats in a single place has reportedly the major beneficial effects for experts of reducing the data research time.

4.2.2 The Early Warning Response System (EWRS)

Since 2007, ECDC supports the Commission by operating the EWRS IT tool. ECDC is also in charge of providing scientific advice and risk assessment concerning messages received through the EWRS. The detailed statistics on EWRS activity are regularly published on the ECDC’s *Annual Epidemiological Report* (AER). In the period considered the number of threats meeting the criteria for notification on EWRS ranges between 60 and 90. This generated, with few exceptions, some 80-100 threads and 200-300 comments on average, per year. A notable exception was 2009, when the pandemic emergency led to some 500 different threads posted on EWRS, followed by more than 800 comments and more than 700 ‘selective exchanges’.⁷⁸ A variable proportion of EWRS-notified threats have been followed up by ECDC with scientific assessments. These were 31% of the total in

⁷⁶ Four in ten respondents affirmed that the clarity and user-friendliness of the system is good or excellent.

⁷⁷ Source: ECDC, Annual Report of the Director, 2013.

⁷⁸ Messages exchanged by a selected number of participants.

2010 and decreased to 23% in 2012.⁷⁹ The recent Decision 1082/2013 on serious cross-border threats, would apparently lead to a substantial increase in ECDC follow-ups.

The responsibilities of ECDC with respect to EWRS are limited to the technical and operational management of the system. Its mission is laid down in the EU regulation and can be revised only through a formal procedure, as it was for instance the case with the Decision 1082/2013, which extended EWRS competence to non-CD health threats. The segregation is dictated by the need to clearly distinguish between the risk management functions (decision-making) to which EWRS is oriented, from the risk assessment functions carried out instead by the public health and disease experts and networks who represent the core of ECDC action. Such distinction of roles is not so straightforward in practical terms, and stakeholders' views on where the boundary precisely is vary greatly across countries, professional profiles, backgrounds and experiences. The most frequent feedback on this point is that at MS level the distinction between such functions is often blurred, and therefore attempts to make it more clear-cut at EU-level inevitably appear somehow artificial.

Connected to this, EWRS integration with the ECDC's EI systems - and namely with EPIS - still attracts some criticisms and perceptions of unduly overlapping or confusion. To be fair, it must be said that such critical views are prevalently expressed by experts who, although self-declaring familiar with EWRS, do not in fact regularly use it. This would suggest that the supposed confusion is mainly due to a lack of in-depth understanding of the two systems. Anyway, since similar perceptions were voiced by EPIS users too, a better integration of the two systems seems needed, although it is worth highlighting that Decision 1082/2013 intervenes also on this point. In the same vein, risk managers rate the degree of integration of EWRS with its 'sister' alert platform for food safety (RASFF) as moderately satisfactory. Conversely, EWRS is seen as complementary and not overlapping with IHR early-warning system, since they have different thresholds (EWRS covers also threats much less serious than IHR's) and different scope (EWRS is a Europe-focussed platform). In order to avoid the burden of 'double notification' the European Commission has agreed with WHO a single-notification system where events are automatically notified on both platforms. This is largely considered by stakeholders as one of the clearest collaboration 'best practice'. For the reasons explained above, direct intervention in support to integration falls clearly outside of the remit of ECDC, but obviously the Centre may contribute its scientific view on how to make the system smoother and efficient.

What is more directly under the responsibility of ECDC are management and support services as well as the clarity and user-friendliness of the interface. On these two criteria, feedbacks are largely positive, although the limited number of observations available does not allow to generalise this result (see Figure 4.3.a below). As concerns operational aspects, there seems to be room to streamline the management of threads of discussion, which in certain circumstances become confusing and overloaded. This is also connected with the relevance of messages shared, which according to some users "*do not really refer to threats or coordination measures*" and therefore reduce EWRS usefulness. Finally, various experts expressed the concern that the expansion of EWRS scope to non-CD health threats envisaged by Decision 1082/2013 may be detrimental to the quality and the utility of EWRS discussions – but seemingly this issue has already been addressed and there are plans for segregating the two paths.

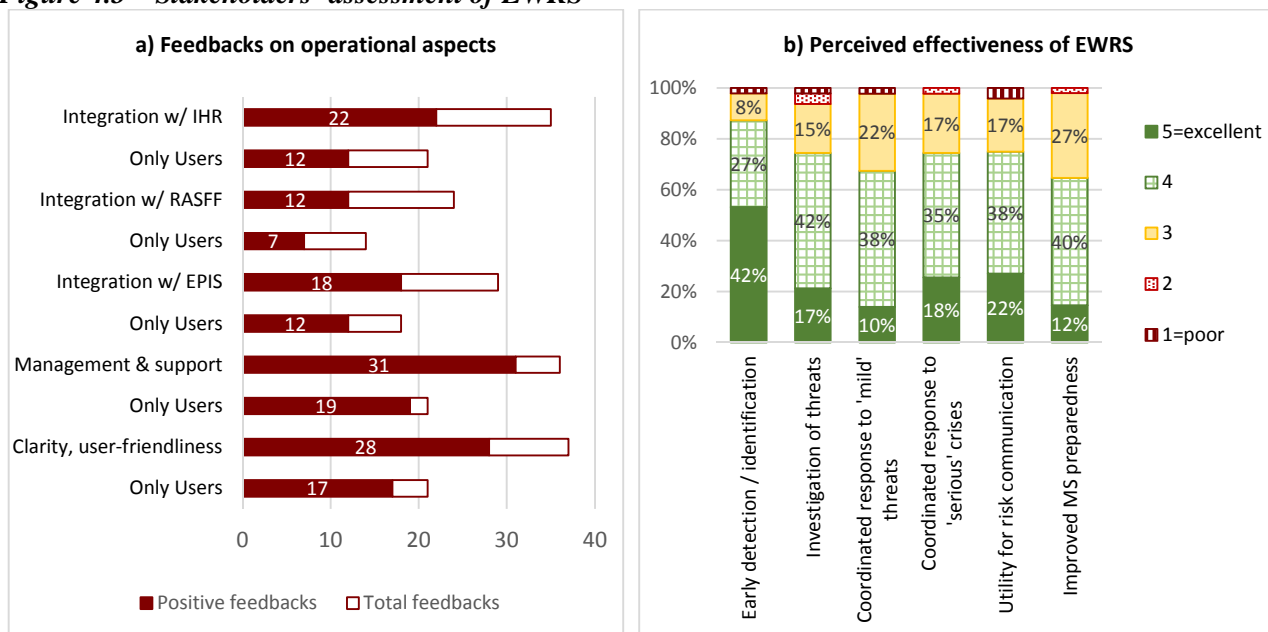
In order to provide a comprehensive view on EWRS role in the overall EU system that comprises also ECDC, it appears useful to briefly recap the feedbacks on its usefulness and added-value provided by directly concerned experts. These are summarised in Figure 4.3.b below, in particular:

⁷⁹ ECDC, Annual Epidemiological Report, 2011 and 2013.

- EWRS was created to facilitate communication exchange between risk managers at national, EU and international level on CD threat. It was conceived as an early warning platform, but overtime it has been used also for crisis management. With respect to the first dimension, interviewees largely confirmed the utility of EWRS (about 50% of ‘excellent’ feedback). However, as far as coordinated response is concerned, various respondents highlighted that EWRS is not really suitable for this purpose. This is particularly the case with serious crises, such as the 2009 influenza pandemic: in such instance the system got quickly overloaded and the abovementioned multiplication of threads generated confusion, to the point that retrieving information became very burdensome. The witnesses interviewed concur that ECDC should have played a more active role in that occasion, by summarising threads and organising in a more efficient manner the information that was posted on EWRS.
- On risk communication usefulness, some stakeholders highlighted the issue of information disclosure. The information published on EWRS is confidential. However, the same information, or part of it, is perhaps publicly available through other sources. This makes that a risk manager who wish to use EWRS information for communication purposes has to first cross-check on other sources which part of the information is already publicly disclosed, with an ensuing waste of time and resources. This could be easily overcome by specifying on the platform the data that can be used for external communication, and those that cannot.

Looking back in perspective, there is a quite unanimous appreciation of how EWRS has evolved since 2008. For nearly half of ‘acknowledgeable’ experts surveyed (i.e. with a professional ‘age’ or experience compatible to provide an informed feedback) such improvement was significant, and only 2 out of 31 believe EWRS has instead worsened.

Figure 4.3 – Stakeholders’ assessment of EWRS



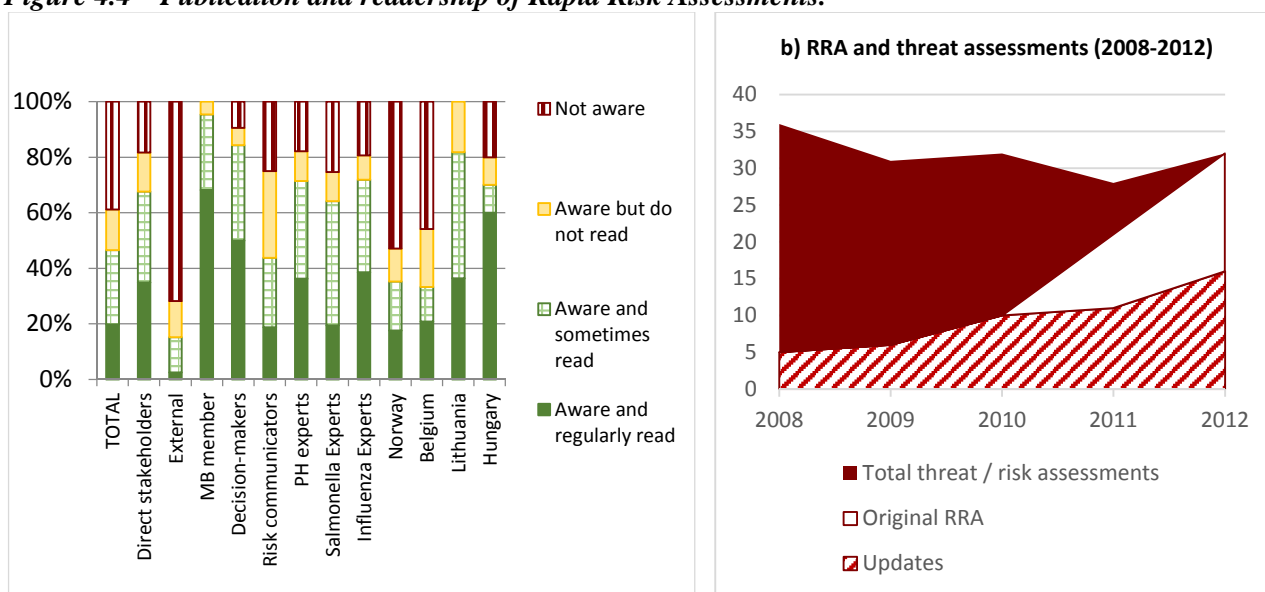
Note: Based on a total of 60 selected respondents (risk managers, member of EC relevant committees, ECDC relevant NFPs). ‘Don’t know’ answers for (b) are not displayed.

4.2.3 Rapid Risk Assessments

The Rapid Risk Assessment (RRA)⁸⁰ has become a ‘flagship product’ of ECDC. The majority of stakeholders surveyed from both the relevant scientific community and decision-makers are familiar with RRAs (61%) and a non-negligible 20% affirmed to read them ‘regularly’ (Figure 4.4). Obviously, RRAs are mostly known among ECDC’s partners and direct stakeholders (awareness rate: 68%), and among them the most regular RRAs readers are the Management Board members (68% of regular readers). The levels of awareness and readership among decision-makers are also particularly high thus confirming its relevance for policy-making. This does not apply to experts with ‘risk communication’ responsibilities whose awareness rate is instead more in line with the average of respondents. With respect to scientific area, influenza experts seem significantly more interested in RRAs than experts of other diseases. Country-wise, RRAs are most read in the Eastern Europe region (e.g. Hungary, Baltic countries etc.), while the lowest readership is registered in the Belgium and Norway.

In the period considered, the production of RRAs (including RRA-like threat reports before 2011) fluctuated between 28 and 36. The lowest limit was reached in 2011 (possibly connected with the internal reorganisation process). Updates of previous ‘original’ arrangements proportionally increased overtime, from one-sixth in 2008 to half total in 2012.

Figure 4.4 – Publication and readership of Rapid Risk Assessments.



Note: (a) total headcount: 638. (b) source: ECDC, Annual Report of the Director.

The abovementioned readership data confirm the overall ‘relevance’ of RRA for stakeholders. This finding is confirmed also by qualitative interviews with experts. RRA responds to a well-established need to address in a coordinated manner health threats that are trans-boundary by nature. In this sense, for its scope and format, it appears as a ‘unique’ product, complementary and not overlapping with similar assessments produced at the national or international levels. There has been, however, some critical views on the relevance of a few specific RRAs that – according to some risk managers – fall outside of ECDC’s domain.⁸¹

⁸⁰ The RRA figures provided in this Section include also the ECDC and EFSA joint rapid outbreak assessments.

⁸¹ This is the case for instance of the assessments on melamine contamination of dairy products in China (2008) http://www.ecdc.europa.eu/en/healthtopics/Documents/081001_Melamine_Health_Impact_Assessment.pdf

The relevance of RRA is strictly correlated with the timeliness of its preparation and dissemination to risk managers (typically via EWRS). As noted by various interviewees, timeliness has remarkably improved over the years and now represents in many instances a key strength of RRA. Since its establishment, however, the performance indicator for RRA timeliness - i.e. 75% of RRAs produced within 48 hours of initial decision – has not been met.⁸² In 2012, only 61% of RRAs met it.⁸³ The main reason for delays according to ECDC is the delay in the receipt of input and data from external experts of the MS. In a few cases the RRA publication was reportedly delayed by decisional processes happening outside of ECDC on potentially contentious matters (e.g. at the HSC level). The general perception remains broadly satisfactory also because reports are typically made available on the EWRS as soon as they have been finalised.

RRAs are generally considered documents of good quality, well-written, clear and scientifically robust. Reportedly, the cases of ‘disagreement’ with RRA scientific methods and/or conclusions have been rare in the period considered and most of times were easily overcome. However, from the in-depth interviews with key informants it emerged that sometimes RRA conclusions are disappointingly generic and/or incomplete, and this is perceived in some cases as the consequence of pressures and interferences that ECDC is subject to with respect to the safeguard of boundaries between risk assessment and risk management roles. The survey data partially confirm this finding, with the ‘independence’ criterion rated comparatively lower than the others.

The usefulness of RRA in supporting risk management is largely recognised⁸⁴ (concrete impact on decision making is discussed in greater details in the following section). The timely issuance of RRA allows decision-makers to take early prevention and control measures in a coordinated manner, and taking into account the ‘level’ of risk implied by a certain threat. To the extent RRAs often involve inputs from scientists in the concerned countries, they can also be seen as a tool to facilitate joint investigation and analyses of threats. Furthermore, for certain stakeholders not directly involved in threat detection, as well as for low capacity institutions, RRA may also have an informative role. Finally, the content of RRA is reportedly often used by MS organisations to prepare country-level reports or other information material for dissemination. This is possibly the area where RRA added-value lies the most, i.e. the fact that in the absence of RRA, MS should prepare their own domestic assessment of emerging threats, with an ensuing huge duplication of efforts (and possible significant disparity of capacity and quality across countries). Some countries still prepare (for certain threats) their national assessments but often they largely utilise ECDC’s information, only adding the country-specific dimension. Overall, along the 2008-2012 period, the usefulness and the quality of RRA improved significantly, according to its main readers, and only a tiny 5% do not see any tangible progress (Figure 4.5.b)

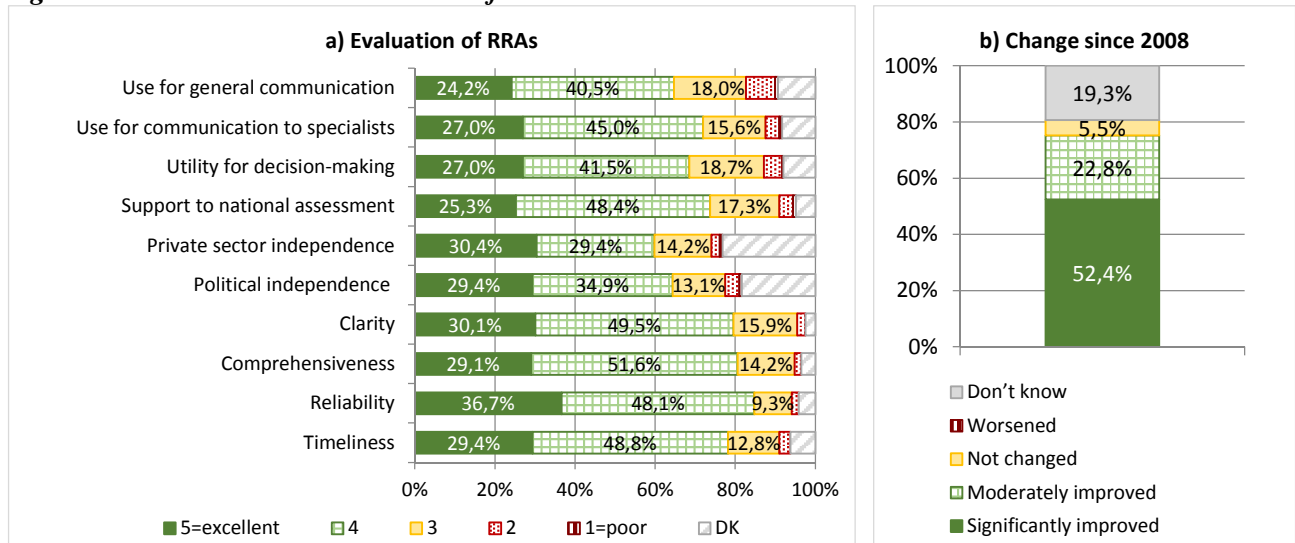
Another example is the volcanic eruption in Iceland (2011) <http://www.sergas.es/cas/DocumentacionTecnica/docs/SaudePublica/incidencias/ECDC%20Threat%20Assessment%20-%20Volcano%20in%20Iceland.pdf>.

⁸² The 48-hour deadline does not apply to ECDC and EFSA joint rapid outbreak assessments.

⁸³ In 2013 the deadline was met by 70% of RRAs ‘with readily available data’. It is unclear how many RRAs fell into this subgroup and therefore what is the percentage of RRAs issued without delay on the total.

⁸⁴ When asked about indicating well-received RRAs, interviewees tended to mention unsurprisingly recent ones related to external threats, in particular on MERS-CoV 2012-2014 (ten updates), and on poliomyelitis in Syria / poliovirus (WPV) in Israel (2013-2014). In both cases policy effects were reported, i.e. the adoption of obligation to report in the first case, and the implementation of environmental testing – as recommended by ECDC – in the second case. As underlined by an interviewee, the usefulness of RRA for risk management of more ‘common’ threats (like salmonella) should instead not be overstated, since the ‘risks’ implied by such threats are already well-known and documented

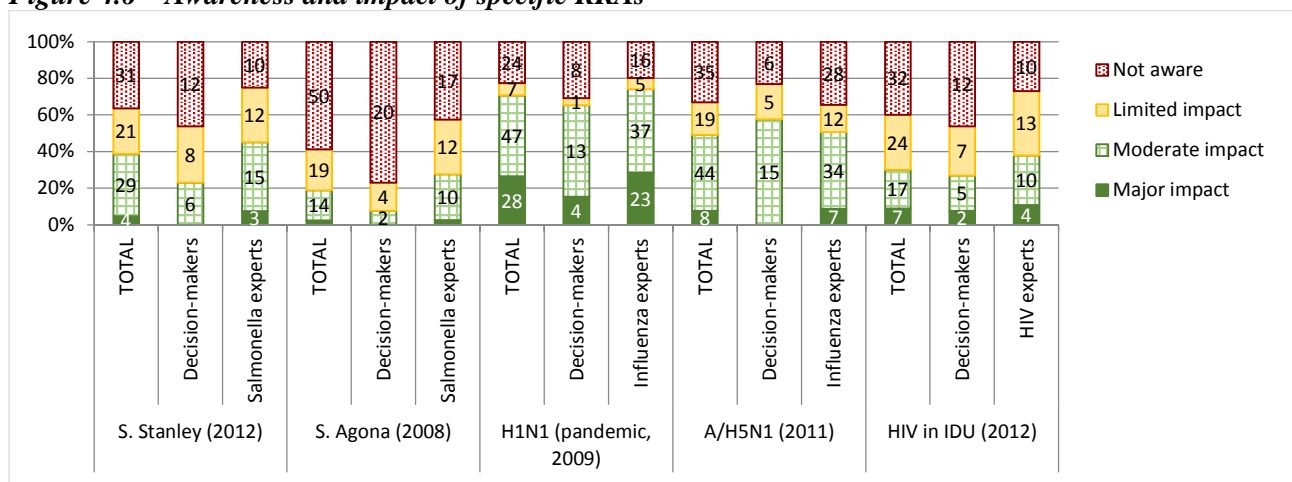
Figure 4.5 – Stakeholders’ assessment of RRA



Note: total headcount: (a) 289; (b) 145 (only respondents with 6 years or more of relevant professional experience).

In order to better anchor the evaluation’s findings to hard evidence, a more focussed assessment of a sample of specific RRAs was carried out. The sample included five RRAs related to the three disease case-studies covered, and the analysis covered awareness and impact of RRAs as perceived by decision-makers and by relevant disease experts (Figure 4.6). The results indicate that in general the perceived impact of RRAs is greater from the perspective of disease experts than among decision-makers, as it was expected given the distinction between risk assessment and risk management functions. Secondly – although the sample selection is not intended to be representative of the ECDC output in a given field – data would seemingly confirm that influenza is a domain where ECDC work receive ample consensus. In particular, despite the numerous difficulties and drawbacks occurred during the 2009 pandemic, a vast majority of stakeholders recognise that ECDC RRA had an impact in framing investigation and strategic decisions. Conversely, the interest in RRA related to HIV/AIDS is unsurprisingly the lowest in the selected sample, due to the characteristics of the disease risk profile (see Section 10.4 on the HIV/AIDS programme).

Figure 4.6 – Awareness and impact of specific RRAs



Note: total headcount: (i) Salmonella, 85; (ii) Influenza, 106; HIV/AIDS, 80.

4.2.4 Contribution to preparedness and response capacity at MS and EU level

This section deals with the overall ECDC added-value when it comes to supporting Member States as well as the EU in the control and the response to PH threats and emergencies. To begin with, it is interesting to compare the extent to which beneficiaries expectations in the various areas of work have been met so far.⁸⁵ The evidence collected indicates noteworthy levels of appreciation for ECDC efforts in rapidly disseminating information on threats (i.e. mostly through RRAs) and for early detection, filtering and threat validation work (i.e. from epidemic intelligence to early warning). In both cases, positive or very positive feedbacks have been expressed by some 65-68% of respondents. The support to investigation and assessment of threats - provided again through RRAs and to a smaller extent through direct field assistance - also received numerous positive feedbacks (58%). Conversely, in the case of support to response capacity and country preparedness⁸⁶ positive ratings are still the relative majority but the proportion of negative or neutral feedback is non-negligible (26% and 36% respectively).

The ECDC contribution to investigation of emerging CD threats is first and foremost demonstrated by the widespread appreciation of relevance and usefulness of RRA – as discussed above. As concerns how concretely RRA support MS threat investigation and response capacity, some factual evidence have been collected.⁸⁷ This can be summarised as follows:

- **Provision of back-up information.** This is seemingly among the most widespread type of impact, especially in ‘high-capacity’ countries. As described by a national expert with respect to the pandemic influenza (2009): “*ECDC risk assessment was instrumental in reassuring us on the comprehensiveness and quality of our own national risk assessment. It gave more strength to our document as our Ministry of Health was satisfied with the convergence of both analysis*”. Similarly, for some experts the utility does not lie in the scientific advice but in the data collected which are often the most comprehensive available.
- **Fostering policy measures.** Connected with the above, numerous cases were reported of RRA providing useful background information for the adoption of national strategies, action plans, guidelines or other actions. This type of impact is registered especially (but not only) in MS with comparatively smaller capacity. Policy on influenza vaccination has been often mentioned by national experts as a case in point. Also in the field of HIV/AIDS various examples were reported. In this area, some criticisms were also voiced. In some expert’s experience: “*responsible persons are aware of the RRA information but do not or rarely used them in their day to day decisions*”. The main issue seemingly concerns RRA recommendations, which sometimes are perceived as too generic, sometimes not sufficiently supported by evidence, sometimes weakened by the need not to overlap with risk management functions.
- **Information and communication.** In various instances, RRA have been used by national PHI and other authorities as sources of information for the production of *ad hoc* national information and communication products. A variety of national-level documents have been cited to demonstrate such effect (see the next section).
- **Support to efficient and coordinated investigation.** RRA are prepared by ECDC staff often with the support of external key experts who provide data and/or state-of-the-art scientific assessment, and this often lays the basis for a coordinated investigation of threats and actual cooperation among experts from different countries. This was reportedly the case with RRA

⁸⁵ This assessment is based on a sub-sample of 69 acknowledgeable respondents including the relevant NFP, and experts with risk management functions at MS and/or EU level (e.g. members of the EWRS Committee etc.)

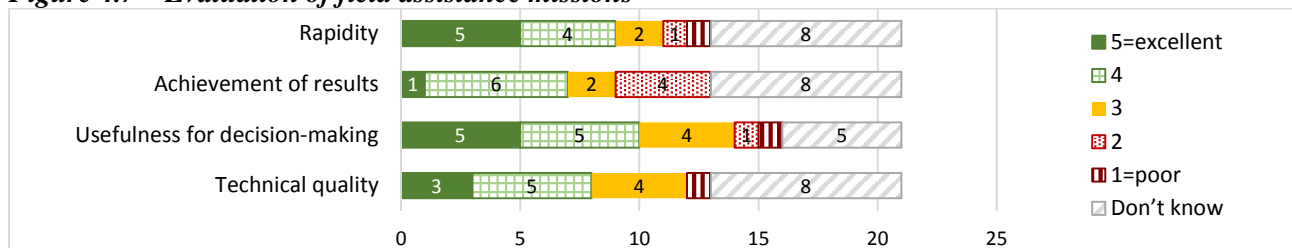
⁸⁶ Country preparedness is a very recent priority of ECDC work and in the period analysed very few activities were carried out. Coherently, this matter is outside of this evaluation’s remit, and it is addressed here only for its complementarity with response capacity aspects.

⁸⁷ The examples collected refer to the five RRAs analysed with greater focus in the previous section.

on *Salmonella Stanley* (2012), which according to some experts supported “a more rapid notification of isolations from different sources and sending of strain to the national reference lab for typing”. This type of impact was however not frequently reported.

In some occasions, direct support to MS was also provided through *on-the-field missions* of experts. These were short missions aimed at assisting a given country in the investigation of and response to a given outbreak, and added up to the numerous other country visits organised by ECDC as part of its ‘partnership’ work programme or in the framework of specific disease programmes. A case in point is the support provided during the influenza pandemic (2009). Other cases include for instance the EHEC/STEC outbreak in Germany (2011). Often, EPIET / EUPHEM fellows participate in field assistance missions. In the period considered the overall number of field mission is estimated at 20-25.⁸⁸ In the Study sample only 21 respondents were aware of ECDC field assistance missions to their country, and several were not in the position to comment it. On a qualitative basis, the most appreciated aspects of field missions are the rapidity of deployment when the need arises, and the usefulness of experts’ advice for taking measures and/or adopting overall strategies to deal with a certain outbreak. The scientific and technical quality of assistance is generally positive, however – possibly due to the sometimes employment of not-so-experienced EPIET / EUPHEM fellows – for some country experts: “most EU countries do not need assistance in outbreak investigation. Usually people sent by ECDC are not more expert than national investigators.” The effectiveness of field missions is less positive than the other aspects, since the assistance not always produced the desired results. In this sense, the major obstacle may be represented by a not always adequate knowledge of the national health systems of the beneficiary country (Figure 4.7).

Figure 4.7 – Evaluation of field assistance missions



Note: total headcount: 21.

The above matter touches upon the more general issue of *ECDC’s response during PH crises*. The perceived added value of ECDC action in this field is positive (48% of positive feedbacks) but less than for other areas of ECDC work. Policy-makers are among the more satisfied with ECDC response during crisis (69% of positive ratings), and so are national experts that are familiar with ECDC work but are not directly involved in its activities (71%). A certain variability is registered also across countries: the highest ratings come from Eastern Europe countries as well as the UK, conversely French and Germans are among the least satisfied. More qualitative feedbacks and explanations for these ratings have been collected through in-depth interviews with reference to specific cases – namely, the A (H1N1) influenza pandemic (2009) and the EHEC/STEC outbreak (2011). These are briefly summarised in Box 4.1 below.

⁸⁸ Reports and information are not available for all mission. These estimate are based on ECDC annual reports, but in some years the report is not very clear on the number of missions carried out and its nature and purposes.

Box 4.1 – ECDC support during specific public health crisis

The ECDC is generally recognized to have played a useful coordinating and supporting role during the A (*H1N1*) *influenza pandemic* (2009), although with the limitations in terms of impact on risk management decisions noted above. The main problems reported by stakeholders relate to the very early stage of the pandemic and to coordination with WHO in two main respects. The EU case definition approved in 2008 envisaged, differently from other communicable diseases, a peculiar notification system based on three different layers of reporting. Probable cases were defined as those who tested positive for avian influenza in a test performed by a laboratory which is not member of the Community Network of Reference Laboratories for human influenza (CNRL) and two different layers of confirmation: a national one to be performed by a National Reference Laboratory participating in the EU CNRL and the WHO confirmed case receiving laboratory confirmation from a WHO Collaborating Centre. It appears that the laboratory criteria agreed by the ECDC for the CNRL, slightly differed from those used by WHO and as these were released earlier during the pandemic, this reportedly created at the beginning of the pandemic some considerable confusion in understanding figures and trends, as the meaning of nationally and WHO confirmed case become blurred for final users and figures apparently inconsistent.

It was also noted that ECDC had uncertainties in releasing scientific advice on warnings for tourists, as WHO usually takes the lead on this, and was probably constrained by concerns on excessive and unjustified travel restrictions. However, as mentioned elsewhere in this report, the RRA were highly appreciated and the overall way information was communicated and debriefed to risk managers by means of teleconferences jointly organized with the Commission deemed adequate and effective. No particular lessons have been highlighted from the experience over and above those already included in the several evaluation exercises made on the subject, although some interviewees would like to know more on degree of uptake and feedback given to those exercises.

Another case spontaneously emerged during interviews with stakeholders is the *EHEC/STEC outbreak* that affected Germany and to a smaller extent other EU countries, in 2011. In that occasion, ECDC provided on-the-field support to German authorities for the investigation of the outbreak, and helped determining the real features of the event and assessing its risk.⁸⁹ On the other hand, such event demonstrated some weaknesses in the overall EU P&R system and in particular: delays in notification to ECDC from MS, the need to invest more in microbiology harmonization, the added-value of greater coordination with EFSA and with food safety authorities in general.

In the period covered by the evaluation, the ECDC strategy also entailed supporting MS in scaling up their *preparedness* to respond to threats and crises. Outside of the institutional training and capacity building activities (first and foremost the training programmes and EQA schemes) – discussed in Section 5 – there have been few actions in this area. The ECDC's 'country preparedness support' section has been only recently established and it is too early to evaluate its effectiveness.⁹⁰ Among the few specific initiatives carried out, it is worth to mention again on-the-field missions, which received very positive feedbacks - such as the preparedness support provided to organising countries of the 2008 European Football Championship.

Other relevant initiatives in this field are simulation exercises. In the period analysed, ECDC reported to have conducted an overall ten simulation exercises. These in addition to exercises under the aegis of the Commission to which ECDC has participated and contributed on technical aspects and implementation. Of the ten exercises reported, only five were open to MS participation, the rest being ECDC internal exercises. Simulation exercises open to external participants were carried out essentially in the 2008-2010 period. The decreasing importance attributed to simulation seems to respond to a more clear-cut distinction between risk assessment and risk management functions, with

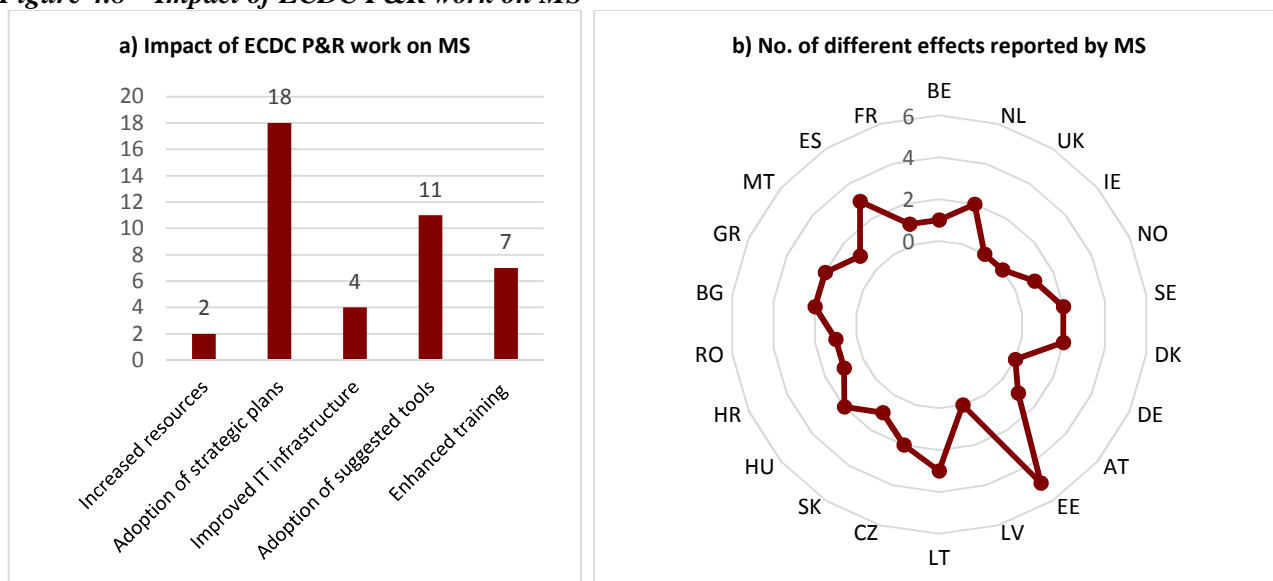
⁸⁹ ECDC Rapid Risk Assessment, "Outbreak of Shiga toxin – producing E. coli (STEC) in Germany", 27 May 2011, http://www.ecdc.europa.eu/en/publications/Publications/1105_TER_Risk_assessment_EColi.pdf

⁹⁰ The Decisions No 1082/2013 will require EU countries regularly exchange information on their preparedness activities. Member States shall produce national 'preparedness plans' which include the basic capacity they have in place to be ready for a public health emergency. ECDC country support is expected to play a role in this process, but it is still unclear which one.

simulations obviously falling under the latter. Still, the evidence collected suggests there is an untapped demand for such exercises from MS, especially for ‘desk’ exercises that allow more staff to participate. Minor criticisms were voiced with respect to the selection of priorities, which for some interviewees should be more ‘driven’ by MS.

The overall assessment of ECDC activities’ impact on MS preparedness and response capacity is not univocal. However, disparity of judgements seems more related to differences in the beneficiary’s starting conditions than to diverse appreciation of ECDC work. In fact, experts from most advanced institutes based in high-capacity countries on average attribute limited added-value to ECDC country, while respondents from low-capacity contexts have taken more advantage of this support.⁹¹ A couple of metrics have been elaborated to describe ECDC P&R work’s concrete effect in MS. The first indicator relates to the frequency of reporting of main types of impact (Figure 4.8.a). The results show that most frequently ECDC helped MS in the adoption of specific plans (preparedness plan) or other strategic documents. Often, MS also adopted specific tools and procedures for crisis management suggested by ECDC and/or scaled up crisis management training activities. Instead, very rarely MS invested in improving the IT infrastructure dedicated to P&R and/or increased the human / financial resources working on it. Secondly, the variation in the extent of effects from country to country has been measured. As illustrated in Figure 4.8.b, it tends to be higher in some Eastern Europe and in Nordic country, while it is low in Germany and the UK.

Figure 4.8 – Impact of ECDC P&R work on MS



Note: (a) overall number of respondents reporting a specific type of impact of ECDC work on the country’s P&R capacity, based on those who were satisfied or very satisfied of ECDC activities in this area (headcount: 35); (b) Sum of the different types of impact reported in a given country, based on the five types of impact tested (figures can range from 0 to 5). Countries without respondents to this question are not displayed.

4.2.5 Contribution to the dissemination of risk communication messages

A more structured analysis of ECDC support to risk communication on CD in the EU is provided in Section 6.2.4 of this report. This Section briefly analyses the influence of ECDC’s activities – and

⁹¹ Such feedback expressed by main PHI and high-capacity country authorities should not be interpreted as a negative judgment on ECDC P&R capacity building work *tout court*. On the contrary, these respondents often highlighted the importance of ECDC assisting the less-advanced entities, since this would improve the EU system on the whole, and therefore would prove beneficial for their countries as well.

particularly RRA – on the dissemination of consistent and appropriate communication messages across MS. The key evaluative aspect is whether RRA (or analogous products) have been taken into account by risk managers / communicators to produce communication products targeting both professionals and general public. The matter is closely connected with the above discussion on RRA support to risk management and ‘how far’ ECDC may go in suggesting risk communication messages. The debate on this point seems rather polarised, with some respondents lamenting a certain ‘confusion of roles’ and asking ECDC to refrain from dealing with communication aspects since these are exclusively in the remit of policy-makers, while others would be in favour of an expansion of RRA recommendations to better cover risk communication aspects, and especially addressing media and the general public. For the former, at communication level, what works in a country not necessary works in another, so there is no way a technical body like ECDC may help national policy-makers in this delicate task. For the latter, greater support in this area would enhance the usefulness and concrete uptake of RRAs and it would not trespass the boundaries of ECDC’s remit since recommendations would obviously not be mandatory. Quite expectedly, polarisation follows the distinction between high-capacity countries (largely in disfavour of ECDC support in the field of communication) and low-capacity ones where – very pragmatically – such support is encouraged. In general, a greater coordination with the National Focal Point for Communication on this point is advocated.

At a more concrete level, some anecdotal evidence of use of RRAs in national level documents was sought. The outcome is that in various instances, but not very often, national risk managers confirm the use of ECDC RRAs for communication activities. The modality varies, and range from a minimum of undocumented, generic stocktaking to the re-publication and/or translation of RRAs for the domestic audience. Some concrete examples and links to the national-level documents found are provided in Table 4.1 below.

Table 4.1 – References to RRAs in national-level documents

Disease	Country	References
H1N1 (pandemic)	EE	http://www.terviseamet.ee/fileadmin/dok/Nakkushaigused/juhendid/Proovivotu_juhis_uus_gripp.pdf ; ()
	ES	http://vgripe.isciii.es/gripe/PresentarNoticia.do?idNoticia=106&tempid=20082009 *
	BE	http://www.influenza.be/fr/content/liens-utiles (*)
	IT	http://www.epicentro.iss.it/problemi/influenza/FluNews.asp (*)
	NO	http://www.fhi.no/dokumenter/dd25af7548.pdf *
	PT	http://www.dgs.pt/directrizes-da-dgs/orientacoes-e-circulares-informativas.aspx?v=1dbf936d-52d0-4968-acc-6a99051b4088 (?) http://www.dgs.pt/directrizes-da-dgs/normas-e-circulares-normativas.aspx ; ()
H5N1	BE	http://www.coda-cerva.be/index.php?option=com_content&view=article&id=163&Itemid=184&lang=en ;
MERS-CoV	PT	http://www.dgs.pt/?cr=24393 ; (?)
Polio	CZ	www.mzcr.cz/Verejne/dokumenty/cestovni-informaceno-va-doporuceni-pro-obyvatele-a-navstevniky-zemi-s-vyskytem-9158_5.html *
Ebola	CZ	www.mzcr.cz/Verejne/dokumenty/ebola-informace-pro-cestujici-osoby-8999_5.html *
HIV/AIDS HIV	CZ	http://www.drogy-info.cz/index.php/o_nas/klicove_indikatory/infekcni_nemoci/infekcni_nemoci_se_vztahe_m_k_uzivani_drog ()
	GR	http://bit.ly/1r7902H . (*)

Note: * explicit reference to ECDC in the text; (*) generic reference to ECDC on the portal; () no explicit citation of ECDC; (?) document not accessible.

4.3 Conclusions and Recommendations

Evidence	Findings
<p>Epidemic intelligence</p> <ul style="list-style-type: none"> • On average 134 threats monitored every year. The amount has decreased more than threefold between 2008 and 2012; • Two in five EPIS fully implemented and used (FWD and ELDSNet). The level of activities on the others is still low; • Perceived added-value is largely proportional to the level of use; • Six in ten users believe EPIS led to a reduction of threat detection time; • Good complementarity of EPIS with other EI sources, but room to improve integration with EWRS; • EPIS technical aspects and management are rated positively, but the transition to EPIS seemingly affected to some extent proactivity and reactivity of participants; • Improved dissemination of EI information through daily (RTR) and weekly (CDTR) bulletins; • The utility of RTR partly hampered by its confidential nature; • Its publication online has boosted access to CDTR from some 300-400 regular recipients, to more than 8,000 yearly visits; • TTT still not accessible to external experts. 	<p>The effectiveness of Centre’s early warning methods have significantly improved in the 2008-2012 period. EPIS allows a more rapid and better focus on threats that deserve attention, but still need to be fully implemented. Bulletins adequately complement dissemination activities. Overall, a better integration with other early warning system in place is desirable.</p>
<p>Early warning</p> <ul style="list-style-type: none"> • A minority of ECDC monitored threats (e.g. 23% in 2012) was followed up through EWRS; • Technical design, user-friendliness and management of EWRS by ECDC is rated as broadly positive; • Integration w/ EPIS is not optimal. The segregation between RA and RM functions at the level of EWRS is not always clear to users; • Confidentiality rules reduce the usability of the information shared through EWRS; • The performance of EWRS during crises is poor. In the past the system became easily overloaded. 	<p>With respect to EWRS aspects falling under the responsibility of ECDC (management and operation), key stakeholders’ feedback is largely positive.. In a more general and strategic perspective, there appears to be room for better integrate and coordinate EWRS and EPIS, and to review EWRS so as it can better support PHE situations</p>
<p>Rapid Risk Assessments</p> <ul style="list-style-type: none"> • RRAs are read by more than four in ten stakeholders, including both ECDC partners and the relevant scientific community; • RRAs are very popular among decision-makers and PH experts, and in particular influenza experts, especially in Eastern MS; • More than 30 RRAs per year (including RRA-like) have been issued on average in the 2008-2012 period. The share of ‘updates’ has increased overtime; • Timeliness is close but have not yet reached the target (75% RRA issued within 48h); • With few exceptions the relevance of RRA is rated high; • Clarity of messages, comprehensiveness, and scientific reliability of RRAs rated positively by more than 80% of users. Significant improvements since 2008; • Usefulness and added-value of RRA for both joint investigation and in support of response. But recommendations sometimes felt either generic or incomplete; • Abundant evidence of impact of RRA on H1N1 and H5N1 outbreaks, more limited in other cases; • Decision-makers comparatively less positive on the impact of RRA. 	<p>RRA emerged as one of the most known ECDC product. Stakeholders both direct and external attribute to it a high added-value both in informing domestic assessments, and supporting joint investigations and the adoption of RM and RC measures - although in this respect RRA’s messages sometimes fail to be specific enough. Timeliness has improved, but there is room to further increase it (with the support of data providers), so as to meet the established targets.</p>

<p>Contribution to MS P&R capacity</p> <ul style="list-style-type: none"> • The contribution is particularly high in the field of early warning while is comparatively less so in the fields of response and country preparedness; • The concrete impact in MS concerns primarily the use of ECDC data and information to back-up domestic initiatives. This sometimes regarded policy measures and/or I&C products; • On-the-field missions were few, especially in recent years, although they are considered useful for policy-making purposes; • ECDC support to response during major crises is rated positively but there's room for improvements; • Preparedness received limited attention in the 2008-2012 period. Impact mostly related to the adoption of domestic, strategic plans. The demand for simulation exercises seems partly unmet. 	<p>In 2008-2012, the ECDC efforts in this area concentrated in particular on the systems and the infrastructure for EI and early warning. By converse, only limited effects were registered by MS as concerns the support to preparedness and response capacity. Generally, the ECDC performances during the 2009 pandemic are rated as fairly positive, although the whole EU system did not work properly – especially at the beginning.</p>
<p>Contribution to Risk Communication coherence</p> <ul style="list-style-type: none"> • It is controversial the extent to which ECDC should support risk communication, and to what extent its recommendations should be detailed and precise in this respect; • The evidence of consistent use of ECDC RA's messages can be found in national documents more or less explicitly making reference to ECDC documents. The examples found are however not numerous and in most cases refer to the 2009 pandemic. 	<p>In various instances the messages of ECDC's risk assessments were used for risk communication purposes. However, a better clarification of ECDC's role in this respect seems urgent.</p>
<p>Conclusion and Recommendations</p>	
<p>The effectiveness of the Centre's early warning mechanisms have significantly improved over the period. EPIS is believed to allow a more rapid and better focused detection of threats deserving attention and is considered a source of good added value. The related infrastructure and systems put in place may have a significant added-value, but their potential has not be fully exploited yet. The scientific quality of ECDC work in this field is well recognised and the best expertise available are employed. Support to RM functions may be further improved, but this would require a better integration of all the existing systems (including EPIS, EWRS, RASFF and others) and a clarification of respective roles. Similarly, the explicit use of ECDC 'messages' in national RC documents seemed quite limited. In particular, better integration of EPIS and EWRS involves in the first place establishing appropriate linkages between events, which may then facilitate the rapid sharing of materials across platforms. This process may also benefits by the (apparently planned) overhaul of the Threat Tracking Tool, making it available to external users. This might help overcoming the EWRS limited capacity when it comes to PH emergencies. Better integration means also better distinction. EPIS should more clearly remain a scientific forum for early-stage discussion on emerging threats. Cases were reported where epidemic intelligence signals 'leaked' too early at the risk management level, causing undue reaction prior to proper validation. There seems to be room to improve procedures to avoid or mitigate such instances. <i>(Evidence strong, priority high).</i></p> <p><i>Recommendation.</i> To enhance the usefulness of EWRS it should be considered the possibility of clarifying the information therein that is really confidential from the information that can be used publicly. This would make the system more supportive for risk communicators, who currently have to cross-check EWRS information with a number of other sources with ensuing waste of time and resources.</p> <p>The RRA have emerged as one of the best known and most valued ECDC deliverables. However, as it is not easy to trace clear boundaries between risk assessment and risk management and stakeholders' views on this point diverge - also because the distinction does not really apply to the reality of some MS - it is regretted that RRA conclusions appear sometimes informed by political considerations, which make them either vague or poorly-substantiated. Political 'clearance' may also affect the rapidity of release, which is the key added value of RRA. Irrespective of views on how division of roles should be, there is agreement on the fact that there is room to further expand the usefulness of an instrument that is already perceived as fundamental. <i>(Evidence medium, priority medium)</i></p> <p><i>Recommendation.</i> The preparation of the RRA is now based on an internal ECDC guideline document but feedback remains informal and not systematized or otherwise codified. Since ECDC already plans to have a "client satisfaction survey" feedback mechanism in place in the next few years it is worth considering whether a specific section on the conclusions of the RRA should be added with open qualitative comments to allow an update of this guidance document every two to three years based on a kind of "lessons learnt" approach, by reviewing and incorporating feedback from</p>	

potentially contentious issues or cases of perceived exceedingly generic conclusions. The document could eventually be discussed with the Commission and the HSC. This might be of some help in aligning expectations with practice and find some common ground among stakeholders themselves. It is understood that the 2014-2021 multiannual programming document already plays down ECDC role in risk communication, which is in line with the findings of this evaluation.

5. CAPACITY BUILDING

5.1 Overview

Capacity strengthening is one of the core functions of ECDC's mandate⁹². In strategic terms, it has been articulated in the SMAP 2007-2013 along three main objectives, namely: (i) developing EU capacity on prevention and control of CD through training; (ii) developing a network of training programmes ('catalytic effect'); (iii) creating a training centre function within ECDC. In operational terms, these functions are in the remit of ECDC PHC Unit that has a dedicated section for PH training.

Since November 2007, the *European Programme for Intervention Epidemiology Training (EPIET)* has been fully incorporated in ECDC activities.⁹³ The EPIET programme consists of two-year fellowships, aimed at strengthening infectious disease surveillance and response capacity in the MS, and developing a network of experts for a better surveillance and control of communicable diseases at EU level. The EPIET programme underwent an in-depth evaluation in 2009-2010, which led to some modifications of its design and delivery mechanism.⁹⁴ Among other thing, in order to level disparities in the utilization of EPIET by MS and prevent the 'brain drain' experienced by some countries, a so-called 'Member State track' was added (in addition to the EU track), consisting of training fellows in his/her country. The *European Programme for Public Health Microbiology (EUPHEM)* was set up in 2008 to complement EPIET with an integrated specific training in microbiological surveillance. The programme came under the full responsibility of ECDC in 2010.⁹⁵ Also EUPHEM has already been evaluated, but the report (Jan. 2013) has not been published.⁹⁶

EPIET and EUPHEM are carried out in partnership with a series of national institutes competent in surveillance, disease control and intervention. The number of "training sites" has increased steadily overtime and as of July 2014 amounts to 48.⁹⁷ The scientific coaching of fellows and the teaching activities are under the responsibility of partner institutions, while ECDC finances directly EU-track fellowships as well as related direct costs for all fellows. Additionally, ECDC coordinates the EPIET/EUPHEM forum meetings, organizes training site visits to EPIET institutions, provides training-of-trainers modules for supervisors, and takes care of the coordination and synergy of EPIET/EUPHEM with other training programmes. In 2011, ECDC has set up an agreement on "sharing resources with *EPIET-Associated Programmes (EAP)*", i.e. a mechanism to allow national field epidemiology training programmes (FETP) fellows to join EPIET cohort without depending on ECDC budget. As of 2012, four EAPs were established, namely with Germany, Austria, Norway and the UK.

The *European Scientific Conference on Applied Infectious Diseases Epidemiology (ESCAIDE)* is a yearly event organized since 2007 by ECDC, which gathers epidemiologists, microbiologists, as well as other concerned scientists and PH experts from EU/EEA National Public Health Institutes,

⁹² Article 3 of ECDC's founding regulation establishes that the mission of the Centre is to "enhance the capacity of the Community and the Member States to protect human health through the prevention and control of human disease". Additionally, the Regulation specifies that, as far as capacity building is concerned, ECDC's responsibilities encompass: (i) diagnosis, detection, identification and characterisation of infectious agents (Art. 5.3) - i.e. activities in support of laboratory networks, and especially the implementation of quality assurance schemes; and (ii) MS preparedness and capacity to respond in a coordinated manner to threats (Art. 8.1).

⁹³ The EPIET programme started as a DG SANCO funded project in 1995.

⁹⁴ Royal Tropical Institute, "External Review of the European Programme for Intervention Epidemiology Training (EPIET)", Sept. 30, 2010.

⁹⁵ Previously, it was a project of the Collaborative Laboratory Response Network of the European Network for Diagnostics of Imported Viral Diseases (ENIVD-CLRN).

⁹⁶ ECDC internal document, "Report of the First Evaluation of EUPHEM", submitted on 29 January 2013 (*unpublished*).

⁹⁷ <http://ecdc.europa.eu/en/epiet/institutes/Pages/Institutes.aspx>

members of ECDC's surveillance and disease-specific networks, and EPIET/EUPHEM fellows and *alumni*. The Conference provides a dedicated platform to EPIET/EUPHEM fellows to present their work and share their experience (some 30-40 fellows each year are offered the possibility of giving speeches to ESCAIDE and presenting scientific posters). The conference in the period considered was held alternatively in Stockholm (2007, 2009, 2011) and in another European city (Berlin 2008, Lisbon 2010, Edinburgh 2012), and attracted every year more than 500 participants.

ECDC's role, as defined in its founding regulation, includes supporting MS in implementing quality assurance programmes with the aim of strengthening overall laboratory quality in the EU.⁹⁸ The main tool set up to this end is the *External Quality Assurance (EQA)* scheme, which typically consists of testing participating laboratories' capacity to accurately identifying and typing pathogens, determining the accuracy of test results reported by individual laboratories, and comparing tests results across laboratories and countries. The EQA activities are typically outsourced to a technical contractor and performed by participating laboratories on a voluntary basis. In the period considered (2008-2012) sixteen EQA exercises have been carried out, covering various subjects but with particular focus on the following topics: salmonella typing, influenza, legionnaires' disease and imported viral diseases.

The bulk of ECDC work in the field of capacity building was absorbed by the abovementioned activities. However, a series of other activities have been carried out, which are worth mentioning, in particular:

- *short courses and training workshops*, covering various thematic, methodological, or technical topics. Overall, more than 1,000 experts from 56 countries have participated to more than 30 short trainings carried out in the reference period.
- *Toolkits and training materials* - e.g. on legionnaires' disease: risk assessment, outbreak investigation and control (2011), and for response to FWD outbreaks (2011) - and the 'Field Epidemiology Manual' (FEM Wiki) – largely based on lectures from the EPIET courses.
- Development of *curricula* – e.g. on threat assessment (2009), AMR-HAI (2010), rapid assessment in complex emergencies (2011), risk communication (2012).

The *budget allocated to capacity building and training* has more than doubled in the period, from some € 2 million in 2008 to over € 4 million in 2012, when it accounted alone for some 20% of title III expenditure and 10% of ECDC expenditure overall (including 13 FTE staff). Most of this expenditure consisted of grants. Disbursement efficiency has been steadily increasing over time. In fact, while committed funds have always averaged some 97-100% of the total, annual disbursements have moved from some 15% of budget in 2008 to over 70% in 2012. This significantly contributed to improving the overall performance of ECDC. Most of the trainings are centrally managed by the responsible unit. Residual amounts - totalling respectively € 270,000 and € 120,000 - have been specifically targeted to the laboratory support component of the disease programmes, of which in the 2011-12 period a total € 20,000 for influenza and €35,000 for the food and waterborne diseases, including training on laboratory techniques for salmonella.

⁹⁸ Regulation (EC) no 851/2004

5.2 Main findings

5.2.1 ECDC Training Programmes

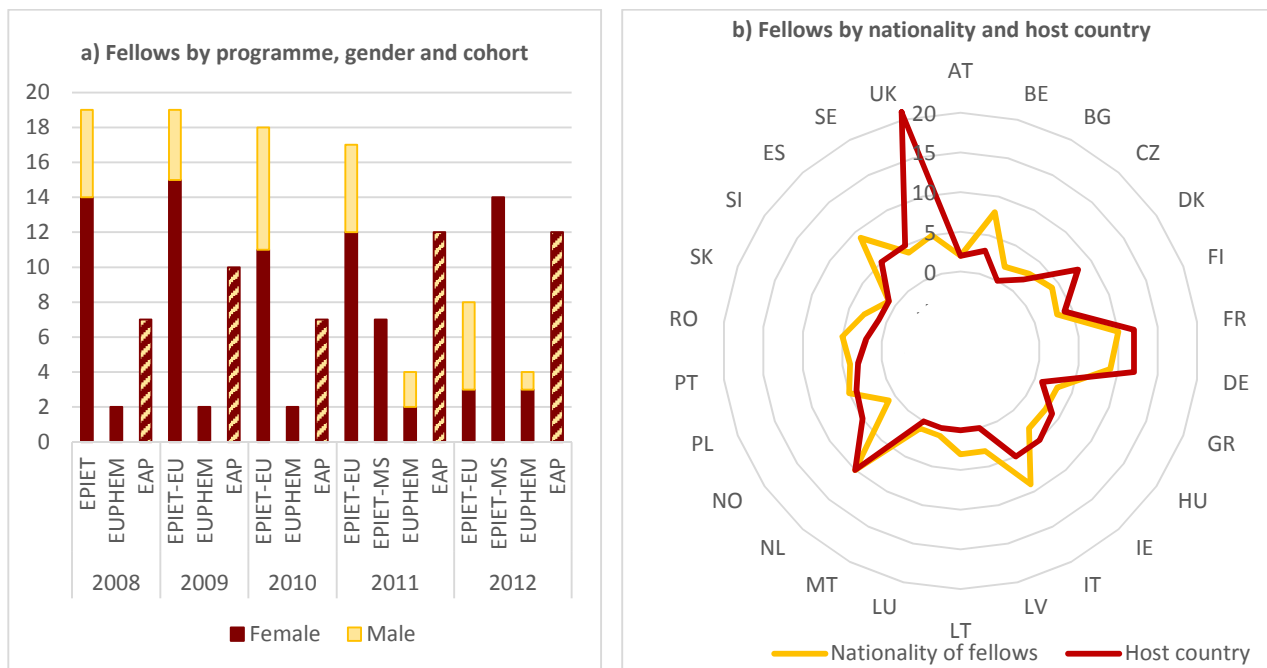
Since training programmes have been quite recently evaluated, the current Study focuses especially on their systemic effects and their added value, not only for fellows but also for partners and MS on the whole. The basic data on fellows' participation to training programmes in the period under analysis is summarized in Figure 5.1 below. Overall, 164 fellows were trained in the period, of which the majority under EPIET (81 in the EU-track and 21 in the MS-track). EAPs total fellows amount to 48, and EUPHEM only 14. More recently, the EUPHEM available seats have been increased to 8 per cohort, and there are plans to progressively increase the number of EAPs fellows to 24 per year since 2015. The goals are ensuring training programmes' sustainability in the medium terms and better harnessing the knowledge and training capacity of MS, fostering synergies and avoiding duplications. With the same objective, a growing emphasis has been placed since its establishment on the MS-track, which currently host as many fellows as the EU-track (12 per cohort). In fact, according to ECDC MB: *"the EPIET MS track can be considered an interim status for countries in the development of their own national EPIET-associated FETP"*.⁹⁹ A particular attention is seemingly placed on 'gender gap', with 3/4 of fellows being women. From a geographic perspective, the UK results the most attractive host country, accounting alone for nearly one-fifth of fellowship sites. The participation is quite proportional to country's size (with possibly Belgium and the Netherlands somehow overrepresented), which makes that there are imbalances between the distribution of fellows by nationality and by host site. As seen the UK – but also France, Germany, Norway and Denmark – are prevalently host countries, while Italy, Spain, Romania, Belgium and the Baltics are mainly 'fellow-givers'.

The introduction of the MS-track adequately responded to the findings of the past evaluation, which highlighted disparities in participation levels across countries, and the existence of a 'brain-drain' effect (i.e. fellows not returning to their home country after the fellowship). In the three cohorts since its establishment (2011-13) the proportion of participants from Eastern Europe doubled over the 2008-2010 period (rising from some 10% to some 20% of the total). As a result, more geographic 'balance' is no longer a priority request from stakeholders. Instead, 'brain-drain' is still seen as a potential risk. The survey showed that for one fellow that maintained his/her workplace after the end of fellowship, there are two who instead changed of employer. For this reason, about half of survey respondents (both fellows and partners) would support further measures to prevent this.

EPIET and EUPHEM have been designed so as to avoid as much as possible competition with existing national training schemes. On the contrary, they are conceived as complementary and possibly synergic (as in the case of EAP), and the planned developments would further reinforce this approach. Complementarities lay in the target – national programmes are typically restricted to health sciences trainees while ECDC programmes have a wider audience – as well as in the contents – ECDC programmes are not limited to scientific aspects. The other important difference is that ECDC programmes offer an outward look and networking opportunities that national programmes normally cannot. This added-value is largely acknowledged by MS partners and stakeholders. Only few of them (about one in six respondents) still see room to increase synergies with national programmes in order to avoid duplications.

⁹⁹ ECDC Management Board, "Minutes of the Twenty-third Meeting of the ECDC Management Board", Stockholm, 9-10 November 2011.

Figure 5.1 – EPIET and EUPHEM fellows’ distribution (2008-2012)



Note: Author’s elaboration of ECDC data. Figure (b) does not include EAP fellows.

With respect to qualitative aspects, the feedbacks collected from fellows, partners, and other stakeholders indicate an overall strong appreciation of EPIET and EUPHEM. The judgment refers in particular to the practical relevance of the topics discussed (‘not taught in ordinary training courses’),¹⁰⁰ the ‘on-the-job’ approach adopted, the quality of contents and of lecturers involved, especially in the case of EPIET. For only two out of 23 fellows surveyed the training was instead not up to expectations. In summary, the programmes demonstrate their utility and effectiveness in the following areas:

- **Improved skills.** EPIET/EUPHEM fellows are considered better prepared and competent than their peers. Having been exposed to models and methods used in other countries provided them with a clearer vision of the ‘whole picture’ and a larger toolbox of skills and competences. However, while all fellows surveyed has declared using the skills acquired in their everyday work, only half of them admitted they have been able to permanently introduce in their organisations methods and techniques learned during their fellowship period.
- **Networking.** The programme is conducive in establishing work collaboration with professionals from other countries. This may prove very useful in the event of CD outbreaks and threats since it would enable an easier and faster exchange of information with other PHIs. Also, it is very helpful for setting up partnerships and joint projects. All fellows surveyed are still in contact with their peers in other countries. As remarked by a training supervisors: “*the gap between fellows and non-fellows in the ability to access international networks is enormous*”.
- **Harmonization and coordination effectiveness.** More indirectly - and largely a consequence of the two above processes - the ECDC training programmes contributed significantly to the harmonisation of competences and knowledge across Europe, which in turn facilitated reciprocal understanding and – when needed – joint action.
- **Enhanced capacity.** Connected with the above, EPIET supervisors and trainers recognise the programme has a concrete utility in improving MS capacity to rapidly detect threat and - to a

¹⁰⁰ On relevance, it should be noted that the past evaluation identified MS ‘need assessment’ as a possible area for improvement. It is not clear whether any concrete step has been taken in this respect.

smaller extent - to adopt coordinated response. In this respect, it is worth highlighting that EPIET fellows are often involved in joint MS efforts to tackle disease outbreaks. A concrete example is the H1N1 pandemic, where no less than 47 EPIET-trained fellows based in 22 host sites in 16 countries had been involved in surveillance (data management and analysis) activities, research and investigation, etc.¹⁰¹

Management and administration of the programmes are outside of the scope of this evaluation, since they have been already addressed in the *ad hoc* one, and many changes have been introduced since then.¹⁰² For instance, the change in the system for the administration of grants (from individual-based to host-based), the reduction of the EU-track salary, which not only redresses disparities (in some countries the amount of fellow's grant was higher than his/her supervisor's salary) but also liberates resources for the increase of 'high-in-demand' EUPHEM seats, the definition of fixed rotation mechanisms for the allocation of available seats among MS, etc. Overall, efficiency of administration is still regarded as the comparatively most problematic aspect of training programmes, although the balance of benefits and burden is positive accordingly to the vast majority of stakeholders.

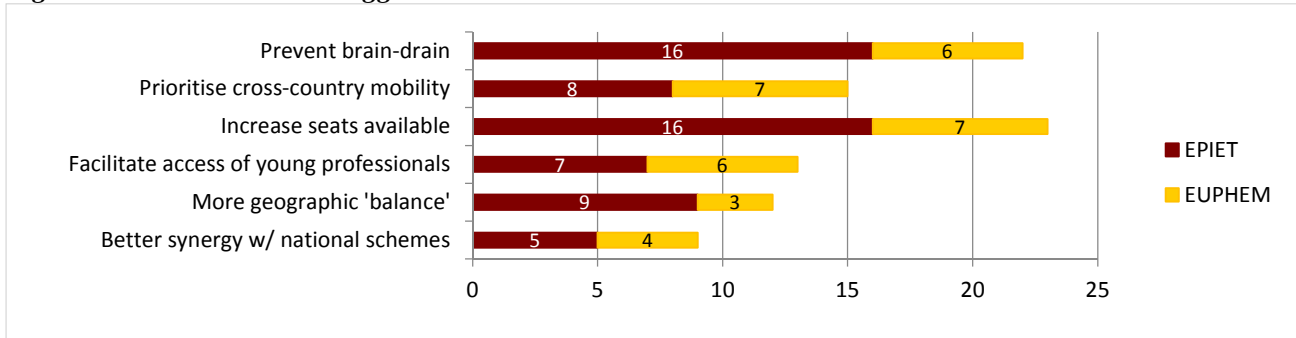
The Figure 5.2 below summarises partners' views about possible future improvements of the training programmes. Combining these results with the qualitative feedback collected it emerges that:

- The effectiveness of the programmes is confirmed indirectly by the largely voiced request for 'more seats available'. In terms of popularity, this request is paired only by the request to do more to 'prevent brain-drain'.
- However, the fear for 'brain-drain' should not lead to a substantial reduction of cross-country mobility, which for many is where most of programmes' added-value lies (especially in the case of EUPHEM). In this sense – and irrespectively of budgetary considerations – an excessive focus on the MS-track has a downside in terms of relevance and utility.
- The selection process is an area that attracted various comments and different positions exist. The selection process is quite strict, which makes the programmes very competitive and high-profiled. According to the past evaluation – as well as by some stakeholders – is perhaps excessively competitive and skewed in favour of 'experienced' fellows, while young talented professionals are somehow penalised (especially in the case of EUPHEM). On the other hand, others fear that relaxing selection criteria would lead to a loss of value and credibility.
- The introduction of the MS-track has effectively tackled the issue of geographic balance, but in the case of EPIET EU-track the criteria for seats allocation are not agreed upon by all. Also, there seems to be room for a greater 'rotation' not only among fellows, but also among host sites.

¹⁰¹ See: V. Bremer et al., "Strong contribution of EPIET fellows to members states' efforts in the pandemic of influenza A(H1N1). file:///C:/Users/utente10/Downloads/2043.EPIET_H1N1_ESCAIDE2009_final.pdf

¹⁰² For instance, the change in the system for the administration of grants (from individual-based to host-based), the reduction of the EU-track salary, which not only redress disparities (in some countries the amount of fellow's grant was higher than his/her supervisor's salary) but also liberate resources for the increase of , the definition of fixed rotation mechanisms for the allocation of available seats among Member States, etc.

Figure 5.2 – Stakeholders’ suggestions about EPIET and EUPHEM



Note: headcount=EPIET (34), EUPHEM (18).

5.2.2 The ESCAIDE Conference

The ESCAIDE conference was evaluated in-depth in 2012.¹⁰³ The conclusions of the previous evaluation are briefly recapped in Box 5.1 below. In this Study, the assessment of ESCAIDE partly builds on the findings of the previous evaluation, and partly on an original analysis of ESCAIDE impact and other strategic aspects, based on interviews with and survey of stakeholders.

Box 5.1 - Summary findings from the previous evaluation of ESCAIDE

- ESCAIDE is generally considered a valuable and authoritative event, complementary to other international conferences and fora.
- The conference topics are deemed relevant. Many participants would like a greater coverage of themes related to microbiology, statistical methods and modelling, and communication and behavioural aspects.
- In addition to contents, the added-value of ESCAIDE lies in the networking among experts of different nationality that it facilitates.
- Attendance is high enough but uneven, with Germany, France and Nordic countries far more represented than other Member States. The location in Stockholm is seen as a potential obstacle for a greater participation from EU southern and eastern countries.
- Organisational and administrative aspects are overall rated positively.

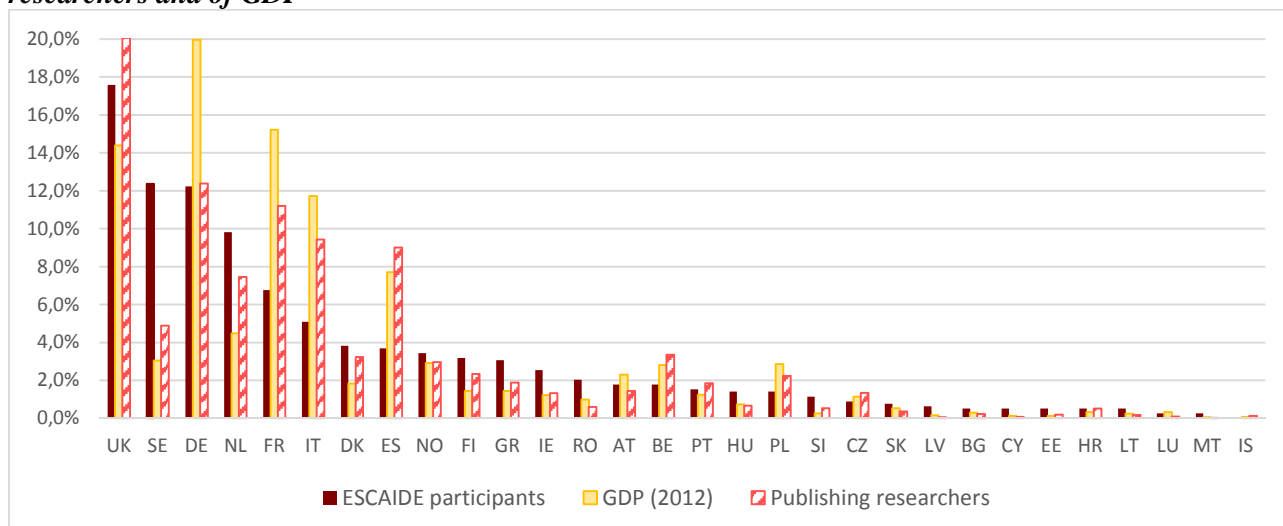
With more than 500 participants to every editions, the overall level of attendance of ESCAIDE appears broadly positive. About three-quarters of participants are from MS’ competent bodies and public authorities as well as from the scientific community. Other participants are from third countries (some 10%), European and International agencies (mostly ECDC, plus a handful from WHO and other EU agencies), and multinational companies and other private players (some 2%).¹⁰⁴ The findings from the past evaluation – also confirmed by some interviews - indicate a somewhat geographically-uneven participation across the EU, mostly due to the burden to reach Stockholm from southern and eastern countries. The analysis of data on 2011-2013 attendance partly confirmed this finding. When compared to (a) the overall number of scholars publishing on relevant peer-reviewed journals, by country of affiliation (2010-2012) and to (b) the national GDP (2012), it emerges that (Figure 5.3):

¹⁰³ COWI, “Evaluation of the European Scientific Conference on Applied Infectious Disease Epidemiology (ESCAIDE)”, March 2012.

¹⁰⁴ Data refer to the 2011 to 2013 editions.

- Nordic countries (SE, DK, FI, NO) have the highest participation rate as compared to their ‘weight’ in terms of relevant scientific community and GDP. In particular, Sweden unsurprisingly account alone for 12% of participants, on average.
- UK and the Netherlands have similar participation patterns, i.e. they are ‘overrepresented’ in the conference, with respect to the size of their economies, but this is perfectly coherent with their above-average scientific community size. The UK is the single most represented country in ESCAIDE, accounting for more than 17% of participants in the period considered.
- Germany (and similarly Austria) displays participation rates quite in line with the size of its scientific community in this field, but well-below its weight in terms of GDP.
- Despite the qualitative evidence from the past evaluation, New MS (essentially Eastern Europe countries) are not particularly underrepresented when compared to the size of their scientific community or of their economies. This applies to some extent to Poland and Czech Republic. Conversely, Romania and Hungary have above-average participation rates.
- The most underrepresented countries are instead the main Mediterranean countries (Italy, Spain) and France. Altogether, their economies account for some 37% of EU GDP, but their attendance of ESCAIDE fails to hit 20%.

Figure 5.3 – Geographic distribution of ESCAIDE participation, compared to the distribution of researchers and of GDP



Note: Percentages are calculated on the total of participants from EU plus Norway and Iceland.

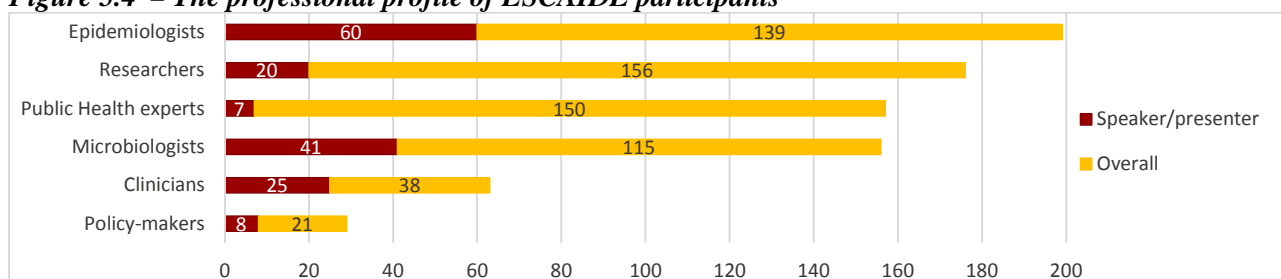
Although clearly connected with ECDC work - and in particular to its training activities - the ESCAIDE conference has managed to acquire overtime an independent scientific ‘profile’ that some stakeholders define ‘unrivalled’ in the field of epidemiological surveillance. Survey data indicate that ESCAIDE is quite popular also among the ‘external’ scientific community and other professionals not linked to ECDC. According to the majority of respondents (60%) ESCAIDE has a good or very good outreach across the EU.

The conference is organized with the support *inter alia* of the EPIET programme and the EPIET Alumni Network, therefore the tight connection with ECDC training programmes is evident. Out of about 1,200 unique participants to the 2011-2013 editions, some 130 (more than 10%) were EPIET / EUPHEM fellows or supervisors. The advantages of this connection in terms of mutual ‘reinforcement’ and ‘multiplying effects’ are apparent. ESCAIDE gives visibility to the results of EPIET / EUPHEM fellows’ researches and offer them an opportunity for discussion and exchange with the scientific community. In parallel, the fellow’s network contributes to the dissemination of ESCAIDE outputs. Overall, dissemination is rated as good or excellent by 58% of survey respondents.

However, some stakeholders believe ESCAIDE is too much entangled with these programmes, and that an excessive focus is placed on EPIET fellows' researches. This finding had been already identified in the previous evaluation. Actually, the space devoted to EPIET fellows has narrowed down over time. The number of presentations in the parallel sessions decreased from 25 out of 100 in 2009 to 15 out of 89 in 2012, and poster presentations went down from 19 out of 130, to 14 out of 150 in the same period.¹⁰⁵

The typology of participants is mixed. The survey data confirm that ESCAIDE is mainly addressing the research community and epidemiologist, but also microbiologists as well as other expert profiles are well represented (see Figure 5.4 below). The participation of microbiologists in particular was seemingly boosted by a progressively increasing focus on public health microbiology and molecular epidemiology – an explicit request voiced *inter alia* by the experts consulted during the previous evaluation.¹⁰⁶ Presentations related to these themes grow from virtually nil in 2008 to some 5% of the total in 2010, to nearly 10% in 2013.¹⁰⁷

Figure 5.4 – The professional profile of ESCAIDE participants



Note: Multiple profiles are possible (total headcount: 557)

Overall the ratings of ESCAIDE participants on the conference's quality and usefulness are broadly positive (Figure 5.5). In particular:

- The most appreciated features of ESCAIDE are the relevance of the topics discussed (82% of positive feedbacks), and its utility for networking (86%), followed by the quality and reputation of speakers (75%). The majority of respondents also review positively ESCAIDE's utility for scientific knowledge (67%) and recognizes its added-value vis-à-vis other similar international conferences (65%). It remains more controversial the utility for policy-makers – assessed positively by only 43% of participants. This appears very coherent with the data on policy-makers participation, which - as seen - are still very low (see Figure 5.4 above).
- Unsurprisingly, conference speakers and presenters tend to give more positive judgments than simple participants. The difference are however marginal and concerns – quite predictably – the assessment on the quality of speakers and on the conference usefulness for networking.
- There exist also some disparities of assessment across respondents, based on their 'profile'. Epidemiologists seem comparatively more satisfied with the scientific contents of the conference. Academic researchers appreciate the quality and reputation of speakers. Microbiologists are instead more negative on such quality, as well as on the overall added-value of ESCAIDE in comparison with other events. Conversely, they are among the most satisfied with the networking opportunities offered by the conference and its possible influence on policy-making. Decision-

¹⁰⁵ Source: ESCAIDE Abstract Book, ed. 2009 and 2012.

¹⁰⁶ COWI, 2012

¹⁰⁷ Source: ESCAIDE Abstract Book, ed. 2008, 2010 and 2013

makers seem the most satisfied group of all, but – as seen – the evidence is based on a relatively small sample of respondents.

Figure 5.5 – Participants’ assessment of ESCAIDE



Note: Tot=total; Par=simple participants (non-speaker); M=microbiologists; E=epidemiologists; P=public health experts; R=researchers; D=decision-makers.

About two-thirds of participants surveyed affirmed the conference had a concrete impact on their work. A summary of the possible uses reported is provided below:

- For the majority of respondents the main impact of ESCAIDE relates to the acquisition and exchange of information relevant for their work, such as data, methods, protocols etc. Some of them reported having used and made reference to conference materials in their later publications.
- Connected with the above a handful of respondents primarily used the information gathered for researches involving comparison and benchmarking among countries.
- ESCAIDE has also the effect of giving some participants new ideas for their research and/or for new projects. This often combines with a perceived generally positive effect in terms of ‘fostering networking’.
- Quite frequently, participants also used the information for dissemination purposes, within their organisation or at country level. This includes also a couple of instances of use for internal training.
- Finally, in a couple of cases, the information gathered at the conference seemingly influenced policy decisions, i.e. supporting the evaluation of certain policy effectiveness, or the implementation of specific measures.

The reasons for not using ESCAIDE materials generally regard the lack of relevance of the topics discussed with the respondent’s work or the lack of specificity. A handful of respondents, however, criticized the quality and the utility of the EPIET-related researches presented. According to them,

fellows are unexperienced and ‘new to the subject’ so their works are often of limited interest for senior experts.

5.2.3 The External Quality Assurance (EQA) schemes.

EQA is the major Capacity Building ‘product’ for public health microbiology (PHM) laboratories. In practice, EQA consists of an evaluation of laboratory’s performance by an outside agency on material that is supplied especially for the purpose. The general aim is to identify ‘gaps’ in laboratory diagnostic capacities and thus the related training needs. The scheme may also help PHM laboratories to obtain accreditation and official recognition at the international level.¹⁰⁸ In the period covered by the Study, a total of 16 EQA were carried out, involving between 16 and 35 laboratories each. The salient features are summarized in Table 5.1 below. For some diseases, subsequent EQAs were carried out overtime: for instance three EQA for Salmonella typing were organized (2009, 2010 and 2011).

Table 5.1 – External Quality Assurance schemes (2008-2012)

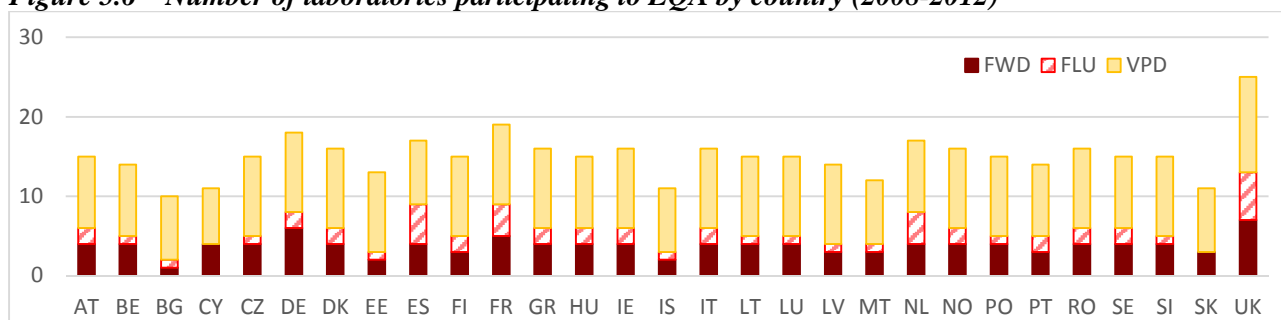
#	Date of implementation	Title	Main Contractor	Number of participants
1	2008 (?)	EQA for Influenza Virus Rapid Detection and Virus Culture	<i>Report not available</i>	<i>Report not available</i>
2	January 2009	EQA scheme for Haemophilus influenzae 2009	Health Protection Agency (UK)	26 EU/EEA
3	March 2009	EQA scheme for Neisseria meningitidis 2009	Health Protection Agency (UK)	26 EU/EEA
4	March 2009	EQA scheme for Salmonella typing	RIVM (NL)	28 EU/EEA 6 Other
5	April 2010	EQA scheme for diphtheria diagnostics 2010	Health Protection Agency (UK)	27 EU/EEA
6	April 2010	EQA scheme for Streptococcus pneumoniae 2010	Norwegian Institute of Public Health (NIPH) (NO)	26 EU/EEA
7	August 2010	Second EQA scheme for Salmonella typing	RIVM (NL)	28 EU/EEA 7 Other
8	Winter 2010/2011	EQA scheme for antiviral susceptibility detection in influenza viruses for the Community Network of Reference Laboratories for Human Influenza in Europe	Health Protection Agency (UK)	16 EU/EEA
9	Winter 2010/2011	EQA scheme for influenza virus detection and culture for the Community Network of Reference Laboratories for Human Influenza in Europe 2010/2011	Health Protection Agency (UK)	27 EU/EEA
10	February 2011	EQA scheme 2011 for Neisseria meningitidis as part of the IBD-Labnet surveillance network	Health Protection Agency (UK)	30 EU/EEA
11	February 2011	EQA scheme for Haemophilus influenzae 2011	Health Protection Agency (UK)	28 EU/EEA
12	August 2011	Third EQA scheme for Salmonella typing	RIVM (NL)	29 EU/EEA 6 Other
13	February 2012	EQA scheme for diphtheria diagnostics 2012	Health Protection Agency (UK)	29 EU/EEA

¹⁰⁸ On this point a technical meeting was held in 2009 with a view to help designing the ECDC possible activities in support of laboratory QA systems. The meeting involved inter alia the International Laboratory Accreditation Cooperation (ILAC) and the European co-operation for Accreditation. See: ECDC, “Ensuring quality in public health microbiology laboratories in the EU: Quality control and areas in need of strengthening”, Meeting Report, Stockholm, 9-10 September 2009.

#	Date of implementation	Title	Main Contractor	Number of participants
14	March 2012	EQA scheme on PCR for Bordetella pertussis 2012	Health Protection Agency (UK)	21 EU/EEA
15	May 2012	EQA scheme for Neisseria meningitidis 2012	Health Protection Agency (UK)	30 EU/EEA
16	May 2012	EQA scheme for Streptococcus pneumoniae 2012	Health Protection Agency (UK)	29 EU/EEA

In geographic terms, participation of laboratories seems quite balanced across countries (Figure 5.6), with the only exception of the UK's 'overrepresentation' (in many instances, national labs from Scotland and Wales took part in the exercise).

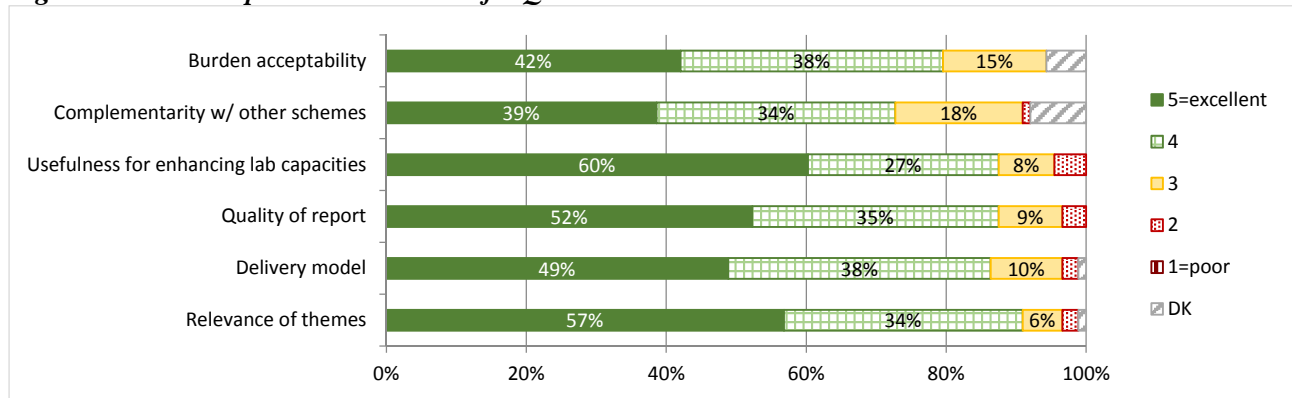
Figure 5.6 – Number of laboratories participating to EQA by country (2008-2012)



EQAs are quite popular among not only ECDC partners but also the PH microbiology community at large. About 60% of the 225 respondents surveyed were aware of EQAs and 40% have taken part in at least one of them. The participation is obviously higher among MS 'operational contact points' (OCP) who participate in the corresponding disease networks.

Interviews with stakeholders and participants as well as survey results showed a generally high appreciation of EQA's quality and utility. Under all respects feedbacks of participating entities as well as of stakeholders are broadly positive (Figure 5.7). The perceived added-value of EQAs rests first and foremost on assuring national authorities as well as international partners about the capacities of participating laboratories in the various areas concerned. In this sense, the evidence largely confirms the usefulness of EQA to detect - and consequently address - capacity 'gaps'. The themes selected are generally considered relevant, but in this respect it is worth reporting that, according to some stakeholders, the degree of MS involvement in the selection of EQA priorities is not optimal and, for instance, some suggests there should be more balance between exercises aimed at the detection of rare strains and 'routine' ones. Although positive, complementarity and synergy with other schemes receive comparatively lower ratings. This is due for instance to cases where Centre's EQA *de facto* duplicated analogous tests already carried out in the framework of other international QA exercise (e.g. promoted by CDC). Participating in EQA implies a burden that - although generally considered as reasonable - for certain laboratories is difficult to afford in the absence of Government's support, which is not guaranteed in all MS.

Figure 5.7 – Participants’ assessment of EQA



Note: Active EQA participants only (headcount=89)

Finally, to analyse EQA’s impact the focus has been placed on a specific subset of schemes, i.e. the EQA for Salmonella typing (see Table 5.1 above for details). The results – based on 20 participants surveyed – can be summarized as follows:

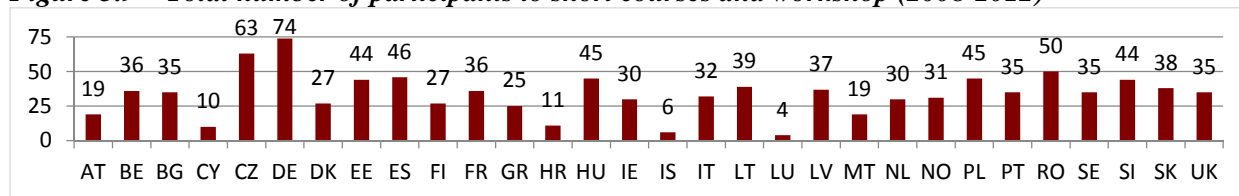
- The primary effect of EQA is helping laboratories in obtaining international accreditation (reported by three in four participants).
- More than half of respondents were able to detect capacity gaps they were not aware before, thanks to EQA, and have by consequence adopted measures to strengthen their capacities in the areas where weaknesses have been identified.
- The demonstration effect of EQA is instead limited, only five respondents affirmed that there has been some sort of domestic follow-up exercise.

5.2.4 Other Capacity Building Tools and Outputs

The abovementioned activities represent by far the majority, but do not exhaust ECDC capacity building work. Other activities that have been carried out in the reference period include short-term trainings, *ad hoc* workshops, development of toolboxes and guidelines, support to curricula development etc. These activities have been assessed in aggregated terms with a view to determine their effectiveness in enhancing MS capacities, also in comparison with the main activities analysed above. The results are indicated in Figure 5.8 below, and can be summarized as follows:

- Short courses and *ad hoc* workshops seem another important ‘pillar’ to achieve ECDC training objective, which is greatly appreciated by stakeholders. Their extent has decreased overtime (i.e. from more than 250 participants in 2008 to 130 in 2012). As shown in Figure 5.9, the participant distribution is greatly skewed toward Eastern Europe countries, which are by consequence the main supporters of these activities.

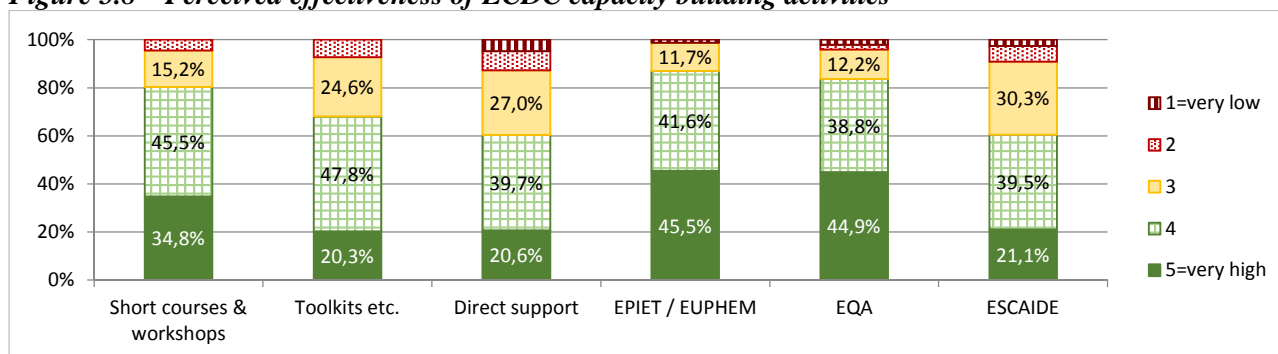
Figure 5.9 – Total number of participants to short courses and workshop (2008-2012)



Note: Some 70 participants from other non-EU countries are not displayed.

- Training toolkits - such as for the legionnaires' disease (2011) or for response to FWD outbreaks (2011) or the 'Field Epidemiology Manual' (FEM Wiki) based on lectures from the EPIET courses (see Box 5.2 below) – are also viewed positively by the majority of stakeholders, but their overall utility is hampered by a suboptimal awareness of such tools, i.e. some 3 in 10 stakeholders selected among ECDC NFP for training, EPIET/EUPHEM partners and ECDC governance bodies are not in the position to assess such tools.
- The examples of direct support to MS capacity are quite rare and normally part of more general field mission for investigation and response support. For this reason, and for the possibly inherent high costs entailed, this is seen as the comparatively less effective mean for MS capacity strengthening.

Figure 5.8 – Perceived effectiveness of ECDC capacity building activities



Note: percentages are calculated on valid ratings, i.e with the exclusion of 'don't know' answers.

Box 5.2 – The Field Epidemiological Manual (FEM) Wiki

The FEM Wiki project was launched in 2010 with the primary aim of making EPIET training manual available online using a collaborative Web 2.0 platform that takes advantage of user-generated input. This way, FEM Wiki intends to offer a collaborative space for creation of training material and to provide a meeting point for not only the EPIET and EUPHEM communities but also to anyone working in disciplines related to epidemiology. The ambition of FEM Wiki is to increasingly attract training experts and to become the key online resource for field epidemiology training global community.¹⁰⁹

For this reason, the evaluation of FEM Wiki focused in the first place on target group's awareness and extent of use of it, and in the second place on the appreciation of users. The results indicate that:

- Of the 202 epidemiologists surveyed only 55 were aware of the FEM Wiki. Interestingly, awareness level is the same among respondents who are to various degree directly involved in the ECDC system and the external ones, which indicate that FEM Wiki has so far been able to go beyond the borders of the ECDC partners' community.
- Among FEM Wiki users, the frequency of access is quite low, with three-quarters declaring to access it 'sporadically'.

¹⁰⁹ Príkazský V. The field epidemiology manual (FEM) wiki: a collaborative eLearning online portal to be launched at ESCAIDE. Euro Surveill. 2010;15(44):pii=19701. Available online: <http://www.eurosurveillance.org/ViewArticle.aspx?ArticleId=1970>

- FEM Wiki is particularly appreciated for the scientific quality of contents. Usefulness and completeness are more moderately assessed. On FEM structure and functionalities, users' positions appear polarised, with a small group very satisfied with them and others quite critic about it.

5.2.5 Impact of Capacity Building Activities on Member States

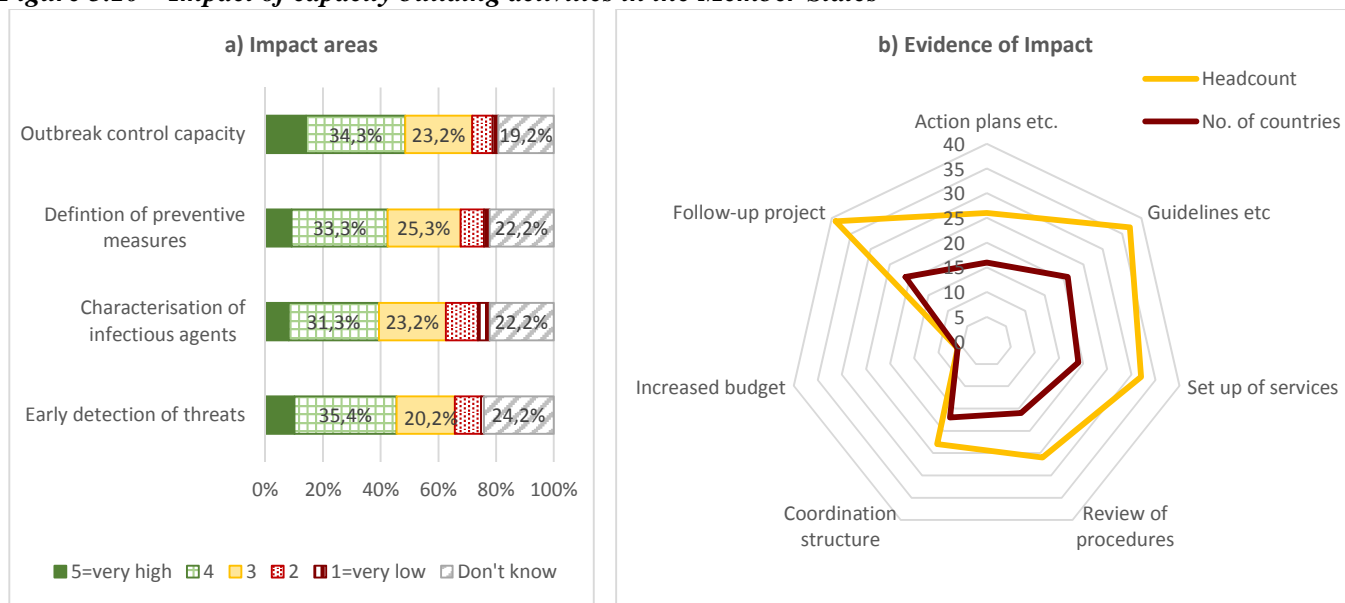
The last aspect analysed relates to the overall impact of ECDC capacity building activities on MS, i.e. to what extent and how such activities have contributed to concrete and lasting changes in country's policies and institutional set up. The findings reported so far in this section generally concur in rating positively the effectiveness of the capacity building activities performed by ECDC, and especially the training programmes and the quality assurance support (see Figure 5.8 above). The evidence of it is obviously more difficult to identify. Training activities are highly immaterial and it would be incorrect to establish 'hard' causal links between inputs and outputs. More consistently, trainings and other educational activities may contribute along with other factors to the adoption of specific measures or to review working methods and/or organizational arrangements within beneficiary organisations.

As concerns work 'areas', the evidence collected indicates that the impact of ECDC capacity building activities was comparatively greater in the field of outbreak control, with nearly half of experts surveyed reporting a 'high' or 'very high' impact, especially in Germany and in Southern Europe. Largely positive is also the feedback on capacity building activities related to early detection of threat and on preparedness, while somewhat less tangible are seemingly the effects on identification and characterization of infectious agent. In this area, positive impacts were reported in particular in various Eastern Europe countries and in France, while below-average effects were registered by the UK and by most of Nordic countries. Also, it is interesting to note that microbiologists' judgment in this area is highly polarized with positive reviews nearly equalled by negative ones.

The 'type' of impact reported also varies. The most frequent effects of capacity building activities were (i) the implementation of initiatives (projects, trainings, quality assessments, etc.) in continuity with previous ECDC actions (registered in 21 out of 28 countries covered); and (ii) the adoption of guidelines, methodological documents and the like (also, 21 out of 28). Specific examples of it include, e.g. (i) the guidance to introduction of HPV vaccines in Europe (UK); (ii) the EUCAST's breakpoints for detection of carbapenemase-producing Enterobacteriaceae (NL); and (iii) a general evaluation of surveillance systems (FR). Often, capacity building activities led to the set up or strengthening of dedicated services and/or coordination structures at national level or within beneficiary organisations, as well as to specific procedural reforms. In some instances, more far-reaching effects at strategic level were reported. Examples of influence on national policy includes: (i) the revision to polio immunisation policy for travellers to high risk countries (UK); (ii) the national policy on Dengue fever (PT); (iii) the West Nile virus infection policy (DE); and (iv) recommendations on local malaria transmission (GR).

National counterparts confirm the existence of a large demand for training caused *inter alia* by evolving technologies, harmonization with international standards, rapid staff turnover, and also – admittedly – to cope with budget cuts registered in various countries. The need is clearly higher in countries with comparatively smaller capacity in these areas. In this respect, it is not surprising that the 'catalytic' effect of capacity building activities on national resources resulted very limited.

Figure 5.10 – Impact of capacity building activities in the Member States



Note: respondents' headcount=99. All countries covered except Slovenia and Iceland.

5.3 Conclusions and Recommendations

Evidence	Findings
<p>EPIET & EUPHEM</p> <ul style="list-style-type: none"> • Previous recommendations were to a large extent followed-up; • Increased and more-balanced fellow distribution (not so much for host-sites); • Demand is high, and various MS are also willing to cover costs; • Programmes address needs that are not covered by other schemes. Synergy with national ones are increasing; • Quality and utility rated very positively by fellows and partners alike (esp. networking); • Efficiency has improved but there is still room for improvement. Selection process remains debated. 	<p>EPIET and EUPHEM are greatly appreciated not only by fellows but also by partners and stakeholders. Beside individual benefits (e.g. on career) there are systemic benefits that are recognised (e.g. better harmonisation and networking).</p> <p>The expansion of EUPHEM responds to a need widely felt, and the introduction of the MS-track has balanced participation and reduced the 'brain-drain' problem. However, it has also reduced mobility.</p> <p>The sustainability of programmes is ensured by a progressive expansion of EAPs.</p>
<p>ESCAIDE Conference</p> <ul style="list-style-type: none"> • Attendance rate is excellent, but not very balanced across MS. Risk managers are a tiny minority; • Mutual reinforcement with EPIET/EUPHEM - but this is not appreciated by all stakeholders; • Scientific relevance and quality is high. Especially useful for networking; • Mostly immaterial impact, less effective than other capacity building actions. 	<p>ESCAIDE enjoys a very positive reputation in the scientific community. Its added-value seems however mostly related to scientific progress and networking. Its possible impact on MS 'capacity' and the corresponding influence on policy-making is still limited, as compared to other, more direct, CB actions.</p>
<p>EQA schemes</p> <ul style="list-style-type: none"> • Relevance, utility and quality ratings are very high; • Delivery and implementation is largely satisfactory; • Very few cases of 'overlapping'; 	<p>The overall level of appreciation of EQA by stakeholders (both participants and not) is very high - comparable to the training programmes.</p>

<ul style="list-style-type: none"> • Number of EQA is slowly increasing, participation rate is quite stable; • Primary added-value of EQA is support to accreditation; • The burden is generally acceptable, although for some labs it represents an obstacle. 	<p>They are also considered among the most effective CB activities promoted by ECDC.</p>
<p>Other CB activities</p> <ul style="list-style-type: none"> • Numerous other short courses and workshop organised; • High attendance rate, especially from Eastern Europe; • Effectiveness of short courses is very high; • FEM Wiki is fairly known also outside the ECDC ‘system’; • FEM Wiki particularly appreciated for the quality of contents, but the use is not frequent; • Direct assistance is rare, and not so effective as a capacity building tool. 	<p>Workshops, short courses, toolkits and other training materials positively add to ECDC effort in the field of capacity building.</p> <p>The level of dissemination and awareness of toolkits and training materials seems sometimes not optimal.</p>
<p>Impact on MS capacity</p> <ul style="list-style-type: none"> • High impact levels registered in virtually all areas, and especially in the field of outbreak control capacity; • Differences in impact levels registered across different MS; • Follow-up initiatives carried out in the vast majority of MS, related to ECDC capacity building activities; • Concrete cases of guidelines and/or strategy documents adopted in connection with capacity building received; • Major effects also on organisation and structure of beneficiaries. • Limited ability to ‘catalyse’ national financial resources. 	<p>While causal effects are difficult to identify, overall ECDC CB activities were able to contribute to the growth of MS capacities in all fields related to the prevention and control of communicable diseases.</p>
<p>Conclusion and Recommendations</p>	
<p>Capacity building and training activities are among the most effective ECDC activities reviewed in this evaluation. Indicators are positive in most of the areas analysed: participation, relevance, quality of outputs, utility and impact. The positive effects do not only concern individuals who participate to specific activities, but involve also partner organisations (networking benefits, dissemination effects, better project capacity, HR skills, quality improvements etc.) and the system on the whole. The sustainability concerns for the training programmes are already being addressed through a policy that promotes EAP instead of ECDC-financed fellowships schemes. This seems an important area of work for future development, since the EU added-value of, for instance, MS-track of the programmes is inevitably limited as compared to real mobility schemes (the measure mostly responded to the need to reduce ‘brain-drain’ from low capacity MS to high capacity ones under EPIET). (<i>Evidence strong, priority high</i>)</p> <p><i>Recommendation</i> The training programmes should not have a substitution effect on national ones.</p> <p>There seems to be further room to improve the geographic ‘balance’, both in terms of participants (both to ESCAIDE and EPIET/EUPHEM) and of training sites (<i>evidence medium, priority medium</i>).</p> <p><i>Recommendation:</i> For EPIET/EUPHEM it is possible to slightly review selection criteria in order to ensure better geographical balancing and not to excessively penalise young, talented experts with limited professional experience (but without relaxing the selection criteria to the point of affecting programmes’ value and reputation).</p> <p>There seems to be a bias in the target groups of capacity building activities and policymakers are not well represented (<i>Evidence medium, priority medium</i>)</p> <p><i>Recommendation:</i> As concerns ESCAIDE, greater participations of decision-makers should be sought, in order to enhance the impact of the conference on MS policies. Moreover certain training ‘products’ such as toolkits, the FEM Wiki etc. seem to suffer from limited awareness among potential stakeholders, and therefore greater dissemination effort would be needed.</p>	

6. HEALTH COMMUNICATION

6.1 Overview

There are three strands to the ECDC approach to communication: crisis communication, risk / health communication and internal communication. The first two areas appear to overlap to a certain extent given the mission of the Centre to provide advice, support and expertise in the area of disease prevention and control. Article 7 of the founding Regulation¹¹⁰ describes how the Centre should operate in what can be described as a ‘crisis communication situation’. The Article states that if there is an outbreak of a disease of unknown origin that may spread within or to the Community, the Centre should be empowered to act on its own initiative until the source of the outbreak is known and then in cooperation with relevant competent authorities.

Meanwhile, Article 12 of the Regulation describes the scope of ECDC communication about its own activities. This relates to what can be termed as ‘risk / health communication’. In this area, the Centre can communicate on its own initiative in the fields within its mission, after having given prior information to the Member States and to the Commission. The Centre has a general obligation to ensure that the public and any interested parties are given adequate access to the results of its work, including through a dedicated website and to publish its opinions. Furthermore, the ECDC is intended to promote coherence in the risk communication process on health threats and cooperate with the competent bodies in the MS and other interested parties with regard to public information campaigns.

The Centre’s health communication mandate is further described in its Health Communication Strategy (2010-2013). The strategy sets the target for the ECDC to become the main reference support point for risk communication on infectious diseases in the EU by 2013, by:

- efficiently communicate ECDC’s scientific and technical output to **professional audiences**: for example via the circa 200 mainly scientific publications produced each year, including on-going series such as the *Eurosurveillance* newsletter and the Annual Epidemiology Report (AER), which are made available via the Centre’s website as well as via direct dissemination to mailing lists.
- developing the means, procedures and necessary partnerships for efficient and coordinated communication of key public health messages and **information to the media and to the European public**; for example via meetings of the network of ECDC communication focal points, and the organisation and involvement in topical events.
- supporting the Member States’ **health communication capacities**¹¹¹: the Centre’s Science Support section supports the disease programmes with studies on risk and health communication and behavioural science. Since 2007, the section has developed six health communication toolkits for adaptation use in settings, such as hospitals and schools by the Member States.

‘Internal communication’ underpins the work of the Centre, providing some of the glue that helps the Centre to operate effectively and providing support to the Centre personnel. Whilst this aspect is not described in the founding Regulation, there is an internal communication strategy to guide the Centre.

¹¹⁰ EC 851/2004

¹¹¹ The Centre also manages a series of planned, on-going and longer- terms activities, which aim to raise awareness and promote health; social marketing of public health programmes, health education and the promotion of health literacy among both health professionals and the public at large. Communication activities can be seen within an internal and external context.

The following section describes our findings from qualitative and quantitative evidence collected during the evaluation, with regards to the relevance, effectiveness and efficiency of the ECDC's approach and outputs and the extent that these add value to what is already available at national level. Findings are provided as follows:

- i. effectiveness of the external communication strategy / approach;
- ii. definition, targeting and reach of audiences;
- iii. satisfaction and use of ECDC materials and products;
- iv. the ECDC as the EU referent for risk communication;
- v. effective procedures and partnerships.

The amount of resources devoted to Communication and Publications has halved in the period, moving from some total € 2 mn in 2008 to € 1 mn in 2012 which roughly accounts for 5% of title 3 expenditure. The total burden on the Centre expenditures is however much higher, as communication activities represent as high as 10% of its total costs, because of the 43 full time equivalent staff allocated to them, because Communication resources have been restructured and reorganized since 2011 with a view to increasing their efficiency by reducing the outsourcing of core tasks. The amount of budget centrally managed by the relevant unit has also been halved between 2011 and 2012 and now reaches some € 0.5 mn. The remaining part is distributed across the DP and to the Resource and Management unit for the publications. In the years for which information is available (2011-2012) the influenza DP got a € 130,000 communication budget, the sexually-transmitted disease programme a € 30,000 yearly allocation, and food and water-borne diseases some € 35,000 in 2012. The share of disbursed funds on annual allocations has moved around the 40-60% range without any clear trend and remains slightly above ECDC average for title 3 expenditure.

6.2 Main findings

6.2.1 Effectiveness of the external communication strategy /approach

The Centre has increased its focus on external communication in recent years. There have been improvements to the website, following the evaluation and development of new website and social media strategies. The Centre has made use of external monitoring and assessment services to allow a more strategic approach to be taken including measuring performance against pre-defined indicators.

The evaluation survey suggests that there is an external perception that ECDC communication activities have improved since 2008. Relevant stakeholders¹¹² with more than 6 years' experience of working with the Centre have noticed significant improvements (40% of respondents) or moderate improvements (32%), and only 4% reported a worsening.

It is difficult for those outside the Centre to make a judgment on the way that the ECDC manages its communication activities, whether there should be more or less outsourcing and whether there are gaps in communication team's skill set. However, feedback suggests that the Centre now has a good strategic communication capacity. No specific complaints were identified and there appears, from insights available to date, to be a level of satisfaction with the operation, and an assumption of communication competence. Feedback from informed respondents (including NFP) suggests that the issues communicated by the ECDC are appropriate and given sufficient weight.

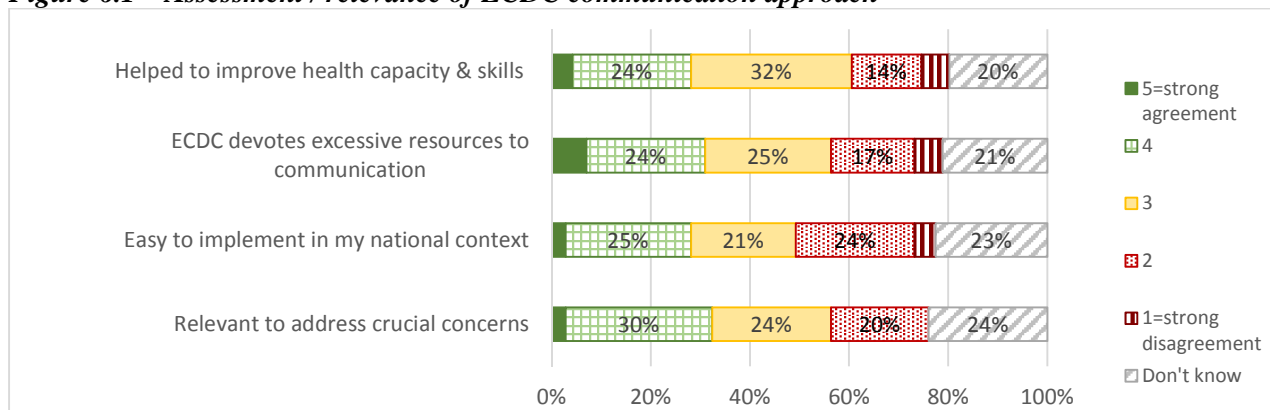
¹¹² The question was posed to NFP for communication, MB and AF members, National Coordinators and other self-qualified 'communication experts'.

However, there are mixed views on the ECDC’s approach to communication. Differences can be identified at country level, but also to some extent according to individuals own levels of engagement with risk communication. For the most part, those who work directly with risk communication manifest greater appreciation / understanding of what the ECDC is able to offer to support communication efforts.

With regards to the ECDC goal of supporting Member States’ health communication capacities: many countries are well able to produce their own health communication materials and have long standing expertise in this area. For these countries, ECDC health communication materials provide an external reference point, which can be used as a benchmark for national approaches and materials. However, those who feel themselves to be more advanced identify potential for sharing good practice with the Centre and other countries, may take account of key messages, but tend to use their own strategy and tools.

In fact, there is significant variation in health/risk communication capacity across the Member States. Some countries express far greater interest in ECDC support for health/risk communication to add value to what is available at national level. Appreciation of ECDC materials varies in relation to different expectations. Those who would like to make direct use of ECDC materials on top of their own resources are not always able to because they consider that materials are not sufficiently tailored to national audience. Other countries do not have equivalent resources at national level and are more open to what the ECDC can offer. These countries would like to make direct use of ECDC materials, but may not be able to because of lack of resources to replicate materials in national languages.

Figure 6.1 – Assessment / relevance of ECDC communication approach

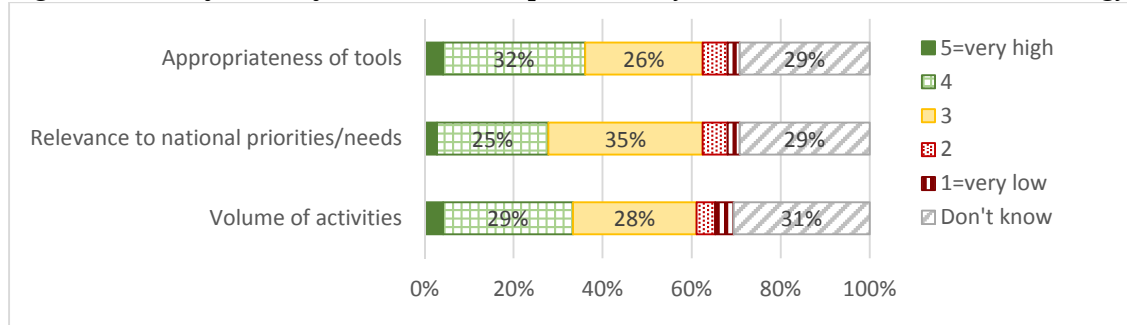


Note: The figures represent the percentage of agreement / disagreement on given statements about ECDC communication activities. Total respondents headcount: 71.

The Figure 6.1 above highlights the mixed assessment of the relevance of the ECDC approach to health / risk communication activities (findings on specific materials / activities are highlighted in a next section). This mixed picture shows ratings distributed across the low to high agreement spectrum in almost equal measure. The results indicate that circa a quarter of respondents are unsure how to assess the ECDC approach, and the other three quarters give a low, medium and high rating of the ECDC approach. The survey results suggest that these are considered to have some relevance to addressing crucial concerns (33%), even if it is not always easy to implement ECDC materials in a national context (only 28% find easy to implement). There are also mixed views with regards to the allocation of resources to ECDC communication activities, with some 31% of key stakeholders who believe ECDC is spending too much on communication. This is a typical area of contention in the planning of communication activities. On the other hand, consideration of the overall appropriateness,

relevance and volume of activities suggests that the communication tools and actions foreseen in the overall strategy (2010-2013) are in-line with expectations.

Figure 6.2 – Fulfilment of stakeholders’ expectations by the ECDC Communication Strategy (2010-2013)



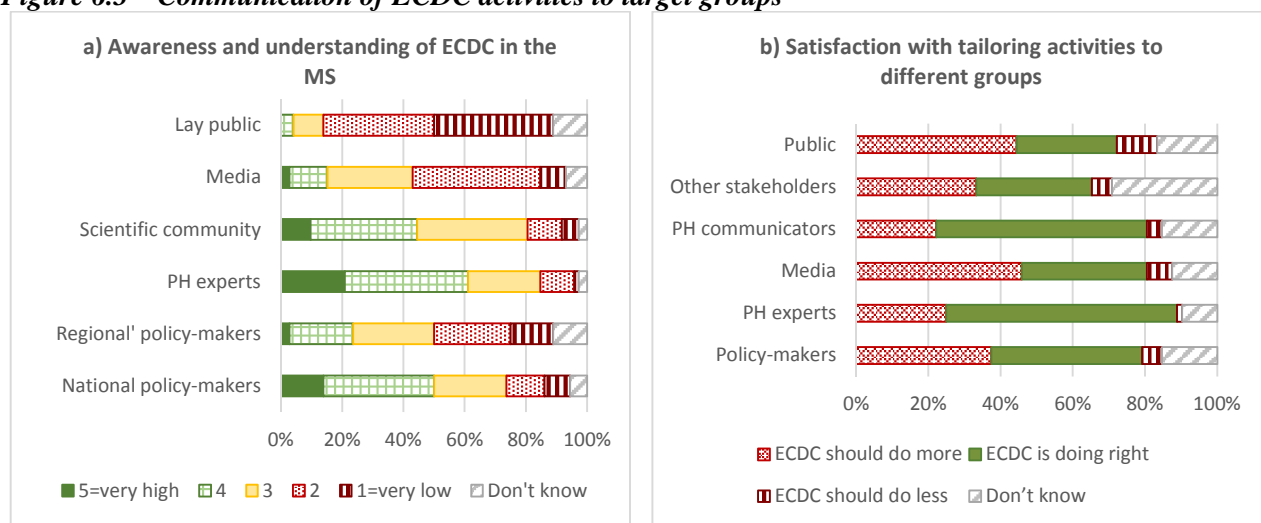
Note: Headcount=72

6.2.2 Definition, targeting and reach of targeted audiences

The Centre has placed an emphasis on defining its primary and secondary *target audiences*. In addition, steps have been taken to allow a better understanding of target group needs and expectations by analysing and developing target group profiles. This type of approach can be considered to be good practice in strategic communication. Evaluation findings suggest that the ECDC is quite well known among the specialist audiences that it targets, for example public health experts, relevant national policy makers and public health communicators; those who are working in infectious diseases and epidemiology. Front line health professionals are reported to not be typically aware of the ECDC, which seems to be realistic given that required instructions / advice are provided at national level and these are considered to be a secondary target group according to the communication strategy (Figure 6.3.a).

The Centre seems to be getting it about right with regards to the way that it tailors communication materials / activities to specialist audiences; 64% indicate that ECDC targeting of public health experts is about right and 58% that targeting public health communicators is also right (Figure 6.3.b). In a next phase it would be interesting to identify how make further improvements to these ratings to push appreciation to the higher end of the spectrum. The survey responses raise some questions with regards to whether more could be done to target policy makers (38% think ECDC should do more). Evidence from desk research suggests policy makers want succinct messages from analysis of research evidence.

Figure 6.3 – Communication of ECDC activities to target groups



Note: headcount=72

External stakeholders perceive that there is most scope for additional focus on the media. Forty-six per cent indicate that more should be done and only 16% agree that the media is aware and has an understanding of what the Centre does in their country. The perception of limited awareness seems to relate to the extent that national communicators themselves point to the ECDC as the source of information rather than journalists seeking information directly from the Centre. Yet statistics on media clippings provided by the Centre, confirm a level of national coverage across the Member States. However, this coverage is for the most part neutral in tone and references are often secondary to other organisations such as the WHO and EFSA. There is a tendency for national media to be less aware of the ‘EU level’. It is difficult to assess the extent to which this element represents a significant weak point.

There seems to be additional scope to for the Centre to build better bridges with the national media and reports from those working at the Centre confirm that a planned approach to increase exposure is currently underway¹¹³. The survey also points to an overall low visibility among the public. This result seems to relate rather to the low public profile of the ECDC (according to 75% of respondents) rather than a need to provide specialist content to the public. Furthermore, an increased focus on the media could impact to a certain extent on wider audiences.

It is difficult for those outside the Centre to make an assessment of the ECDC’s approach to *disseminating its information and communication products*. The Centre’s website is a key information repository, which ensures continuous access to main communication outputs. It is noted that significant efforts have been made in recent years to increase the potential dissemination of information / materials provided by the ECDC. This relates not only to the setting of targets for outreach for example for media coverage and newsletter circulation, but also to increasing the accessibility, reusability and shareability of information. There has been an increased focus on the use of open formats to allow stakeholders to adapt to their audiences / needs, which is in-line with

¹¹³ Some national level experts suggests that this should be done by placing a greater focus on creating stories to support the data available, rather than just making data available. The recent WHO call to the public to cut sugar consumption was cited as a good example of how to ‘sell research.’ Others recommend joint branding of media activities, to raise awareness of the ECDC as a source of information for the media in all EU Member States, and enhanced information for the media on the ECDC website. However, as there is a clearly signposted specific entry point to the Centre’s website for the media, with targeted materials, it seems that improving the website is unlikely to change levels of media awareness

approaches taken elsewhere including by WHO. The development of a social media strategy and increase in social media use, which anecdotal evidence suggests is at appropriate levels also contribute to the goals of increasing outreach.

The evaluation survey suggests that stakeholders who feel in a position to comment, tend to be more positive in their assessment of ECDC dissemination and target group coverage than negative, but there is still room for improvement.

The availability of national materials and ECDC materials in national languages are key factors that seem to limit their distribution potential through the Member States. Even when translated versions are provided the number of copies may not be sufficient if there are no national resources to provide supplements. It does seem that ECDC communication outputs are more likely to remain at national level than to filter through to the intended health professionals. Conversely where there is no language issue, there is evidence that ECDC outputs are disseminated and even sought out directly from the ECDC website, by those working outside the national administration. Language is clearly an important element and it seems another area where there are mixed views. This raises questions as to the extent and desirability of the Centre tailoring certain materials for specific countries, particularly executive summaries targeted to decision-makers.

6.2.3 Satisfaction with and effective use of ECDC communication products

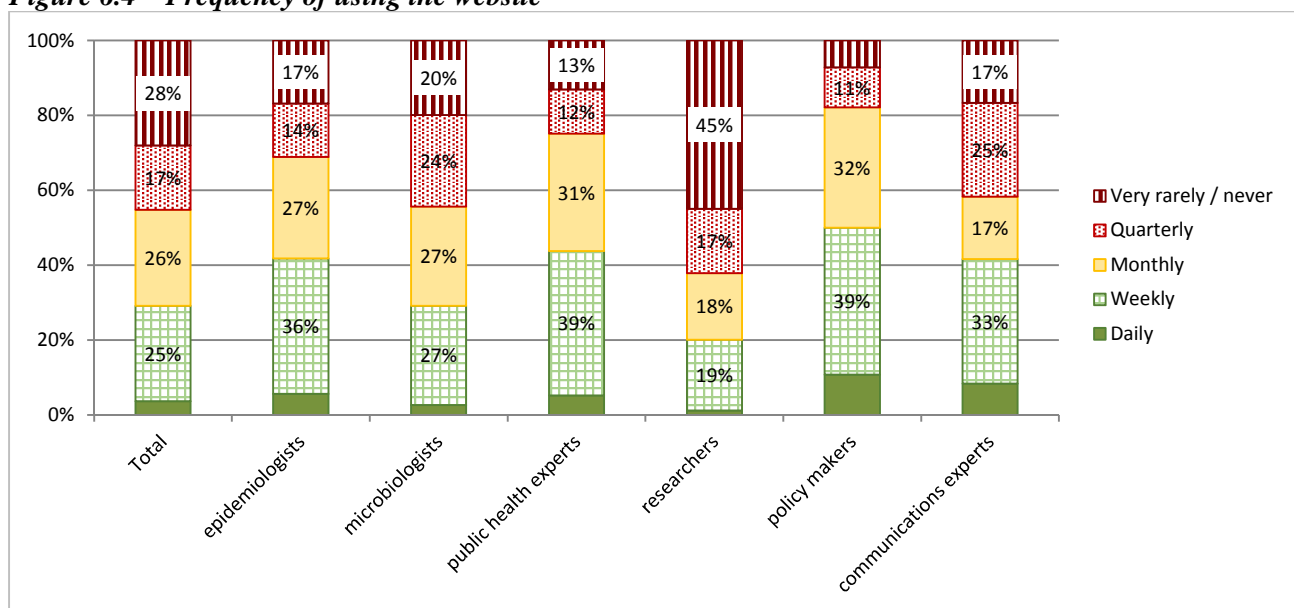
The Centre provides a very wide range of technical and practical communication products. The following paragraphs review in particular (i) the communication aspects of technical reports; (ii) the ECDC website; (iii) toolkits and guidance materials; (iv) Public Health Information Campaigns and (v) other support materials / data.

Technical reports: the assessment of ECDC technical reports is that they are of high quality and are appropriately pitched to relevant to specialist target groups. There are different information needs at country level, meaning that not all topics are relevant to all. Technical reports are most useful when they add value to what is already available. A fuller appreciation of specific reports / publications is provided elsewhere in this Study. However, with regards to the global appreciation of technical publications, consideration could be given to focussing on areas that complement what is available nationally. This finding is backed up in the survey where most (79%) agreed that ECDC outputs tend to overlap with what is available nationally. There is, however, a smaller group (11%) for whom ECDC reports provide inputs that would not otherwise be available nationally. This raises the question as to the extent that the ECDC should focus supporting a smaller number of countries with resource / expertise issues and / or on activities that are broadly utilised / add value to all countries. The above finding can be aligned with a call from some quarters for greater collaboration with the communication focal points that have been established. It could be that there is scope for greater discussion / forward planning on where to focus publication / communication resources so that the Centre achieves greater 'added-value'. At the same time, this could lead to the identification of high quality resources at national level that could possibly be adapted by the Centre for Member States that are less resourced. This would extend the identified ECDC potential to raise the overall EU standard / reduce discrepancies at national level.

ECDC website: the main key finding is that the website is one of the Centre's critical resources. The ECDC website is currently of a good standard and it is reported that there have been significant improvements over the last years, reflected by the additional efforts made, for example to benchmark other health communication websites, review the overarching digital approach and increase the

usability / presentation of information to engage specific target groups. In the past, the website was reportedly complex to navigate and not so informative, while at present it makes accessible a lot of information in a well-structured way to specialist and semi-specialist audiences. In some cases, the ECDC website may be better than equivalent national level sites. The usefulness of the website is inferred *inter alia* by the frequency of visits. From more than circa 390 respondents who answered questions on the ECDC website, just over half of respondents indicated that they used the website frequently (25.5% weekly and 25.6% monthly). Yet circa a further quarter of respondents (28%) indicated that they rarely or never use the website. When considering profiles, researchers are the group making lowest usage of the site, which seems to be most used by epidemiologists, public health experts, policy makers and communication professionals (Figure 6.4). More statistics on access to the website and to specific document's homepage on the website are given in Box 6.1 below.

Figure 6.4 – Frequency of using the website



Note: Total headcount=396

Box 6.1 – Access and use of ECDC websites

The new ECDC portal was launched in mid-August 2009. Unique visitors have grown steadily overtime from less than half million in 2010 to about 800,000 in 2012 and 945,000 in 2013 (exceeding the target of 800,000 unique visits set by the Management Board). Visits have grown along with the wealth of new scientific publications made available on the website year after year. These amounted to some 43 in 2009 and grew five-fold to 240 in 2012. Statistics on number of views of publications are mostly not available – a gap that is suggested to address in the future in order to support a better assessment of awareness and utility of ECDC outputs. For some key outputs, basic statistics on page views have been collected, covering the period June 2011 to December 2012. For illustrative purposes these are reproduced below¹¹⁴:

- Annual Epidemiological Report homepage: **2,457** page views
- CDTR homepage: **12,584** page views
- WISO homepage: **6,953** page views
- HIV/AIDS surveillance report homepages: **2,532** page views
- Toolkit for investigation and response to FWD Outbreaks with an EU dimension: **3,489** page views

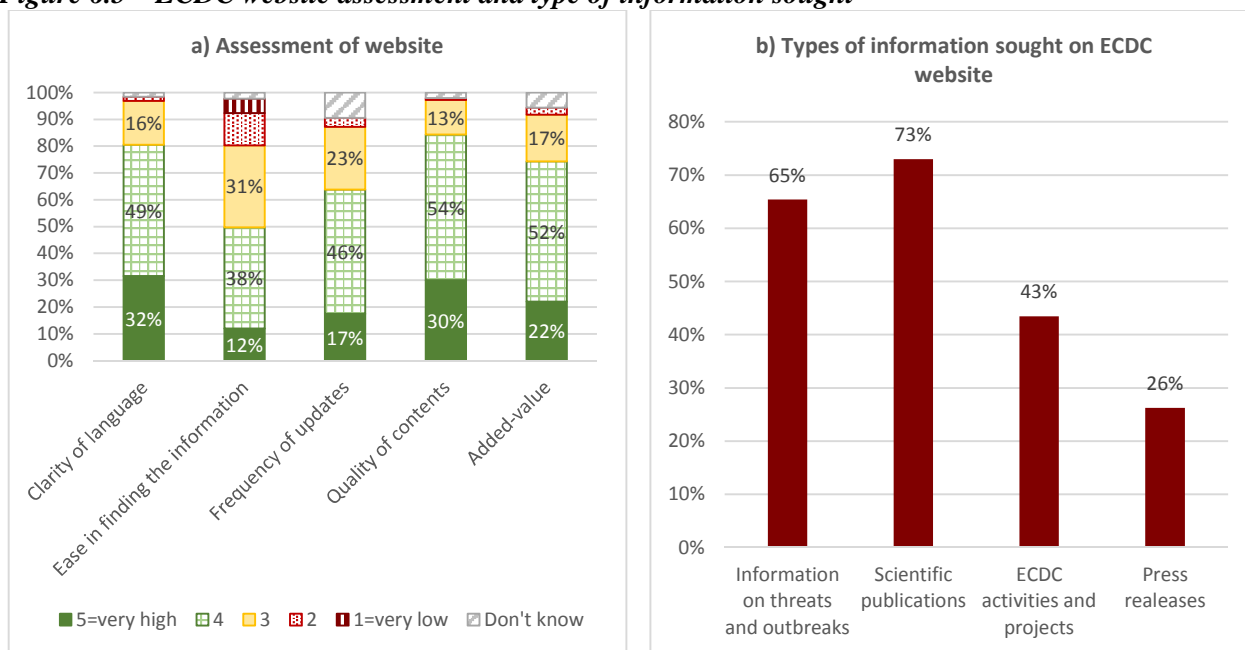
¹¹⁴ The numbers presented do not represent downloads but the number of views registered on the homepage where these publications are listed. Considering that there are several paths a user can take to get to the final file, they are not to be taken as exact indicators of access to a given document.

The relatively high weekly / monthly usage suggests that the Centre is doing a good job at keeping the site alive with fresh information and that the information posted is considered to be relatively useful / interesting. These assumptions are backed up by survey findings (Figure 6.5.a). It appears that the quality and reliability of the information provided on the website is rated most highly (84%). A further 74% consider that the information made available on the site provides added value. There appear to be no major concerns with regards to the clarity of information provided and frequency of updating of the site. However, some 17% still have some difficulties finding the information that they are seeking, an issue likely to be less relevance to frequent users.

In terms of the types of information sought (Figure 6.5.b), it appears that the main reason for accessing the site relates to searching for scientific publications, reports and articles (73%), followed by searches for up-to-date information on potential threats or disease outbreak evolution (65%). As would be expected, few look for press releases / materials for the media and general public (26.3%), as only a proportion of all respondents to questions on the website had a public relations / external communication focus in their work.

One suggestion for enhancing awareness of the site was to create a website banner and information that communication network members could post on their respective websites, for example in media sections of sites.

Figure 6.5 – ECDC website assessment and type of information sought

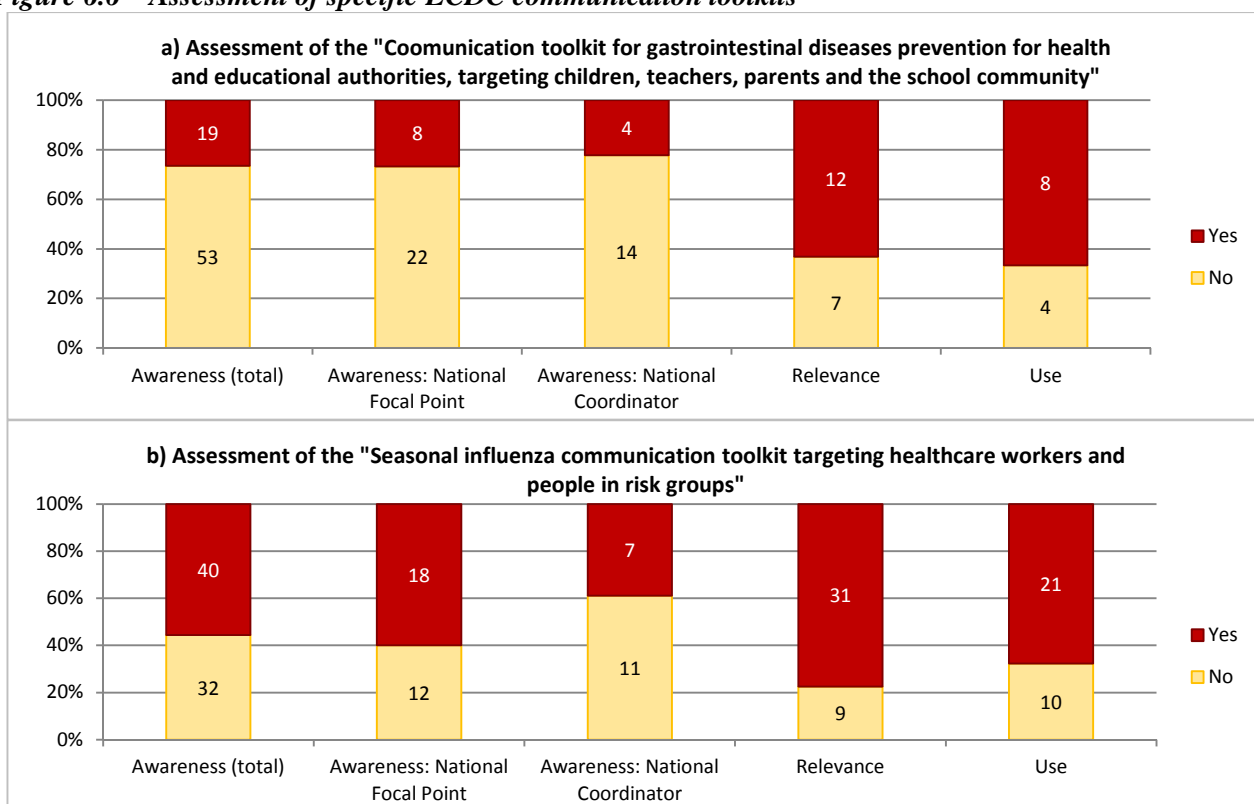


Note: (a) Headcount=390; (b) Headcount = 396.

ECDC toolkits and guidance materials are thought to be professional. There are question marks over the extent that cultural / linguistic differences mean that toolkits are not directly applicable and limit their likely take up, particularly by administrations that already have access to national expertise in this area. However, even for these administrations, ECDC materials can be used as a useful external reference material. Capacity / resource issues within some national administrations restrict the ability to make best use of materials not provided in the national language. There may be some value in exploring a more targeted approach, for example toolkits where they are most needed with local and national linguistic versions provided. Nonetheless, ECDC toolkits and campaign materials represent an opportunity to raise the European standard by increasing the potential for Member States with less resources / expertise to develop health communication campaigns.

Awareness and use of two specific communication toolkits were tested in the evaluation survey. Whilst levels of awareness are not high for the “*Gastrointestinal disease toolkit*”, the survey suggests that both kits have been used, which suggests that they add value to what is available nationally in some countries (see Figure 6.6 below). What is unclear is how countries make use of the toolkits. It seems likely that some may use the toolkits as reference materials rather than being directly implemented and this is supported by other survey data suggesting that it can be difficult to implement tools as well as anecdotal evidence pointing to lack of resources to adapt tools. Comments in the ‘free text box’ of the survey confirm that messages from ECDC toolkits were integrated into national materials and that some countries had plans to make use of materials in the future and that more advanced preparation is required to allow national level stakeholders to have meaningful inputs. The example of the pilot materials on influenza is one where more advanced preparation is reported to have increased the potential value of the activity.

Figure 6.6 – Assessment of specific ECDC communication toolkits



Note: Total headcount=72

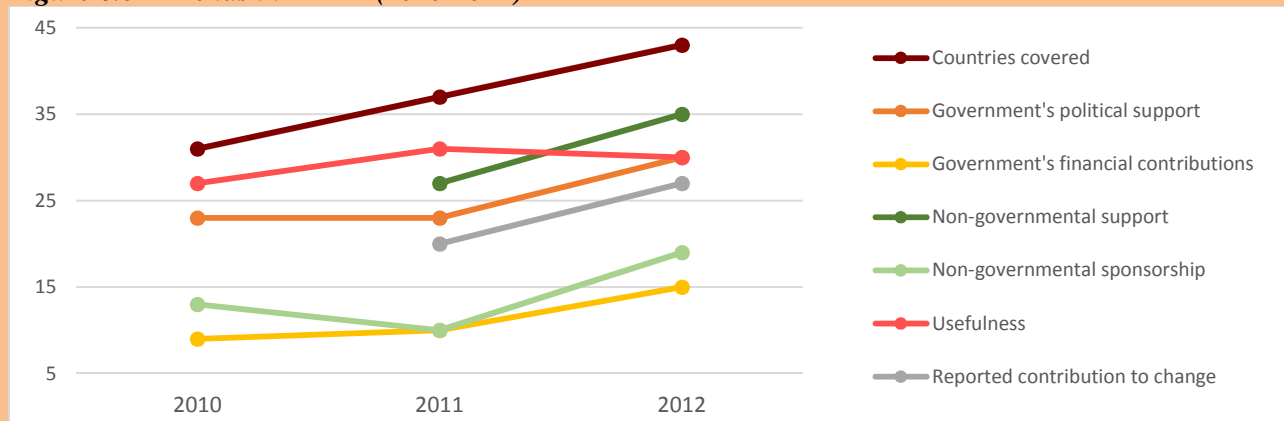
Public Health Information Campaigns. Collaboration on public health information campaign - such as the *European Antibiotic Awareness Day* (see Box 6.2 below) - is a concrete activity that brings the ECDC into close contact with national players. Evaluation survey respondents were asked to indicate whether or not their organisation had participated in an ECDC public disease communication day. A majority of respondents (38 out of 72) reported that their organisation had participated. Nineteen respondents were not aware of the different initiatives. Those who had worked previously with the ECDC were asked to comment on this collaboration. The results suggest a broad level of satisfaction with partnerships established for the implementation of campaigns, In particular one in three respondents affirm to be very satisfied, and none declared to be not satisfied with the partnership established.

These actions represent an opportunity for an inclusive EU-wide approach, but actual effectiveness on the ground / outcomes have not been substantiated. Indeed it can be difficult for these types of EU-wide initiatives to generate actual impact unless national partners take the lead. Some skepticism has been expressed by key informants, particularly those not directly involved in external communication as to their real added value. Others highlight the significance of providing opportunities for all MS to engage in this type of activity, particularly those with more limited expertise / resource.

Box 6.2 – The European Antibiotics Awareness Day

Since 2008, in the week of 18 November, ECDC organizes in collaboration with MS the *European Antibiotic Awareness Day (EAAD)* - a platform for supporting national campaigns on prudent antibiotic use in humans. Since 2012, the WHO/Europe is also supporting the initiative in the whole WHO European Region, and the total number of countries cover by EAAD hit 43. The specific focus of the various editions change, and ECDC support consists of the provision of a number of materials, e.g.: the PR & media toolkit, the social media guidance (translated in all languages), the NGOs mapping as well as patient stories. The materials are then used in various ways at national level, the most common is the preparation of information leaflets and web based materials, posters, brochures, TV spot. The statistics summarized in Figure 6.8 below (for the 2010-2012 editions) show growing trends in terms of both Government and non-governmental support – including financial support, although in absolute term it is still quite limited. Perceived usefulness is not growing proportionally with the overall coverage, but tangible effects are reported by an increasing number of countries.

Figure 6.8 – Trends in EAAD (2010-2012)



Note: 'Usefulness' includes countries considering EAAD 'very helpful' or 'helpful'.

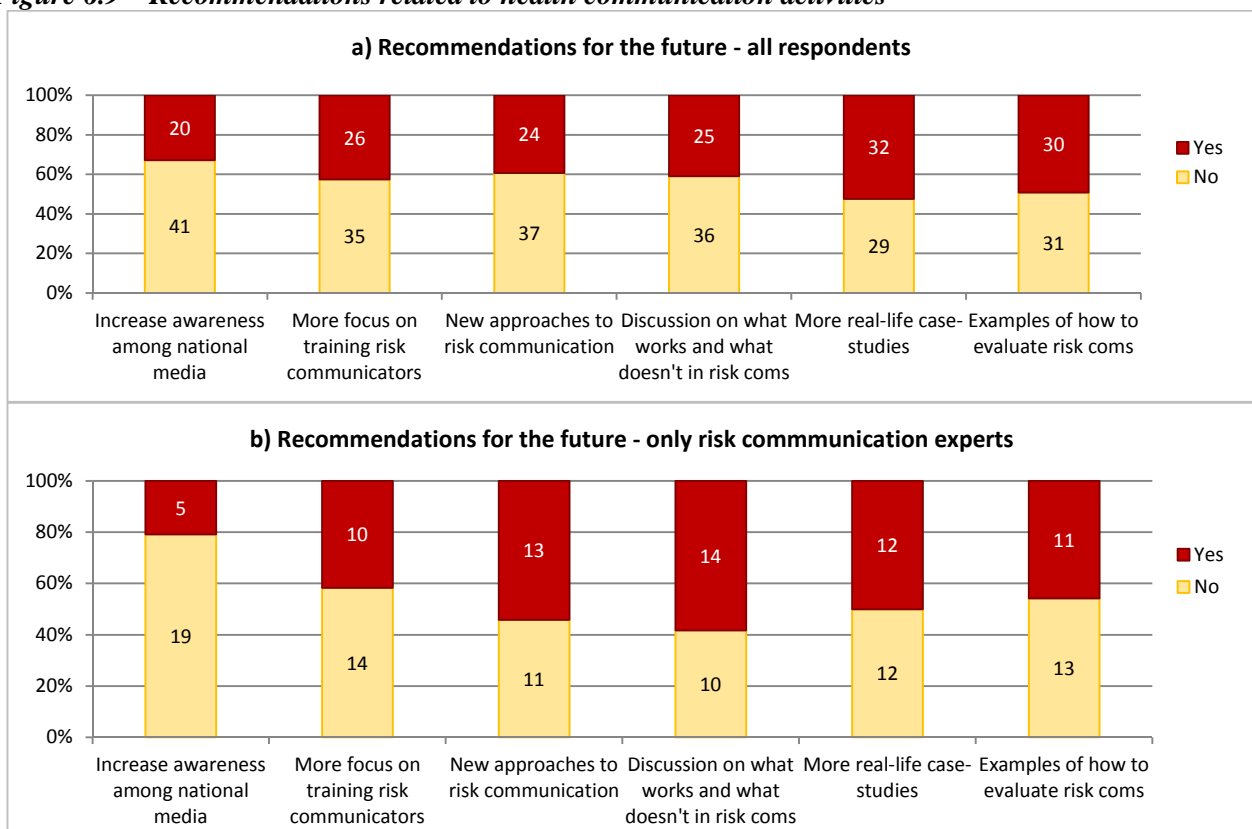
Other support materials / data. The provision of research on risk communications is particularly welcomed. The work being done is considered to be exploratory and there is scope for lessons to be learned at national level. Furthermore it was suggested that the research also has the potential to increase the status of this specific area of risk communication.

The survey was also used to test whether or not survey respondents were aware of the “Literature review on effective risk communication for the prevention and control of communicable diseases in Europe”. The majority of respondents (50 out of 76) had not read the review and this outcome was similar for survey respondents significantly involved in risk communication. The majority of survey respondents who had read the review indicated that they had found it quite useful.

Options for the future. The evaluation survey was used to test possible options for the future (Figure 6.9). Options were sourced from initial interviews held with external stakeholders. Perhaps unsurprisingly, responses to the survey indicate a mixed picture of what to focus on, which is likely

to reflect the differing needs interests at national level; a recurring theme running throughout this assessment of the Centre’s communication outcomes / impacts. Responses are provided below and show a difference between what all stakeholders perceive to be important (with varying levels of involvement in risk communication) and what specialist risk communicators (with a high level of involvement in risk communication) perceive to be important. Specialist risk communicators place an emphasis on an increased focus on new approaches to risk communication together with more practical examples of what works and what does, which could mean more sharing of actual practice among Member States. It is noted that these points are aligned with the outcomes of National Communication Focal Point meeting held in October 2013, which also sought to define areas for additional focus.

Figure 6.9 – Recommendations related to health communication activities

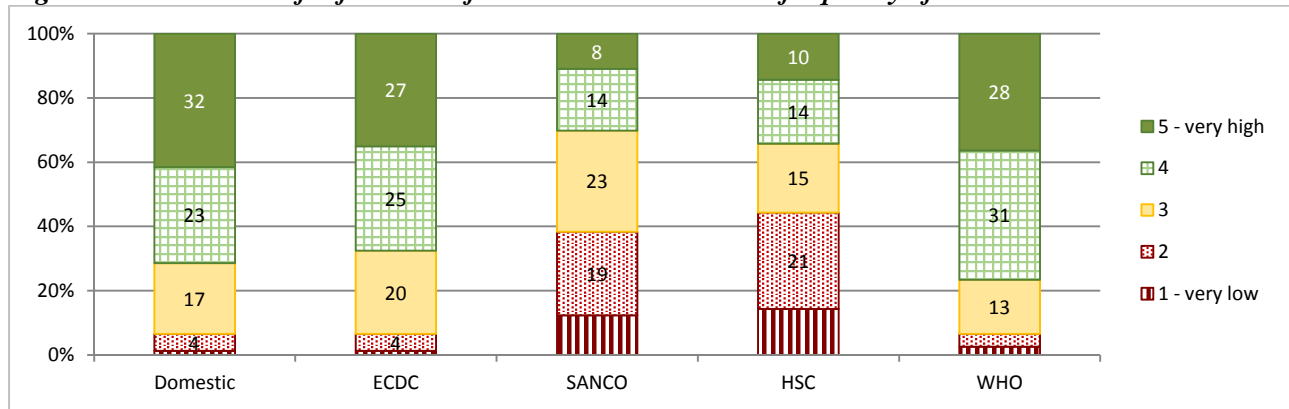


Note: (a) headcount=61; (b) headcount=24

6.2.4 ECDC as EU referent for support to risk communication

The evaluation survey points to the important role played by the ECDC with regards to risk communication. Respondents were asked to indicate the sources of information that they rely on for risk communication. The aggregated results suggest highest levels of reliance upon information from WHO (Figure 6.10). However, responses to this question can be differentiated according to the level of involvement of the respondent in risk communication and this reveals a somewhat different picture. For those at the forefront of risk communication (high level of involvement), domestic sources of information are rated most highly, followed by WHO and ECDC in almost equal measure (20 respondents rating the ECDC and 21 rating WHO as most important). This assessment of the ECDC confirms its role in crisis communication situations, which was a key finding from the interviews held with informed independents.

Figure 6.10 – Sources of information for risk communication – frequency of use

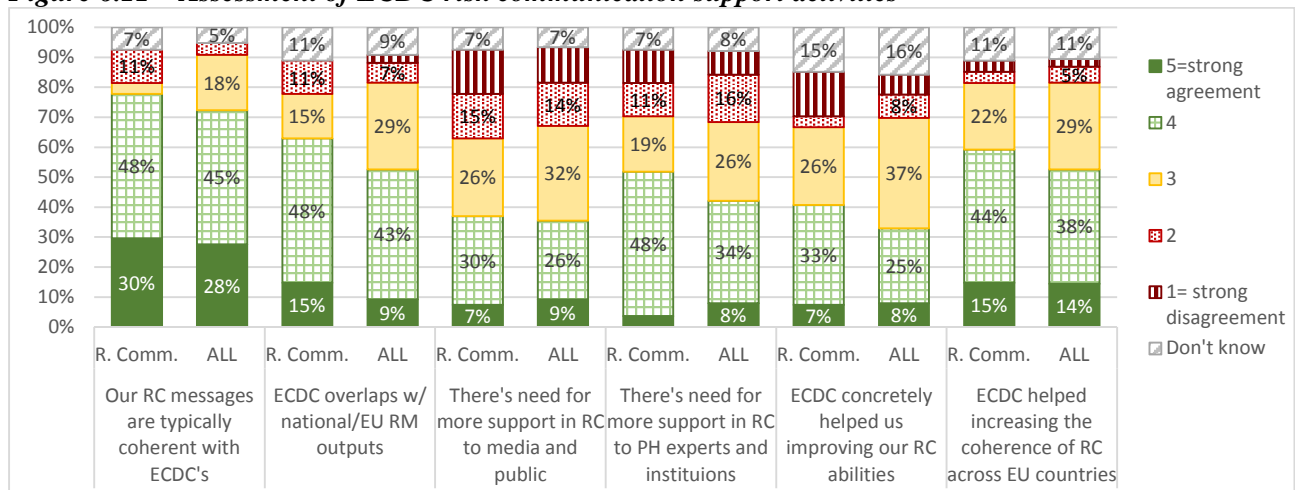


Note: Headcount=87.

Whilst different national administrations may make use of health communication materials to varying degrees, there appears to be greater consensus on ECDC added-value with regards to contribution to coherence in crisis communication. This is where the ECDC complements or extends information available at national level and / or is able to take a coordinating role, which supports the affected MS¹¹⁵.

As well as complementing or extending information or approaches at national level, the ECDC role as a referent for risk communication is somewhat confirmed by its impact upon risk communication at national level. Survey respondents were asked to give their appreciation of the ECDC’s risk communication role, with regards to risk communication messages, tools and activities and support (Figure 6.11). The Centre appears to be facilitating a common approach to risk communication messages at European level, which is an important achievement. A mixed appreciation is given with regards to the extent that tools and activities have helped to improve national competence / capacity in risk communication, and this reflects earlier findings of significant variation from country to country.

Figure 6.11 – Assessment of ECDC risk communication support activities



¹¹⁵ Several examples were cited to the evaluators, including the ECDC’s role in the E. Coli crisis in Germany in 2011. Making available statistics to determine a ‘common case definition’ at the start of a crisis is very valuable, which allows national administrations to gain an EU-wide view, which can be very difficult for MS to access otherwise, as is the timely provision of common messages / a common line to assist MS in their relations with the media. The Centre is considered to be fairly trustworthy, efficient and fast with regards to the information that it provides in times of crisis.

Note: “R. Comm”= experts whose professional responsibilities significantly involve managing risk communication on CD. Headcount= All (76), R. Comm.(27).

6.2.5 Effective procedures and partnerships in place

It appears that the appreciation of how to work best with the ECDC varies from country to country. The amount of contact between a national administration / public health organisation and the ECDC appears to be a factor that influences views on its perceived added value. Some national administrations have much more frequent contacts with the Centre on risk communication issues than others. It is unclear the extent that this should be a concern or this it is simply a natural reflection of different national circumstances. However, the fact that some administrations may not know who to contact on risk / health communication issues is not optimal. Furthermore, there are differences of view with regards to the volume of information provided by the ECDC. Some report that contacts and information have increased with more emails and sharing of plans. Others have a sense that the frequency of information has slowed down.

The National Communication Focal Point Network is relatively new, but is considered to be potentially very useful, given that it is operating in a relatively niche area. There are questions over the frequency and duration of meetings. Mixing different participant profiles may also be an issue with different levels and types of contribution because of the mixture of technical and communication people. Changes in membership of the network can reduce its effectiveness because of the need for familiarity and trust between members to facilitate exchanges of information. This is perceived to be a problem area. Anecdotal evidence suggests that the newly established Communication Focal Points network could be used to greater effect, for example to discuss priorities for risk communication support, announce advanced planning of actions to allow better alignment and in the development of approaches for sharing best practice and materials among Member States. There appears to be a need for clarity with regards procedures and definitions related to crisis communication and risk communication. This need is felt to be particularly acute with due to the new legal framework. It may be unclear where one type of communication starts and the other ends. The need for greater clarification relates to the potential overlap between DG SANCO’s HSC – Communicators and the ECDC. Furthermore, there is a call for a clearer description of who is responsible for risk and crisis communication in each country. In a crisis communication situation it is important to have a solid list of known contacts to facilitate rapid information exchange, particularly because social media require instant updates.

6.3 Conclusions and Recommendations

Evidence	Findings
<p>External Communication Strategy / Approach</p> <ul style="list-style-type: none"> • Levels of awareness / understanding of the strategy high, but mixed views on overall relevance of approach to communication; • Perceptions of overall relevance / utility / volume of activities broadly in line with expectations; • Perceptions of evolution of ECDC communication, resources and staffing as improving over time; 	<p>The Centre has increased its strategic focus on communication, which seems to have paid off: stakeholders recognise improvements have been made. Staff are considered to be competent and there have been some efficiency gains through the current approach to reducing outsourcing. These are not necessarily visible outside the Centre and there are some questions regarding levels of resourcing.</p> <p>Stakeholders have mixed views on the Centre’s overall communication approach. This reflects the different types of capacity and levels of need at national level.</p>

<ul style="list-style-type: none"> • High share of stakeholders believing ECDC still invests too much in communication. 	<p>Those more directly involved in risk communication understand what the ECDC is trying to do. The types of activities carried out are perceived to be broadly relevant and have potential utility.</p>
<p>Definition, Targeting and Reach of Audiences</p> <ul style="list-style-type: none"> • Evidence of definitions of target audiences / profiling in line with best practices; • Documented actions taken to increase outreach and use of materials by targets; • Positive perceptions of awareness and targeting of relevant audiences; • Poor visibility in the media; • Poor visibility among the public; • Improvements in the website strategy and indicators to monitor progress. 	<p>There is a clear internal understanding of primary and secondary target audiences, which is backed up by research into target audience profiles.</p> <p>The use of open formats / new channels (social media) gives users more flexibility, yet resource and capacity, as well existing tools at national level seem to limit take up. Some see and welcome materials as reference tools others have higher expectations and need tools in national languages to allow greater use.</p> <p>Specialist audiences are most likely to be aware of the ECDC and what it does. Technical reports are appropriately pitched to these groups. There may be scope to do more to target policy makers who are looking for succinct analysis of information rather than raw data.</p> <p>The ECDC has a low public profile. The public are not considered to be a key audience. There is a call for the Centre increase its focus on the media.</p> <p>The availability of ECDC outputs in national languages is a factor that is perceived to limits their take up and usage /as does the availability of other similar materials.</p>
<p>Satisfaction and Use of ECDC Communication Products</p> <ul style="list-style-type: none"> • ECDC website reported as frequently used by stakeholders; • Frequently mentioned requests to move from paper reports to more interactive deliverables; • Limited level of awareness of toolkits; • Mixed use of toolkits and campaign materials sometimes below potential; • Very diverging needs for communication products. 	<p>ECDC technical reports are of high quality and appropriate to specialist target groups.</p> <p>ECDC outputs are considered to overlap with what is available elsewhere, which suggests a need to prioritise and focus on how to add value.</p> <p>The website has improved over the years and is an important information resource, which is rated highly by external stakeholders.</p> <p>There are mixed views on the usefulness of toolkits relating to national expectations /capacity and availability of other resources. The survey suggests lower than desirable awareness.</p> <p>There are mixed views on where to focus in the future, but specialist communicators highlight the importance of a focus on new approaches / practical /real-life examples of what works and what doesn't.</p>
<p>EU-Wide Recognition of ECDC as the EU Referent for Risk Communication</p> <ul style="list-style-type: none"> • ECDC not recognised yet as a prime referent for direct risk communication to the public and the media; • Contribution to enhanced coherence in crisis communication widely recognised. 	<p>The Centre has succeeded in facilitating a harmonisation of risk communication messages across the EU.</p> <p>It is recognised there could be a scope for ECDC to target more the public and the media but very few stakeholders fell the need for it or deem it a positive development.</p> <p>Whilst there are mixed views on the usefulness of some outputs, the Centre really adds value in a crisis situation, taking a supportive / coordinating role.</p>

	<p>The provision of cross-country data to provide a common case analysis is invaluable to the Member States, because it cannot be sourced at national level. Related workshops and training have proved to be extremely useful.</p>
<p>Effective Procedures And Partnerships</p> <ul style="list-style-type: none"> • Very mixed patterns of partnership in communication; • Difficulties in identifying ECDC contact persons for risk communication purposes. 	<p>Different countries have different levels of contact with the ECDC and this affects their perceptions of collaboration / frequency of contacts / need for additional information.</p> <p>Those who collaborated with the ECDC on EU disease days were satisfied with the partnership developed.</p> <p>There are questions as to whether the Communication Focal point network could be further invigorated, for example to ensure an increased focus on added value vis-à-vis what is available nationally.</p> <p>There is some confusion with regards to procedures / definitions relating to risk communication and crisis communication, which need to be addressed in the light of new legislation.</p>
<p>Conclusions and Recommendations</p>	
<p>The Centre has made progress on health / risk communications since 2008, which have increased the professionalization of the approach. There is now a strong communication capacity which has translated into high quality outputs. The website is a particular strength of the overall approach. Different target audiences have different needs and wants. To date the Centre's focus has been to provide a common level of support / information / resource to all. Inevitably this has led to very mixed views on specific communication outputs / activities. As a result the Centre's high quality outputs, which are not sufficiently tailored to what countries need only achieve an average rating (<i>Evidence strong, priority high</i>).</p> <p><i>Recommendation:</i> It is recommended to consider: a) a differentiated approach targeting specific materials /activities at subsets of countries with a more tailored outputs – this should increase levels of satisfaction In particular There is a feeling that ECDC outputs / activities overlap with what is available elsewhere. This raises questions about the need to define procedures to identify overlap/where to add value; reduce the overlap with national materials / reuse / adapt materials available in certain MS for use by others, thereby increasing the harmonisation role of the Centre; b) Articulating changes to key stakeholders to manage expectations. There is scope to increase awareness of the Centre as a source of data / reference for European Campaigns. An increased emphasis on joint branding of media action / information with national stakeholders would be supportive. There is also a growing demand for the centre to act as a lighthouse in the field of new communication tools and in the assessment of effectiveness of different approaches.</p>	

7. PARTNERSHIP

7.1 Overview

The country cooperation and institutional partnership function has had many locations within the ECDC organigram until becoming a staff office to the Director. It has also changed focus over time along its four main directions: 1) cooperation with MS, 2) with candidate and potential candidate Countries, 3) with European and International Organisations and 4) with third Countries. ECDC naturally has partnership and cooperation relationships with MS national Governments (including at a more formalized level with candidate and potential candidate countries), the European Commission, and - by means of *memoranda of understanding* (MoU) - with other European Agencies, with WHO and WHO/Europe and other global partners, such as CDC, Public Health Canada, China CDC, Israeli Public Health, etc. MoUs were to provide a general framework for collaboration without being too specific in order to allow for flexibility in implementation. Particularly, those for Countries outside of Europe (e.g. China or Canada) were purposefully worded in cautious and generic terms. In the 2007-2013 SMAP, it was originally envisaged that ECDC would also develop fully-fledged support and cooperation programmes on communicable diseases with each MS, but these never materialized. Letters of intent where a programme of further collaboration is formally agreed upon are being preliminarily drafted only as a follow-up of the IPA-funded ECDC assessment of compliance with the *EU acquis* on communicable diseases in candidate Countries¹¹⁶. Institutional relations with the MS have been mainly carried out by means of a programme of annual Country visits¹¹⁷. However, the total has covered a subset of MS so far. In particular, all the 'New' Member States (NMS), where the bulk of ECDC capacity building support has concentrated, have been visited at least once either for general support purposes or specifically on HIV, antimicrobial resistance, or TB.

At the *European level* relations with the Commission are managed by means of (bi)monthly coordination meetings at the senior management level, eventually resulting in exchanges of letters on specific issues. However, there are also other layers of interaction at both the mid-management and day-to-day operational level. By invitation, the ECDC Director regularly addresses the Parliament ENVI Committee to give updates and assessments on the epidemiological situation. He has also occasionally participated to the ministerial meetings of the Council. From time to time, ECDC experts have participated in the committees of civil servants that prepare the ministerial meetings. Bilateral agreements regulating procedural aspects for joint cooperation and exchange of information have then been signed with all the relevant European agencies bordering ECDC activities (in particular EMEA, EFSA, EMCDDA) but EHAC, for which an agreement is still pending also due to uncertainties as to the future governance of the executive agencies. In addition, in all these cases, as with the Commission, there are parallel interaction layers downstream the organization.

¹¹⁶ Since September 2011, all EU enlargement countries/ECDC IPA beneficiaries have officially nominated one national coordinator for all official relations with ECDC, usually through the ministries of health or other pertinent ministries. ECDC organized three workshops for all EU enlargement countries/ECDC IPA beneficiaries in 2011 (Croatia, Turkey, and the former Yugoslav Republic of Macedonia, Albania, Bosnia and Herzegovina, Serbia and the UN Administered Province of Kosovo). The first one focused on public health training needs within ECDC's mandate; the second on the systematic collaboration between ECDC and the countries; the third focused on health threats and the involvement of EU enlargement countries in epidemic intelligence. The majority of the activities supporting EU enlargement countries were implemented through extra budgetary dedicated IPA projects, in particular the IPA II 2009-2011 project and the IPA III project currently ongoing with a budget of some € 400,000.

¹¹⁷ In the period under consideration, a total nineteen Member States have been covered by Country visits, of which two (France and Poland) three times and seven (Bulgaria, Romania, Estonia, Portugal, Greece, Hungary and Latvia) twice. All the others were visited at least once with the exception of course of Sweden and of other eight Member States, notably the UK, Spain, Germany, Ireland, Luxembourg, Austria, Italy and Cyprus. An accession-related Country visit was made to Iceland.

As far as other *international organizations* are concerned, both the WHO Headquarters¹¹⁸ in Geneva and WHO/Europe represent key partners for the ECDC. An administrative agreement between ECDC and WHO/Europe was approved and signed in the margins of the trilateral ECDC, European Commission, WHO/Europe Senior Officials Meeting. This is articulated into further annual action plans. The agreement envisages the establishment of a Joint Coordination Group. At a technical level, there is an ongoing collaboration in the following priority areas: HIV, tuberculosis, influenza, antimicrobial resistance, preparedness and outbreak support. Joint activities in 2011 included HIV, TB and influenza surveillance for all 53 WHO European Region countries and the publication of surveillance reports. The ECDC has also signed cooperation agreements with the US CDC, China CDC, Public Health Canada and the Israeli public health agency, although in these cases relations have been mainly informally maintained at the operational level, including possible instances of detached staff to ECDC during the pandemics. No agreements have been signed with NGOs or foundations in the period under consideration. Also in this case, informal contacts have been maintained for instance with the HIV/AIDS Civil Society Forum and some scientific societies have been invited to take part to specific projects.

The *budget for cooperation and partnership* has heavily fluctuated over the period and often been subject to substantial reprogramming. Initial allocations were often cut by half and programmed expenditure has gyrated from € 600 mn in 2008 down to some € 100 mn in 2011 and 2012. Because of its mandate ECDC figures are much lower and hardly comparable with the over € 1 bn of EFSA that has a dedicated programme of research contracts for its partners, or with the over € 2.5 bn of EMCDDA that heavily finances its REITOX focal point network. In 2012, partnership accounted for some 3% of ECDC ordinary budget, including eight full time staff equivalents. Moreover some total € 700 mn were received over the period from parallel IPA financing under different projects. In spite of the several budgetary reallocations, the partnership function has been characterised by a very low disbursement of the funds committed (often to the tune of some 15-16% of the total, 0% during the year of the pandemic) and has therefore represented one of the major contributors to delays in budgetary execution. The funds allocated to country cooperation and partnership were centrally managed by the related function and never distributed along the ECDC matrix to the DPs or to other functions.

7.2 Main findings

7.2.1 Satisfaction with Overall Partnership

There are mixed views about the partnerships and collaborations in place that mostly depends on the informants' role and position. All the stakeholders interviewed at the MS and multinational level have expressed fair satisfaction with the partnership of their organisation with ECDC and the related operations, although it was often noted there is room for further improvement on specific matters. According to survey results the level of satisfaction with partnership is 'significant' for 43% of national stakeholders, and 'moderate' for another 40%. One particularly contentious issue was represented in the past by the ECDC practice of arbitrarily inviting to meetings, as MS representatives, experts coming from their roster of consultants, even if they were not appointed as such by the respective MS. However, with the recent introduction of the CCB the situation has reportedly improved, although cannot be considered as completely solved. In fact, specific instances

¹¹⁸ Relationships with the WHO headquarters are particularly relevant when it comes to the global early warning systems, including the sectoral rapid alert ones like salmonella.

would reportedly persist, also due to the difficulties in synchronizing rapidly evolving databases of experts.

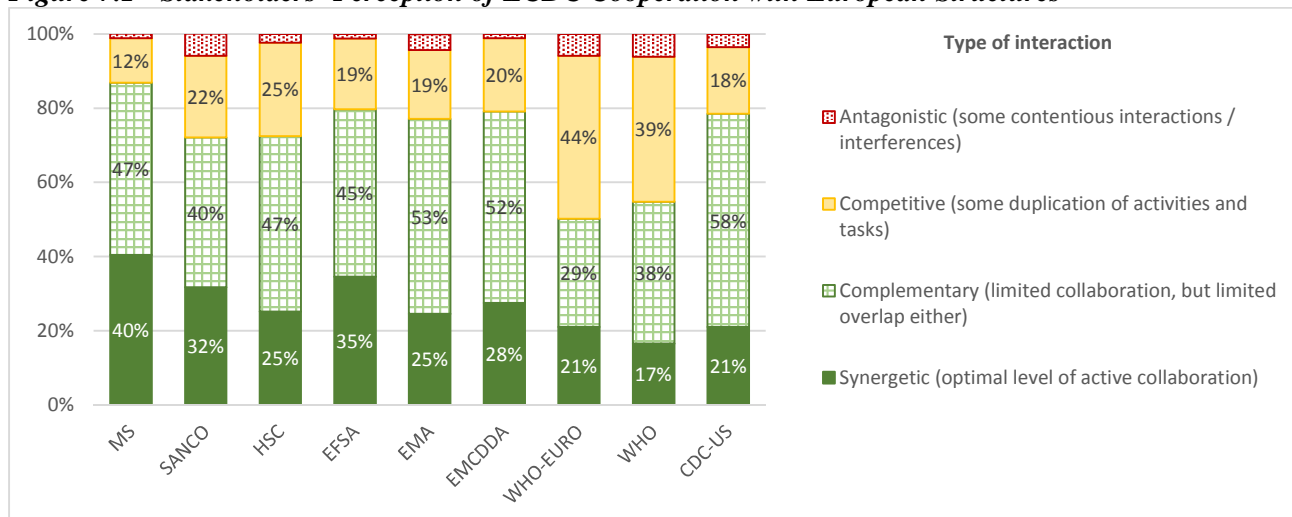
Most importantly, what appears by far as the most contentious issue is the perceived ECDC lack of knowledge of operational conditions, the different policy needs and the way surveillance systems concretely work at the MS level, which is only partly compensated by the knowledge acquired during the Country visits. In other words, on-the-field experience with MS conditions at the senior management level would hardly flow through to the more operational layers underneath and hinder a deeper mutual understanding. Finally, there is a subset of interviewees (mainly but not exclusively from new Member States) that - while showing appreciation for the added value brought by the Country visits in raising communicable diseases' importance in the Government's agenda - would like to see ECDC play an even stronger advocacy role, by agreeing more concrete initiatives and ensuring their follow up, to avoid that momentum is quickly lost.

Results from the survey show that cooperation between ECDC and other European Structures is generally considered by national stakeholders in worse terms than cooperation between ECDC and their own MS. All in all, synergies with European Structures are considered optimal by some one third of survey respondents or less, against 40% for synergies with MS structures (see Figure 7.1 below). This compares with some 20% to 25% of national stakeholders who tend to have a negative view of how cooperation works at the European level and mainly complain about ***duplication and overlapping of activities***, as the table below demonstrates. It is regretted by some that the endless issue of the distinction between risk assessment and risk management might characterize the collaboration between the Commission and ECDC as antagonistic for some 6% of stakeholders. It is perceived that there remains duplication of activities and tasks with all the European structures concerned, but in particular with the Health Security Committee (again on risk management issues, preparedness and support matters).

Cooperation with international organisation is qualified by national stakeholders in even worse terms than cooperation with European Structures and all in all considered as optimal by 'only' one fifth of survey respondents. This compares with some half of stakeholders or so, who tend to have a rather negative view of how cooperation between ECDC and WHO/Europe works and mainly complain, again, about duplication and overlapping of activities as the table below demonstrates.

Partnership with US CDC, China CDC, or Public Health Canada has been implemented only at the operational level or on specific projects where they have generally been appreciated. This explains why they are generally considered as complementary as the figure above shows. Actually, ECDC is reportedly considering discontinuation of the partnership agreement as such, as they currently appear redundant. Memoranda of Understanding drafted in generic terms can however be of use to partner organizations, mainly as legal frameworks for budgeting purposes or to justify expenses for missions and meetings.

Figure 7.1 - Stakeholders' Perception of ECDC Cooperation with European Structures



Note: 'don't know answers not displayed'. Total headcount (including agnostics)=448

7.2.2 Satisfaction with Communication

Information and communication flows are generally reported as very effective, smooth and professional at the operational and project level, but increasingly complex and cumbersome the higher the level of institutional involvement and procedural approval required and in more formal patterns of relation, which is also in line with the findings reported in the section on organization and management below. As far as institutional communication is concerned, ECDC staff is also reported as only limitedly aware of the complexities and fragmented competencies of the EU institutional framework, and of the need to involve or keep informed other relevant institutions in their institutional communication. They appear very focused on scientific and content issues only.

As outsiders, partner organizations also share the usual difficulties in understanding who is responsible for what within ECDC or who they should turn to eventually to discuss possible ideas for project cooperation. There is some evidence of widespread information flows channelled through networks of informal contacts that are also used to find one's way through the organization and identify who the right counterpart is for more complex and horizontal issues. This emphasis on informal personal communication at the expert level and a certain disconnection between different management layers also means that communication and information bottlenecks are suddenly experienced in more complex partnership relations. These happened, for instance, when procedures had to be found to allow cross-participation of experts to more formal cooperation venues, such as joint panels and the like, or to allow mutual access to databases or agreeing exchange of information. In a number of cases, these problems were tackled and eventually solved through *ad hoc* approaches and empirical troubleshooting, as they had not been anticipated in any framework for reference.

To this aim, it is particularly regretted by some stakeholders that a formal procedure to tackle disagreements between EU agencies at an early stage, before the matter escalates to a full crisis, has not been agreed yet and left to the informal interaction between responsible staff and other random factors. Much in the same vein, some would like to see again an annual venue where EU institutions and agencies can meet and talk about their work plans, possible common agendas and matters open for cooperation, a role that was reportedly played by the Commission in the past but then discontinued. Finally, the need for more formal communication and informational exchange procedures would have been only partly addressed and would remain there for certain issues. In

particular, there is a request from partners at all levels of being better informed about ECDC programming of activities as early as possible in the programming cycle, in order to make comments and avoid possible duplications or exploit synergies (see last paragraph of chapter 3 on scientific advice).

7.2.3 Clarity in Division of Labour

As could be easily imagined in the case of a newly established organization, unclear division of roles and responsibilities with other neighbouring institutions has stood out as one of the most contentious issues at the commencement of relations between ECDC and their partners at the European and International level. There were obvious concerns on how a newly established partner would behave in order to get recognition and visibility in the arena of public health institutions. Therefore, both instances of overlapping and overstepping into other institutions' mandates have been frequently reported, although it is generally acknowledged that the situation has certainly improved over time in many respects, as long as division of roles has become clearer and uncertainty on partner behaviour has diminished thanks to better mutual knowledge. Some regret that the complex puzzle of allocation of responsibilities between different EU agencies, in the light of the subsequent stratification of EU regulations over time, could be addressed on an empirical basis only through a learning process. Difficulties arose without a clear broader legal framework for reference to decide on overlapping missions, and the discussion often ended in assessing how "full" were the different mandates attributed in the various areas, and how, conversely agencies could claim only an indirect competence in the same area. This attains firstly to the division of responsibilities with EMA in the field of monitoring of vaccine effectiveness in both ordinary and emergency conditions, but also with EFSA on who should take the lead and how in joint investigations of outbreaks of foodborne diseases (see box 7.1 below).

Some interviewees have stated not to be entirely at ease with ECDC growing involvement in technical assistance activities for candidate and potential candidate Countries. They are afraid this could translate into ECDC losing focus on its core tasks, also in the light of the fact that WHO/Europe is usually taking the lead in the provision of technical assistance in the region and is unclear to them what role ECDC should play which does not ultimately overlap with what WHO/Europe already does, including overlapping of surveillance and related notifications. To put these comments into a better perspective, however, it is worth noting that the funds earmarked for enlargement have hardly exceeded 0.5% of total ECDC financing, and represented a maximum 1.5% of staff salaries. Therefore, even if precise figures on allocation of ECDC staff are not available, even in the worst of possible cases, these are unlikely to have exceeded a total 2-3 full time staff per year and have thus remained marginal overall, especially when compared to other agencies such as EMCDDA where they have a much larger weight. It is true, however, that procedural problems as to surveillance reporting in TESSy for candidate and potential candidate Countries and for WHO purposes have been experienced and had to be solved.

Other more specific instances of overlapping and unclear division of labour with WHO/Europe and other institutions have also been mentioned in the case studies, particularly when it comes to room for potential savings, as reported in the box 7.1 below. To this aim, some stakeholders have commented they would like to see more transparency and openness in dealing with the issue, possibly starting from a comprehensive and detailed baseline study on overlapping activities. Also, they would question the appropriateness of the current management model, based on triangular meetings and work-plans "agreed behind closed doors" without any MS involvement in defining a pathway for streamlining of activities and open discussions at the MB level. However, it is also acknowledged

that the signature of these agreements remains the executive role of the Director and they are brought before the MB in order to inform them on strategic issues, although not strictly within the MB's mandate.

Box 7.1 - Unclear Division of Labour with International or European Agencies - Evidence from the Case Studies

Influenza. Cooperation with WHO or lack thereof is by far the outstanding issue among stakeholders in the field of influenza. Although cooperation with WHO has improved - surveillance data are no longer sent twice and a joint annual surveillance meeting is organized - there still remains substantial duplication of activities. There are two parallel weekly bulletins, which to some appear as an inefficient way to communicate. The rationale behind having the two parallel laboratory networks in place is also controversial, as this poses problems with conflicting communication and leadership, particularly in emergency conditions. There are also small discrepancies in the use of indicators and the way data are presented between the two organizations that are potentially confusing for national users.

HIV-AIDS. A certain confusion on who does what was reported. The fact that ECDC is responsible for the Dublin Declaration and Commission Communication monitoring but not evaluation is a source of confusion, together with division of roles with WHO/Europe in the provision of technical assistance at the Country level.

Salmonella. Coordination with EFSA in trace-back investigations and common databases of data from human and animal sources are confirmed as operational preconditions of paramount importance to make the best value of investment in molecular surveillance and it is regretted that the importance of these enabling factors has been fully appreciated with some delay. For example, in the field of molecular typing the much-awaited issue of the joint database of human and animal data has required long discussions on access and management procedures before being solved, and appears only now close to finalization.

A still confused framework for reference, particularly when it comes to coordinating cross-country on-the-field investigations, is reported in the relationship between ECDC and DG SANCO, which represents a particular cause of concern for some MS.

Finally, and possibly most importantly to some interviewees, there appears to be some overlapping between what ECDC and EAHC contract out in terms of content areas without a clear understanding of who does what or of a clear rationale behind allocating project management responsibilities¹¹⁹.

7.2.4 ECDC Involvement in National or International Information Campaigns

It never appeared during this evaluation that specific arrangements were made for ECDC to specifically contribute to ***national campaigns***, but these eventually exploited materials made available by the Centre. Awareness of and active participation in ECDC information and communication initiatives at the national level is reported by slightly more than half of concerned respondents, preferably located in Eastern Europe and in the Mediterranean, while instances of total lack of awareness are mainly to be found among the Nordic Countries and in the Benelux. These spotty patterns of cooperation are considered as a moderately effective form of ECDC / Member State

¹¹⁹ For instance in the field of HIV In the period under consideration, EAHC funded, among others, the SIALON II project to build capacity to combine targeted prevention and HIV surveillance among MSM. Then while ECDC has supported a project which aims to improve HIV - TB surveillance by mapping co-infection and related surveillance systems and practices in Europe, a parallel project to improve access to HIV/TB testing for marginalized groups (IMPACT), was funded by EAHC with the aim of monitoring trends in HIV and TB infection among people who inject drugs, including migrant and IDU.

partnership by some half of the respondents who were actively involved in these activities and therefore have had a hands-on experience of it. The areas of particular interest where ECDC contribution has been particularly welcome are extremely skewed. In fact, in some 75% of cases, particularly well-received contributions make specific reference to antimicrobial resistance and antibiotic awareness, while influenza vaccination, hand washing or other items are much more sporadically reported. It is possible that this is also due to a cognitive bias for which more recent instances of use are more frequently recalled. It is worth noting that these figures are based on statements only and evidence of concrete use could be provided by respondents only in a very few cases.

Instances of ECDC direct and indirect involvement in *international information and communication campaigns* include both campaigns originated at the EU level and those sponsored by WHO. This encompasses in certain cases participation to the campaign board, although these are also often deemed as unexploited or only partially exploited opportunities. Examples include the World Health Day, European Antibiotic Awareness Day, the World Tuberculosis Day, the World AIDS Day, the European Immunization Week and the Flu Awareness Day. ECDC participation usually consists of publication of reports and materials on the promoted day, when relevant jointly with WHO/Europe, and to participation in the campaign sites as an institution or as individual experts. As matter of fact, MS tend to use ECDC communication materials as support tools to promote these initiatives at the national level, thereby achieving some kind of multiplier effect. It was sometimes regretted by stakeholders that the current level of ECDC involvement in these initiatives is insufficient and more should be done by international organizations to act in synergy, and also with the initiatives implemented at the national level. Some have also regretted that perceived concerns about institutional visibility issues between the different institutions involved have not allowed to exploit the full potential of these campaigns and the impact they could have had on the media to sensitize both the medical professional community and the public at large.

7.2.5 Evidence of Added Value

There is some preliminary evidence that partnerships, although sometimes difficult to implement in practice for the reasons mentioned above, could enhance the added value of ECDC deliverables in certain areas for the final users. For instance, some risk assessments made in cooperation with European agencies are considered by peers as examples of absolute best practice in the field, also because they broaden the range of issues considered and give insights on several aspects previously poorly considered from different perspectives.

There is also some evidence pointing to the fact that ECDC itself has learnt in the process of mutual cross-fertilization of experiences and adapted the routine content of their documents accordingly. In turn, also ECDC has provided epidemiological expertise and methodologies that have been deemed highly valuable by partners in broadening the views reflected in the document they produce and enhancing their perceived quality and added value. For instance, the use of ECDC-developed burden of disease methodology and software was reported.

Furthermore, country visits made in cooperation with WHO/Europe have enhanced in certain cases the added value for recipients, because they materialize in reports where improvement of the surveillance system is seen as a component of improvements in the underlying healthcare system

reform and the two aspects work in synergy. This improves political visibility and commitment to reform and can result in more effective, better structured and monitored reform processes¹²⁰.

There is more limited evidence of partnership with ECDC contributing to cost savings, as these are marginal, and instances of duplication in data gathering and limited harmonization of surveys remain. At any rate, cases of partner organizations reporting use of ECDC deliverables as a way to save on allocation of internal resources have been reported, particularly in the field of RRA.

In international partnerships established on a voluntary basis as they are, almost by definition, the added value received more than justifies the cost, although it is often acknowledged that efficiency considerations could further improve if instances of duplication or overlapping were further streamlined and simplified to the extent made possible by the existing regulations.

7.2.6 Evidence of Cooperation with European Structures, International Organizations and NGOs

According to outsiders, cooperation between the ECDC and DG SANCO has improved over time, particularly in the key field of early warning of health threats, where substantial improvements are reported as compared to the pre-pandemic operational framework. As to the family of European Agencies, ECDC has mainly cooperated with EFSA, EMA and EMCDDA respectively on 1) foodborne diseases, 2) influenza and vector-borne diseases, vaccines and antimicrobial resistance and 3) HIV/AIDS. This cooperation has usually resulted in joint reports and has become clearer and better structured over time. All in all cooperation is reported as successful and the main grey areas are represented by studies on vaccines and leadership in investigating outbreaks of foodborne diseases covered by separate EU Regulations and included under RAFFS.

ECDC is also an active member of the network of EU Agencies and participates in its sub-networks providing a platform to exchange information, best practices, to formulate positions on matters of common interest. There is evidence this has resulted, among others, in the adoption of standardized practices and fruitful contamination of experiences, so far mainly with reference to procedural issues and the need for SOPs, harmonized programming system, terminology issues in the delivery of scientific advice and conflict of interest policy.

ECDC has cooperated with WHO/Europe and WHO in several disease areas, including HIV, influenza and salmonella but, above all, in sharing intelligence on health threats, including EWRS messages and IHR notifications. In particular, a communication protocol has now been established, in which WHO/Europe provides feedback to ECDC within one hour from reception of a draft RRA to better allow coordination of information sharing. As mentioned above there is also some collaboration in the promotion of communication campaigns, although this is often deemed still insufficient.

¹²⁰ For instance, following a WHO and ECDC joint mission and related recommendations, in 2012 a national forum for partnerships in the field of tuberculosis was established in Hungary to implement the National TB Programme (NTP), while at the same time, the Ministry was preparing a new SMART action plan to scale up TB prevention with a vision to eliminate TB in Hungary. There is also a pilot initiative drafted in the new health system strategy of the Ministry that aims to launch a new policy coordinator mechanism to strengthen the policy management of the NTP. Surveillance was also modified as a result of the process and the mandatory chest X-ray (CXR) screening for the general population was canceled and resources switched to focus more on at-risk groups. At the same time, the national guideline for treatment of TB has been updated. It is generally believed that if the planned measures for the development of the NTP are successfully implemented, then the Hungarian NTP would appear as a model and a proxy for reforms in other sectors of the health system within the country with substantial improvement in surveillance.

There is broad consensus among interviewees that ECDC has managed to have a very balanced relationship with scientific societies NGOs and has not outstretched into relations with lobbying organizations or advocacy groups of more uncertain nature and financing

7.3 Conclusions and Recommendations

Evidence	Main Findings
<p>The Level of Satisfaction With Partnership</p> <ul style="list-style-type: none"> • 43% of survey respondents significantly satisfied with partnership at the national level and 40% more moderately so; • interviewees in International/European partner organizations generally happy with their collaboration with ECDC; • too limited first-hand knowledge of local conditions at the MS level reported as main constraint to enhance partnership at the national level. 	<p>Level of satisfaction with partnerships is mixed and varies also depending on the point of view of respondents. Stakeholders at the national level tend to be more critical of how cooperation works between ECDC and other European and International organisations and mainly complain about overlapping and duplication of activities</p>
<p>Communication with ECDC</p> <ul style="list-style-type: none"> • communication generally reported as good at the project level on operational issues, less so the higher the hierarchical level of interaction is and for organisational matters; • difficulties in identifying counterparts within ECDC often reported; • heavy reliance on informal communication also caused delayed development of procedures for more complex information flows. 	<p>Partnerships have often naturally evolved from informal contacts to more structured and formal relations. This is sometimes accompanied by more difficulties in communication flows and, above all, a certain lack of clarity in identifying counterparts within the Agency.</p>
<p>Cooperation and Mutual Understanding of Roles</p> <ul style="list-style-type: none"> • division of labour with other organisations long represented a sensitive subject in relationship with them, although attitude has been relaxing over time; • instances of overlapping and duplication still reported by national stakeholders as the main problem area in relations with other International and European organisations; • agreements with international organisations to streamline activities not fully transparent and participatory enough to stakeholders; • instances of conflicting instructions received by ECDC and DG SANCO on certain operational issues related to cross-border investigations sometimes reported as confusing; • perceived balanced relationship with scientific societies and NGOs. 	<p>Cooperation and mutual understanding of roles has increased over time also by means of better mutual knowledge. Steps have been undertaken to address areas of overlapping and clarify grey areas but the process is perceived as slow and not participative enough by the stakeholders concerned, who would like to have stronger say.</p>
<p>Contribution to Information Campaigns</p> <ul style="list-style-type: none"> • ECDC materials actively used by some 50% of respondents for their campaign communication purposes and deemed only moderately effective by some 50% of them. Use of campaign materials highly skewed in geographical terms and by subject matter. • ECDC materials often used in synergy with European campaigns. 	<p>Support to national information campaigns has been largely untargeted and has mainly concentrated in one subject area. There is an untapped potential in further exploiting synergies with European and International Campaign initiatives.</p>

<p>Added Value of Partnership</p> <ul style="list-style-type: none"> • partnership have sometimes increased the perceived quality of the output for the final users; • more limited evidence of partnership contributing to cost savings for ECDC and partners. 	<p>Although relations with international and European partner organisations tend to be at first of a competitive nature, when cooperation is established the added value of joint outputs for the final recipients can be enhanced.</p>
<p>Conclusions and Recommendations</p>	
<p>There is a clear need to strengthen the ECDC knowledge of local conditions at the MS level and promote closer interaction (<i>Evidence strong. Priority high</i>)</p> <p><i>Recommendation.</i> In the evaluator’s opinion this can include together with other more substantial recommendations made elsewhere in this report a review of patterns of staff participation to Country visits, mechanisms to allow staff to better share their knowledge about MS. Also internal repositories of MS systems, programmes and procedures could help in this respect. .</p> <p>Similarly to what reported in other parts of this evaluation report there is a compelling need to make ECDC an organisation more intelligible to outsiders. (<i>Evidence strong. Priority high</i>)</p> <p><i>Recommendation.</i> Experience elsewhere shows that this can be achieved through very simple means such as enhanced use of directories and better explanative organigrams. If dedicated webpages were built on projects or initiatives in the pipeline these should include as a rule references to responsible contact persons within the organisation. The practice of rotating staff responsible for the same project that was sometimes reported by interviewees as an inconvenience and a cause of disruption of activities should be minimised and kept monitored.</p> <p>In spite of past and current efforts there remains a need to further streamline operations with other International and European agencies and avoid duplication and overlapping of activities. (<i>Evidence medium. Priority medium</i>)</p> <p><i>Recommendation.</i> Coordination mechanisms are often in place but when they are not they should be established or resumed. Since most of the evidence available is based on subjective judgements and sometimes substantiated by past examples no longer applicable to the current situation or anecdotal in nature, it is difficult to discern to what extent this is substantial or depends also on poor communication. To this end ways should be found to make the process more participative and involve also stakeholders at the MS level in the dialogue on identifying need for streamlining activities and avoiding duplication of efforts between ECDC and other international organisations and contributing to propose related action plans outside of the usual hierarchical channels. For instance public consultations or restricted public consultations could be held on draft programmes of activities to allow for comments and make the process more participative, and progress reports published on the progress achieved to give a feedback and inform about developments.</p> <p>There would be still room for further improving and clarifying/formalising partnership procedures between ECDC and SANCO in selected areas to improve their intelligibility to outsiders (<i>Evidence anecdotal</i>).</p>	

8. ORGANISATIONAL, ADMINISTRATIVE AND LEGAL FRAMEWORK

8.1 Overview

In the period under evaluation ECDC still had to go through a part of its establishment phase. In particular, in the original plans, 2008-2010 was to build up the ECDC in terms of staffing and organisational functions. However, this was partly hindered by the H1N1 pandemic emergency, and the overall process was consequently delayed. As shown in Table 8.1 below, in the whole 2008-2010 period ECDC could never meet its budgetary targets for expenditure in personnel (Title 1 budgetary allocations) and had to transfer resources to other chapters of its budget. In particular, it had to substantially increase spending on ICT equipment (Title 2 allocations) and outsource scientific advice activities (Title 3 allocations). It is only with the 2011 exercise that the original recruiting programmes could be resumed and expenditure eventually aligned with provisions.

Table 8.1 - Original budgetary provisions and final revised ones in the 2008-2010 period (thousand euros).

	2008		Δ	2009		Δ	2010		Δ
	Original Budget	Final Revised		Original Budget	Final Revised		Original Budget	Final Revised	
TITLE 1	16,590	15,430	-1,160	22,625	20,560	-2,065	27,430	26,595	-835
TITLE2	6,060	5,725	-335	6,535	6,875	+340	6,735	6,735	0
TITLE 3	17,250	18,879	+1,629	19,940	21,819	+1879	23,735	24,489	+754
TOTAL OUTCOME	39,900	40,034	+134	49,100	49,254	+154	57,900	57,819	-81

In 2010 ECDC's *organization* was also restructured along a matrix dimension, organized with operational public health functions in a 'vertical' dimension and the disease programmes in a horizontal one. New units were also added¹²¹. Together with reallocation of staff to new positions, the organizational reform was also followed up by some notable turnover among staff, which appears on the high range when compared to similar European agencies, although possibly on a slightly declining trend. The table 8.2 below reports total staff and recruitment procedures in the period under consideration. If one considers that starting from 2010 data on selection procedures report only the number of newly hired staff – including internal procedures - but no longer include unsuccessful procedures, these figures provide a rough feeling of the extent of the phenomenon in both absolute and relative terms and of the related effort made in recruiting new staff.

¹²¹ The organizational structure of ECDC is now based on five units: 1) the Office of the Chief Scientist; 2) Surveillance and Response Support; 3) Public Health Capacity and Communication; 4) Resource Management and Coordination; 5) Information and Communication Technologies and seven disease programs: 1) Antimicrobial Resistance and Healthcare-associated Infections; 2) Emerging and Vector-borne Diseases; 3) Food- and Waterborne Diseases and Zoonoses; 4) STD including HIV and Blood-borne viruses; 5) Influenza and respiratory diseases; 6) Tuberculosis; 7) Vaccine-preventable Diseases. Administration is finally responsible for service provision, facilitating the operational activities of the Centre, ensuring that the human and financial resources are properly and efficiently managed. It also includes an internal communication function. Corporate Governance provides advice and support to Director, organizes and assists the meetings of the Management Board (MB) and the Advisory Forum (AF), including the weekly meetings of the Senior Management Team (SMT) and updates lists/communication with the Competent Bodies and partners' organizations.

Table 8.2 - ECDC staff and selection procedures 2008-2012

	2008	2009	2010	2011	2012
Total Staff	154	199	254	270	282
Selection Procedures	97	119	133	56	49

Source: ECDC Annual Reports.

Starting from 2010, a number of improvements were also undertaken to the *management processes and information systems*. Prioritization of activities done through annual work programmes linked to multi-annual strategic plan was refined and made more transparent through a scoring mechanism at the Advisory Forum level. Activity-based work plans were complemented by activity-based budgeting, although an activity-based reporting of the use of internal resources is not yet possible. Quality management was also introduced after 2010 to manage the internal quality system (a quality assessment exercise was carried out, highlighting the lack of a clear mission as the key problem area among staff), its information support, and monitors progress towards the achievement of the strategic multi-annual programme (SMAP) objectives, also by means of indicators. A Programme Management Information System was established to ensure that all ECDC Work programmes are directly linked from the strategic multi-annual programme down to operational activities.

In 2011, ECDC started to map its internal work processes across different units also with a view of harmonizing them by means of common procedures. This activity is still ongoing at the time of writing this report. Indicators were developed for the 2007-2013 SMAP first and the annual programmes then, but mainly for external reporting and accountability purposes. It is only in 2012 that an internal monthly dashboard has been developed to present an overview of budget execution and the level of implementation of ECDC Work Programme for each Unit and Disease Programme. Moreover, in 2013 ECDC started a reflection on systematic cascading of its missions and strategic objectives toward individual contributions and an objective assessment of job performance.

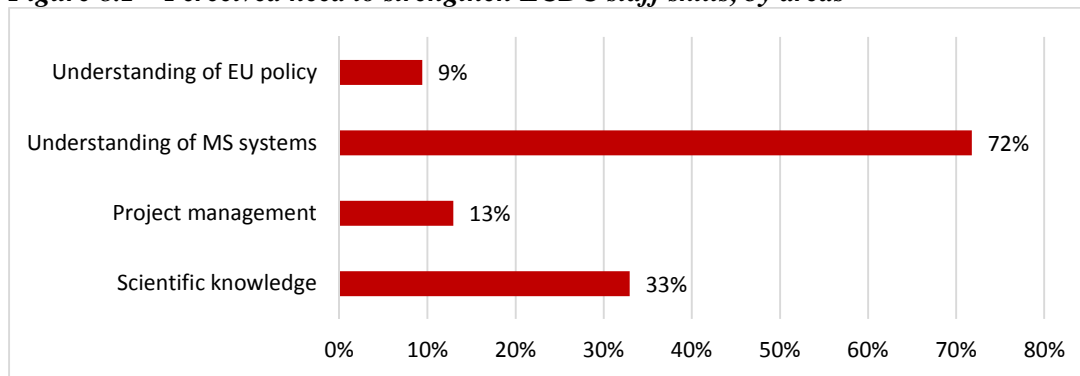
Although budgetary matters have been improving over time, as activities consolidated and became more routinary, over the period considered ECDC has always had difficulties in disbursing funds, up to the point that the high level of carryover, coupled with a low level of accrued expenditure (5,4 million euro), was even be found at odds with the sheer principle of annuality in the opinion of the European Court of Auditors (ECA). At the end of the period considered here, however, funds committed accounted for some 93-96% of budgeted resources, and expenditures averaged at some 76%, up from the 50-70% of previous years.

8.2 Main findings

8.2.1 Human Resources and Staff Skills

There is broad consensus that, in its core tasks, ECDC *staff skills* have been broadly adequate to coordinate activities effectively and to get, on average, good quality deliverables. Complaints mainly focus on an insufficient understanding of MS healthcare systems and related surveillance features (Figure 8.1). Nevertheless, as better reported in Box 8.1 below, as far as the disease programmes are concerned, a certain bias towards epidemiological skills vis-à-vis other kinds of expertise is reported. In fact, some one-third of survey respondents think that ECDC staff skills should be strengthened in terms of scientific expertise available.

Figure 8.1 – Perceived need to strengthen ECDC staff skills, by areas



Note: Headcount=85

It is generally recognized that Stockholm as a location for ECDC has caused a number of problems in attracting and maintaining the best available expertise in Europe, but this is no longer considered as a key issue. By far, the most important problem reported by interviewees and confirmed by the survey results concerns the composition of the ECDC staff. Because of high staff turnover and the general EU policy of recurring to temporary agents, ECDC job positions are filled with too many relatively young and therefore inexperienced scientists that are only partly balanced by a few seasoned top staff, familiar with concrete policymaking and with an in depth understanding of how the different MS public health systems work. A certain shortage of mid-management positions is also noted together with the need to strengthen line management skills among them.

This excessive reliance on junior staff would cause a number of unfavorable side-effects. On the one hand, ECDC reputation would depend on the standing of a few key senior staff and this would slow down the process of building the credibility of the ECDC as an institution. On the other hand – and most importantly - there would be far too little staff familiar with the concrete working environment of the different MS, their priorities and ways of proceeding (including first and foremost the practical difficulties in data gathering related to the different features of the healthcare systems). Furthermore, there would be an overall too limited awareness of the different MS priorities. While the problem is not generally acknowledged by respondents at the MS level, stakeholders more familiar with the functioning of EU institutions also report a certain lack of understanding about the Centre’s position and peculiar mandate in terms of EU dynamics, as well as a limited first-hand knowledge of how to interact with the complex EU institutional machinery. These limitations would become more evident in times of crisis or on contentious issues, when scientific skills have to be complemented by deeper knowledge of on-the-field conditions in the different MS to produce valuable advice.

Secondly, some note that these relatively junior staff have been required *de facto* to do little scientific work on their own, which further contributes to the problem of recognition above. They have been mainly to manage outsourced contracts and do that kind of administrative work that administrative assistants should do, without having the background and skills required and without receiving adequate training and preparation for that. It is only after the comments of the ECA on some administrative mistakes made in managing contracts and a few major cases of underestimated contractor’s failure to perform that ECDC has reportedly started a training of trainers programme to tackle these aspects. However, this solution only partly addresses the structural unbalances above – because a mid-management staff is perceived as somehow missing at any rate. Moreover, training can do little in terms of a more fundamental misalignment of incentives, as the long-term career prospects of the scientific staff employed on a temporary basis by ECDC will continue to depend on their publications and scientific credentials rather than on their grasping of the MS policymaking context or administrative details.

Box.8.1 - Adequacy of ECDC Human Resources and Staff Skills. Evidence from the Case Studies

Influenza. ECDC management of the influenza DP has been generally considered highly professional and extremely competent on the subject matter, with a clear focus on scientific arguments rather than speculative approaches or authoritative opinions. Since activities are proposed at the task-group level and strongly prioritized on technological grounds, it is only with the delayed hiring of a microbiologist/virologist among the DP staff that – according to some interviewees - the full set of required skills could be deemed fully covered. In this respect, limited interaction with the microbiology unit is also reported. Needless to say, those more keen on strengthening behavioral aspects, particularly in the Mediterranean, would like to see a stronger expertise available in those areas, or at least stronger cooperation and interaction with the ECDC communication unit. In Eastern Europe, it is regretted a certain neglect of the cost analysis dimension among staff.

HIV. The management of the HIV programme has experienced staff turnover but it has nevertheless ensured all over the period a good coverage of epidemiological and policy analysis aspects. Other areas, such as virological resistance or modelling, would have remained comparatively weaker and too reliant on external contractors, which could represent – according to some – a potential reputational problem in the long run because, when the quality of subcontracted work is lower than anticipated as sometimes reportedly happened in the past, ECDC standing would suffer.

Salmonella. The DP is reported as professionally managed, although stronger in epidemiological aspects than in microbiological ones. This is bound to become a growing gap as the technical complexity of molecular surveillance is projected to increase dramatically in the next few years. The level of integration and cooperation with the Communication Unit is considered as an example of best practice within the ECDC. Conversely, it is also noted a certain lack of interaction with the microbiology unit, whose role is not always clear to participants. High staff turnover is also reported by some stakeholders as an impediment to develop an in-depth understanding of the technicalities of the subject matter. Conversely, some stakeholders from Eastern Europe complain about excessive specialisation for the sake of technical specialisation and neglect of the cost and policy analysis dimension among staff.

In terms of ***allocation of staff***, some stakeholders have reported the impression that scientific activities are relatively underrepresented as compared to other functions and administrative tasks in particular. This impression is only partly confirmed by available figures and it would deserve at any rate some important qualifications. According to the breakdown of staff by task available for 2012, ECDC staff devoted to scientific activities are some 50% of the total, which is on the lower range of similar European agencies but broadly in line, for instance, with EMCDDA levels. The main difference between the two agencies is that EMCDDA carries out the bulk of its scientific advice activity in-house, while ECDC makes extensive recourse to subcontracting.

It is certainly true that the share of ECDC staff devoted to administrative tasks (26%) is well above the average of other broadly comparable European agencies. However, this is because administration at the ECDC also includes a number of management tasks (quality management, publications, etc.) that in other European agencies are generally attributed to governance units directly attached to the Director office. In fact, ECDC staff allocated to governance functions (9%) appears below average so that these two opposite unbalances in a way tend to compensate each other. So, it cannot be said that the level of administrative staff - broadly speaking - is higher than in other similar European agencies, but rather that it is distributed differently between the staff to the Director and the line units. Furthermore, the resource and management units tend to be comparatively overburdened with an unusual and fairly peculiar number of different tasks and responsibilities going well beyond traditional administration.

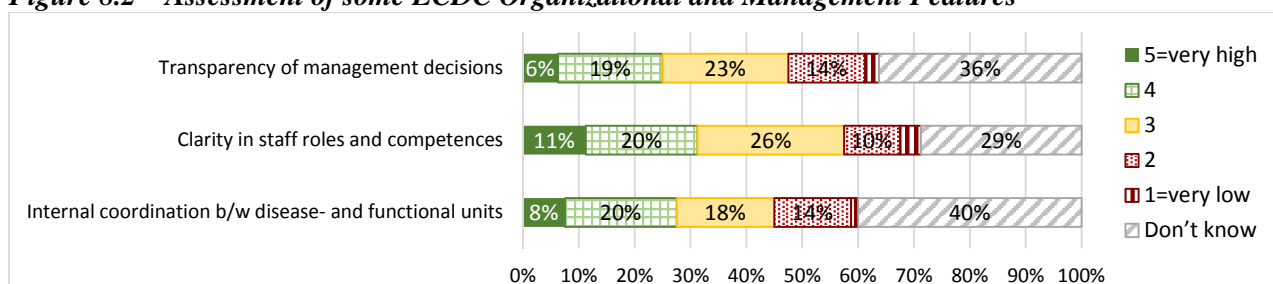
What is certainly true is that the amount of ECDC staff devoted to communication activities (14%) is on the high range and well above the average of other similar European agencies. This results as extremely controversial to those who have strong *a priori* reservations on the relevance and added

value of ECDC communication activities or tend to be critical of ECDC involvement in risk communication interfering with MS responsibilities.

8.2.2 Overall Processes and Management Systems

An operational restructuring along a *matrix model* to achieve more flexibility in the use of pooled resources and be able to reallocate them where needs are at very short notice is not a unique development among European agencies. On the contrary, it appears a fairly standard response whenever work conditions are subject to particularly stringent operational constraints¹²². So, it is little surprise that also ECDC decided to move in that direction, presumably also after the first-hand experience gained with the H1N1 pandemics of the serious limitations, in terms of staff rigidity, of the previous organizational model. In some respects, from the Centre’s point of view this can be considered an almost necessitated move for which there were little available alternative options. It is therefore little surprise that the organizational reform, though extremely controversial to some outsiders, is strongly supported by ECDC senior management staff. What makes the ECDC case peculiar is the unintended consequences this has had in terms of the prevailing management culture and systems within the organization and the cascade effects this has had on external stakeholders, and the satisfaction of the internal staff with the working environment. To outsiders, the organizational restructuring and the way activities are now managed have turned ECDC into a kind of black box rather difficult to understand – unless of course ECDC staff insider knowledge is available - in terms of who does what, the concrete contributions to the different activities and the way these are organized and financed and decision making is managed¹²³. In the survey this is also captured by the very high number of respondents who claim to have an insufficient knowledge of the subject (Figure 8.2). As a result of this, just some one-third of survey respondents rate as good or excellent the clarity in the definition of roles and competences of staff or the internal coordination between the vertical and the horizontal units within the matrix organization. Furthermore, as low as one-fourth of them are fully satisfied with transparency in decision making, while in some 15% of cases, even voice their open dissatisfaction.

Figure 8.2 – Assessment of some ECDC Organizational and Management Features



Note: Headcount=80

Consequences of the organizational restructuring on the management of internal staff have been heavier because, within ECDC, two management cultures would have in theory to coexist. One management culture is functional to remain constantly alert to manage potential threats, to react

¹²² For instance, also EFSA moved towards a kind of matrix structure of some of its units when faced with mandatory deadlines for releasing authorization opinions. Since these tended to have a poorly predictable inflow in the different areas of activities a mechanism was needed to ensure reallocation of staff from one area to another at very short notice.

¹²³ A number of interviewees, also outside Europe, mentioned this and also this evaluation team had to spend considerable time in Stockholm just to understand how activities are organized and divided across the various units as this was not apparent at all from the organizational matrix.

extremely fast¹²⁴ (RRA have to be delivered within 48 hours from request as a default rule), operates within the permanent context of a “war room” and is therefore necessarily prone to management by exceptions. It has therefore to be fairly hierarchical and vertical in its communication to ensure that circulation of information is restricted only to concerned staff and reaction time is as quick as possible. The other management culture would require patient consensus-building to manage the open method of coordination in the field of communicable diseases through participative horizontal approaches and detailed scientific discussion. With a matrix structure, an organizational culture tends to prevail over the other and this inevitably creates tensions into the system. Unsurprisingly, whenever there are attempts at harmonizing procedures this reportedly faces internal resistances and requests for exceptions. Since there is overwhelming consensus among the stakeholders and the MS consulted that the core mission of ECDC lies in its rapid reaction to threats, while all other activities are more controversial especially in terms of added value to different subsets of stakeholders, then it is the first inevitably prevailing.

This can also be seen in survey results: as high as 50% of survey respondents agree in rating as good or excellent the adequacy of current management practices in ensuring rapidity in response and a speedy follow-up of stakeholders’ enquiries, which appears by far the area with the highest degree of consensus among stakeholders as far as management is concerned. Only 6% of respondents voice some form of open dissatisfaction in this respect.

This creates the paradoxical situation in which the management practices (centralization of decision making, vertical communication, management by exception and limited implementation of routine procedures) that make the organization so successful in its core tasks, providing the bulk of its perceived added value, are the same that contribute to staff dissatisfaction. And, together with other important factors (contractual arrangements, anticipated reduction in staff, location in Sweden), they also contribute to high staff turnover. ECDC management seems aware of this conundrum and has taken some steps to try to tackle it, but the process is still ongoing and it cannot be said that the conflict has been solved yet.

All in all, this confirms the comments made by some stakeholders that, until recently, daily management of activities was left to the goodwill of the staff and the initiatives of the different individuals. ECDC as such had only a very limited number of real procedures to speak of, compliance with which could be eventually crosschecked by outsiders and those that were in place had difficulties being implemented due to the conflictual requirements of the different units. The DPs, for instance, still reportedly maintain different management styles and practices, which can further be used as an indicator of limited harmonization and cross-fertilization of experiences.

8.2.3 Prioritization Mechanisms

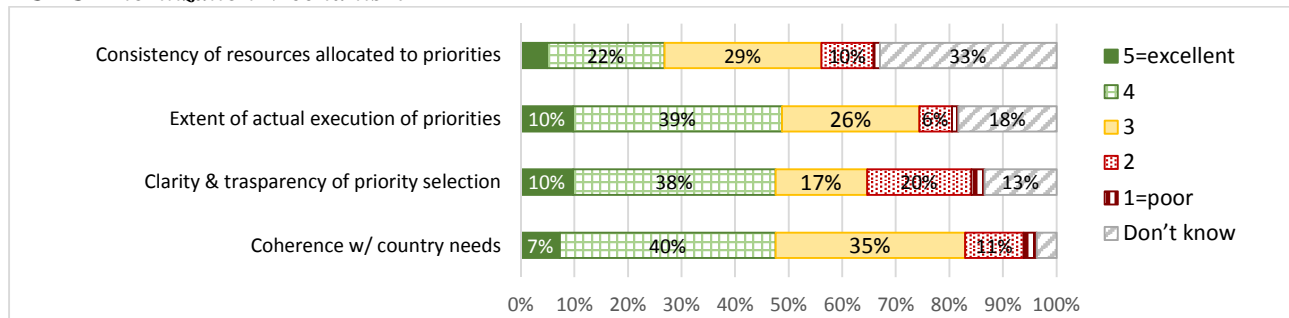
Prioritization and activity planning mechanisms are reported as considerably improved in their clarity and transparency at the end of the evaluation period, particularly after the pilot introduction of the scoring software to rank priorities in the field of scientific advice that would eventually materialize into the IRIS project¹²⁵. However, lack of transparency in prioritization criteria remains the main

¹²⁴ For instance, at the time of the E. Coli emergency it was decided to establish a network of clinicians to exchange information on effective therapies and ECDC could mobilize the relevant expertise at a very short notice.

¹²⁵ The IRIS software was born in 2011 as a pilot prioritization tool for five projects of evidence-based guidelines with a view to extend it after the necessary refinements in a second phase to the entire WP, which would happen only in 2013 therefore outside the period covered by this exercise. Some note the fact that the AF is given in the current interpretation of the ECDC regulation such a typical management role remains an absolute oddity in the broader field of the governance

cause of concern for over 20% of survey respondents, as better reported in the Figure 8.3 below. As can be seen, this is paralleled by a very high number of respondents (one third of the total also evenly distributed among the various MS) who do not feel sufficiently informed to judge on the consistency of this prioritization with the underlying budgetary mechanism of allocating funds or are neutral about the subject. Nevertheless, it is widely acknowledged that the mechanism is broadly coherent and actually followed-up by the concrete implementation of the priorities identified. This is also confirmed by evidence from the IRIS system. Some 90% of three highest-ranking topics highlighted in each area in the IRIS 2011 exercise were actually included in WP 2012.

Figure 8.3 - Degree of Satisfaction among Survey Respondents for the Following Quality Features of the ECDC Prioritization Mechanism



Note: Headcount=82

This confirms the results of the interviews, reporting that the main shortcomings of the current mechanism are to be found upwards and downwards of IRIS. The process underlying the selection of general scientific advice priorities proposed for scoring remains somehow obscure and poorly transparent to the process participants, as well as that of the priorities identified at the DP level. Little information on the filtering of grassroots proposals is available, as well as on their level of outreach among participants. Then the scoring mechanisms relate to the selection of the scientific subject areas only, and there is little transparent link with the underlying allocation of budgetary resources that is decided at the MB level. The criteria according to which the AF ranks priorities remain entirely subjective (although presumably related to their perception of national needs as also the survey broadly confirms) and are not known to those who then have to vote on the budget. Some stakeholders would like to see a link also to more objective criteria, such as the existence of an underlying EU strategy, the burden of the disease, its economic impact, etc.

Secondly, the process remains misaligned with the parallel programming of Commission activities that takes place at least six months later. So, the stakeholders involved have only a very preliminary idea of what EU work priorities will be two years after. This is a cause of uncertainties and last minute changes, that are not always clear and transparent to process participants, as the founding regulation explicitly requires that the Centre shall consult the Commission with regard to the planning and priority setting of research and public health studies. It is worth noting that this need for flexibility is also an explicit request from many stakeholders at the MS level, who give much more importance to the fact that ECDC short-term programming of activities should remain very flexible to cope with unexpected needs than to any detailed content of medium or long-term activities.

of European Agencies, but the IRIS mechanism per se is appreciated and even reportedly considered for replication (although at the MB and not AF level) by other European Agencies.

8.2.4 Monitoring and Feedback Mechanisms

The emphasis on short-termism and flexibility noted above, as well as the importance attached to specific projects or issues has notably decreased the level of interest in indicators among stakeholders. The 2007-2013 SMAP had a set of indicators, sometimes extremely theoretical and impact related (e.g. influenza vaccination rates), and not all of them have been regularly collected or quantified over time. The level of progress in their achievement was only sporadically presented to the MB, and hardly entered among the issues debated there. The sectorial strategies of the different units were also often drafted without any indicator at all to allow monitoring of progress towards the achievement of objectives. In spite of the weaknesses above, this has hardly represented a cause of concern and the majority of informants surveyed appears satisfied with the information available from the monitoring and reporting systems (51% of 'high' or 'very high' level of satisfaction). Only some stakeholders specifically complained about the total lack of indicators on the degree of progress achieved in microbiological laboratory surveillance.

It is only as late as 2012 that these SMAP indicators were complemented by a new separate set of (mainly output) indicators for annual programme reporting purposes. These indicators have also started being used internally by staff as a *tableau de bord* for the management of their activities, which is a clue that the management by indicator culture is gaining ground within ECDC. However, it is only after a certain pressure exerted from outside¹²⁶ to align ECDC practices with broader EU governance requirements, that a new set of strategic indicators has been proposed for the next SMAP. Still, the importance and the significance of the subject remain poorly understood by stakeholders who are to a large extent unaccustomed to management by indicators techniques.

In the period considered here, the ECDC has put in place very limited feedback mechanisms to elicit the degree of satisfaction of the stakeholders with its activities, or their perceived quality and impact; anyway, a small pilot exercise has been carried out on a limited number of scientific advice outputs in cooperation with the AF and the Scientific Advice NFP. However, differently from the first list of SMAP indicators, the newly proposed set of indicators for the next programming period¹²⁷ also include feedback mechanisms (see Table 8.3 below), such as degree of stakeholder satisfaction level, in line with what is being implemented also in other European agencies. Furthermore, a regular stakeholder satisfaction survey is already reportedly in the pipeline, starting from 2015 and it is already envisaged that an action plan will be submitted annually to the Management Board to address and improve areas where performance is not considered satisfactory. The main feedback mechanisms in place so far have related to internal staff satisfaction surveys that have been repeated twice during the period and whose results and their unclear interpretation have represented a cause of concern for several stakeholders. It is worth noting that similar exercises were implemented also in other European agencies over the same period, with broadly comparable results in terms of trends and similar difficulties in extrapolating significance.

The new set of indicators will in particular feed into the existing quality management system and the internal evaluation process to be launched in 2014. It will also contribute to the internal evaluation of ECDC's activities and outputs or the improvement/reengineering of the Centre's internal work

¹²⁶ This was also made necessary as from 2016, following the new EU Financial Framework Regulation, both multi - annual and annual work programmes should be integrated in a single programming document, which should be revised yearly. Therefore the indicators of the work programme will continue to be reported annually to the Management Board, as part of the annual report, but also with a more long term perspective showing how the MAP is implemented over the longer period.

¹²⁷ It is already foreseen that if necessary, adaptations will be made to the list of indicators, while keeping overall a sufficient level of stability, to ensure comparability of the measurements over the 7 year period.

processes, as be used as a basis for discussion by the Quality Management Steering Committee and the Senior Management Team in order to improve the efficacy of the Centre.

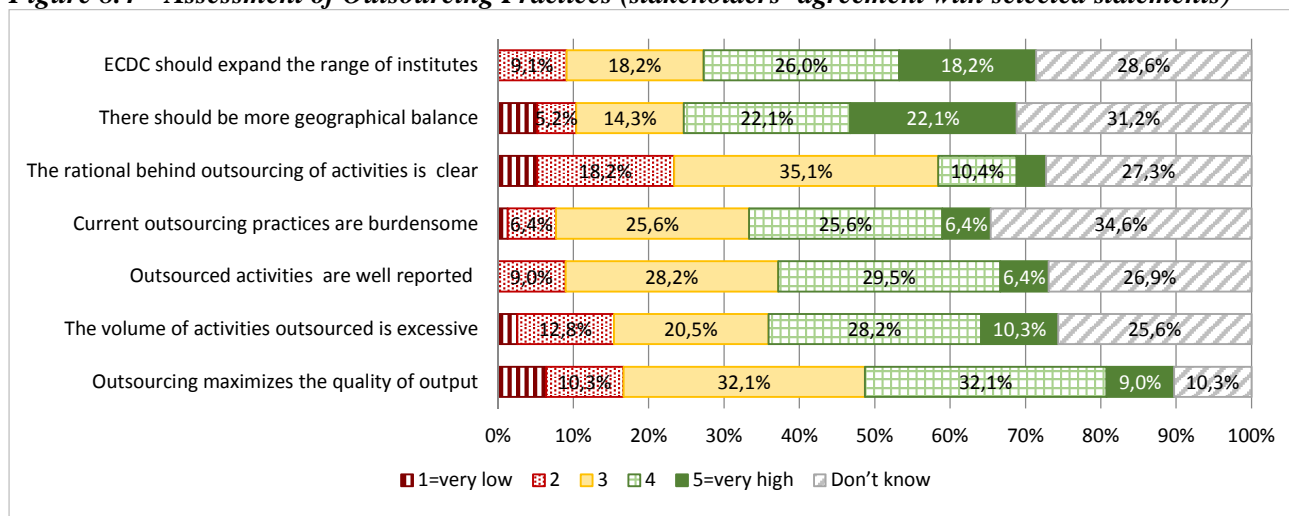
Table 8.3 - List of indicators to be measured through the annual stakeholder survey

Area	Objective	Indicator	Target
Collaboration and Cooperation	Achievement of a high level of effective communication and coordination between ECDC and its Competent Bodies	Satisfaction of the Coordinating Competent Bodies on the communication with ECDC	80 % satisfied with communication and coordination
Surveillance	High level of user friendliness and quality of uploading surveillance data	Level of positive feedback from the Member States using machine to machine to upload TESSy data	80% users satisfied
	Interactive outputs available for all diseases under surveillance	Satisfaction with functionality	80%
Epidemic intelligence and Response	Provision of relevant, timely and quality rapid risk assessment to support the risk management carried out by the Member States and the Commission	Proportion of rapid risk assessment assessed positively by Member States through the annual stakeholder survey	80 % yearly satisfaction of respondents
Scientific Advice	High level of timely and adequate response to requests for scientific opinions by providing authoritative and reliable evidence-based scientific opinions and guidance to Member States, Commission and Parliament	Use of evidence-based opinions and guidance produced by ECDC	80 % of opinions and guidance by 2020
Health Communication	Publication of topical online information within ECDC's remit through the web portal and social media channels	Usage of the ECDC web portal and social media channels [Measure on quality will be in annual stakeholder survey]	No

8.2.5 Pros and Cons of the Current Outsourcing Practices

From the ECDC point of view, outsourcing acts as an obvious multiplier of activities and allows access to external expertise but always implies a risk as to the timeliness and quality of deliverables. Instances were reported where perceived quality of ECDC outputs has been heavily influenced by how contractors did their job and procurement procedures managed and implemented. Among similar European agencies, ECDC has one of the highest amounts of budgetary resources devoted to outsourcing activities (18% of the total budget in 2012). ECDC heavy reliance on outsourcing, while to some extent certainly a remnant of the previous DSN system, leaves limited room of maneuver to build expertise in-house. There are in place little clear rules behind the decision to outsource first, and to distinguish the rationale behind outsourcing on a pilot basis when entering new fields and entering PHP-type “network based” projects then. At present the decision to outsource or not often seems to be triggered mainly by the origin of the request for ECDC intervention. If it follows a mandate usually issued by the Commission, it ends being dealt with as a rapid or an ordinary risk assessment, and therefore mainly implemented with recourse to in-house resources. Projects originated through the DP and SA pathways – the so-called self-mandated initiatives - are far more likely not to say almost routinely implemented as subcontracted activities, with ECDC supervision and contribution to authorship in finalization of results. Survey results, as reported in Figure 8.4 below, confirm that stakeholders generally believe that the volume of ECDC activities outsourced is excessive and some core competences should be kept in house. Moreover, only a minority of respondents find the rationale behind outsourcing always clear and transparent, while the results achieved through outsourcing are often found as adequately reported, but by a minority of respondents usually located in the Mediterranean or in Eastern Europe.

Figure 8.4 – Assessment of Outsourcing Practices (stakeholders’ agreement with selected statements)



Note: Headcount=77

In particular, ECDC would enter into far too many subcontracting activities also for relatively small things (the average contract was worth some € 80,000 in 2012). The result is poor focus and a number of deliverables difficult for stakeholders themselves to follow, particularly in certain areas (see HIV/AIDS case study in the Box 8.2 below). Since activities are managed as service contracts, the benefits of supporting networks do not necessarily materialize, but even tend to backfire on good intentions. In this new scenario, outsourcing somehow interferes with networking, because the current contractual mechanism is poorly conducive to inclusiveness and small and medium MS have difficulties in applying and in getting recognition for their work from contractors and are underrepresented. A need to rebalance outsourcing in geographical terms clearly emerges from the survey as the figures above demonstrate.

The transition from the DSN to ECDC has resulted in conflicting roles for network members. On the one hand, there are expectations from several sides they should contribute in detail to the programming of activities; on the other hand, they are put in a position to have somehow privileged information on the content of future tenders and, eventually, steer their chances accordingly. This would subtly interfere with the perceived fairness of the process, because mistrust and a climate of suspicion is created among network members themselves. It is totally irrelevant whether these suspicions are substantiated by hard facts or not, as the damage already lies in the sheer fact they are there. Also, access to a more diversified range of expertise would reportedly be hindered in the process. Eligibility criteria appear to some stakeholders as so stringent and financially demanding that the institutions awarded are very few and always more or less the same ones, and they obviously rely on their networks of experts. The result, however, is that the range of expertise involved is insufficiently diversified and this negatively impacts on the comprehension of the overall European context. Therefore, the current outsourcing practices make it difficult to ECDC to have access to the best expertise available whenever the top experts in a given field on a given subject are located in peripheral countries or at any rate outside of the usual consulting circle. The result is an overwhelming perception (44% of respondents and over 60% of responses, if the ‘don’t know’ answers are not considered) that the range of contractors involved into ECDC activities is too narrow and has to be somehow broadened.

Box 8.2 - Pros and Cons of Outsourcing. Evidence from the Case Studies

Influenza. This heavy reliance on outsourcing activities to external parallel networks, at least according to some interviewees, bears the potential risk that ECDC reputation and standing – including in visibility terms - is misunderstood for that of the networks it has funded. The sustainability of outsourced activities would also be more uncertain. From the point of view of the public health institutes involved as outsourced contractors, the joint authorship of related reports and the ECDC publication policy appear as rather controversial and potentially contentious issues. A substantial share of resources attributed to the DP have been devoted to ERLI-net funding and therefore steered by the related task groups¹²⁸. This has created a situation in most regards not too dissimilar from that of the previous grant scheme. However, contractors are now in a *de facto* privileged position vis-à-vis other network members, as regards access to information and materials (reagents and the like), which is perceived as somewhat unbalanced and not totally fair by some interviewees who would prefer that all members would be treated on equal grounds.

HIV. At present, it is noted that there are no clear procedures to decide what core functions should never be outsourced but should be left in-house; also, the work programme is fractioned in a number of projects still implying too many meetings, even if their number has been drastically cut of recent. From the point of view of beneficiaries, current outsourcing practices would create barriers to the smaller organizations that cannot cope with the administrative and financial requirements. Also in the case of HIV, ECDC publication policy appears controversial and complaints are voiced that ECDC does not adequately recognize and give scientific visibility to the role of data providers at the Member states level in a way similar to what the VENICE project, for instance, does with their data gatekeepers. Finally, and possibly most importantly to some interviewees, there appears to be some overlapping between what ECDC and EAHC contract out in terms of content areas in the field of HIV, without a clear understanding of who does what or of a clear rationale behind allocating project management responsibilities.

Salmonella. Reliance on outsourcing would require a command of procurement rules and related understanding of possible room of maneuver in implementation that is not always to be found among staff. Outsourcing would also pose problems with sustainability of activities and a limited capacity to react quickly to unforeseen circumstances. For instance, the unified platform for molecular surveillance was very slow at the beginning, and this caused considerable frustration; it took a lot of time and effort to make it more fast and user-friendly.

8.2.5 Impact of Organization and Administrative Framework on Operational Efficiency

It is generally difficult for stakeholders to comment on efficiency of operations and the impact of organizational and administrative factors on it. As high as 40% of survey respondents claimed they are not sufficiently informed to judge on the overall cost-effectiveness of the organizational machinery and the majority remains neutral on the subject. This is also partly a by-product of more general difficulties in understanding how the organization works and reading the related budgetary allocations in the annual work plan (which however have been available only since 2011).

Some more specific features are better known and understood. An effort, for instance, is acknowledged in reducing the number of meetings by means of teleconferences. Meetings were more than halved down to some 150 at the end of the period and there is broad consensus that this is the way ahead and the process can be pushed even further¹²⁹. However, for some reasons, this has not

¹²⁸ There are four task groups: 1) virus characterization (TG1) advising on antigenic characterization of influenza viruses and developments in serological techniques. 2) molecular diagnosis and sequencing (TG2) steering activities on molecular diagnosis and characterization of influenza virus strains 3) antiviral susceptibility (TG3) which also provides training and supporting documentation on antiviral susceptibility testing techniques and finally 4) quality and training that used to be responsible for the organization of EQA panels and training activities before these responsibilities were transferred to ERLI-Net contractors and now produce guidance materials and publish the EQA results.

¹²⁹ It is noted that work is also organized by means of meetings on grouping countries on a broad geographical basis. This is considered a suboptimal way of proceeding and a further indicator of ECDC difficulties in understanding the different national priorities. If more emphasis were given to national priorities in grouping Countries participation to meetings would increase in both quantitative and qualitative terms as better informed and more specific experts would take part

resulted in a parallel decrease of budgetary allocations over the period that have remained stable at around € 2 Mn after a sudden drop to €1,6 Mn in the 2009 budget, but just in a reduction in disbursements not always proportionate to the reduction in the number of meetings.

Operationally speaking, the main visible weakness that has not been really addressed yet is the decision-making bottleneck created at the top management level. Operations are often described as exceedingly centralized, and as the agency has grown in size, this has resulted in increasingly time-consuming and burdensome processes. Even the simple organization of meetings is reported as a very complex authorization procedure, requiring several different steps for approval. This would result in a very slow reaction time for the organization of even simple events and the problems would be very poorly highlighted and monitored by existing performance indicators.

Finally, it is noted that, as long as the disease programmes are no longer structured by typology of disease only (respiratory diseases, foodborne disease), but proliferate also according to a policy dimension (vaccine-preventable, health-care related infections and so on), adequate operational mechanisms seem to be missing to cover overlapping areas or shared responsibilities, which could appear a bit of a paradox in a matrix organization, but is part of the broader tendency to manage communication vertically. This would ensure proper information sharing and a joint approach to mandates of a horizontal nature.

8.3 Conclusions and Recommendations

Evidence	Main Findings
<p>Overall Appreciation of ECDC Management Procedures</p> <ul style="list-style-type: none"> • Widespread uncertainties are reported among stakeholders about division of labor at ECDC, related allocation of responsibilities among staff and related coordination mechanisms; • Decision-making processes not always transparent to outsiders and staff; • Improvements recently made and others in the pipeline to management processes and procedures, but related compliance checking mechanisms still to be developed; • Delays in disbursing funds and implementing activities were experienced in the past and also reportedly due to organisational bottlenecks; • Administrative unit overburdened with functions when compared to other similar European Agencies; • Very high number of staff in comparative terms devoted to Communication activities; • Current management practices are generally found very appropriate to ensure quick response to urgent needs. 	<p>ECDC has taken major steps to improve its management systems and processes in the period considered, although this effort started later than originally envisaged. While it is acknowledged that there is still a lack of harmonisation in management practices across the various sections, there are good reasons to believe that certain sets of procedures should remain distinguished in the different areas. While the matrix reorganisation has certainly brought about a number of pros, there are certain unintended side effects deserving some redressing action.</p>
<p>Staff and Skills</p> <ul style="list-style-type: none"> • Relatively high staff turnover; • Staff skills generally deemed adequate, although missing in certain areas; • Too limited first-hand knowledge among staff of MS working environments. 	<p>Some marginal improvements can be undertaken in the mix of ECDC skills available among staff, but these remain overall adequate to ECDC core tasks. By far the most important request coming from the evaluation is to strengthen staff first-hand experience with the way MS concretely operate.</p>
<p>Monitoring and Reporting Mechanisms</p> <ul style="list-style-type: none"> • Previous MAP indicators not always gathered and reported; • Past sectoral strategies typically lacked indicators; • Output indicators subsequently introduced as management tools; 	<p>ECDC has gradually built a reasonably effective monitoring system with suitable indicators and reporting practices, starting</p>

<ul style="list-style-type: none"> • Generally high level satisfaction among stakeholders on current; monitoring and reporting practices, although with some limitations on certain specific areas; • ECDC has already taken steps to make substantial improvements in this respect. 	<p>from a situation with several weaknesses. There is still some room for improvement in certain areas, but the bulk of work appears to have already been done. The main problem is that there is still limited experience with it and the difficulties in benefiting from this appear to be more cultural than substantial.</p>
<p>Programming</p> <ul style="list-style-type: none"> • Transparency of programming mechanisms has substantially improved in the period reviewed, although still reported as a problem in certain areas; • Consistency of programming with parallel allocation of resources not entirely clear to many stakeholders and budget remains obscure and poorly intelligible to some stakeholders; • Difficulties in synchronisation with Commission programming remains an objective constraint to prioritisation of activities. 	<p>Programming practices and prioritisation mechanisms also have substantially improved, although more with reference to scope of activities than to related allocation of resources. There are converging indications ECDC should refrain from overprogramming activities and leave more room to cope flexibly with <i>ad hoc</i> requests.</p>
<p>Outsourcing Practices</p> <ul style="list-style-type: none"> • Strong consensus the current weight of outsourcing should be reduced and in-house expertise strengthened; • Rationale behind outsourcing not always clear to external stakeholders; • Strong requests to have more geographical balancing of contractors and a wider range of institutes involved. 	<p>ECDC has stuck fairly rigidly to the standard contractual approaches and little has been done to find contractual solutions within the limited room of manoeuvre allowed by the current financial regulations - for the problems outsourcing creates in the new scenario to facilitate networking among MS.</p>
<p>Impact on Operational Efficiency</p> <ul style="list-style-type: none"> • Very limited information is now available to assess efficiency of operations and the link with related budgetary figures is not always clear; • Excessive centralisation often reported as a cause of operational inefficiencies and delays, but the problem is poorly monitored with figures; • Current organisational arrangements would require more information sharing across units that is reportedly the case today. 	<p>There is a notable shortage of information to judge on efficiency of operations, although this should be remedied in the next programming period. So far, current organisational features, management systems and processes can be deemed reasonably effective with the limitations reported above.</p>
<p>Conclusions and Recommendations</p>	
<p>There is converging evidence from several sides that ECDC has long relied on informal procedures and centralised decision making and this has negatively impacted on operational and budgetary performance and internal information flows. It appears that the Centre has already taken steps to redress these weaknesses although it is too early to see results. (<i>Evidence strong, priority high</i>)</p> <p><i>Recommendation.</i> The process of creating internal procedures should be encouraged and adequately monitored through appropriate mechanisms to control compliance, although we would warn against making procedures necessarily homogeneous across the Centre and carefully consider the peculiarities of the various functions. Also the current process of administrative decentralisation of decisions is worth encouraging. Indicators to monitor possible problems in processing contracts, disbursing funds and ensuring compliance with procedures should be developed and routinely reported to MB.</p> <p>Several aspects of staff management (lack of mid management, high rotation of staff, insufficient skills in certain area) appear suboptimal to stakeholders and would deserve to be redressed in more strategic terms and also with a clearer vision of the tasks to be developed in-house and those to be outsourced. (<i>Evidence strong, priority high</i>)</p> <p><i>Recommendation.</i> Borrowing from the experience of other European agencies, it is worth considering preparing strategy documents (or a joint strategy document) , inclusive of monitoring indicators on staff development and outsourcing policy, whose implementation could be eventually discussed with the Management Board and could also serve as a guide in the future to avoid possible overlapping with EAHC.</p>	

There appears to be at the same time excessive recourse to outsourcing and underutilisation of outsourcing as a tool to build more inclusive networks and enhance cooperation and partnership with the MS (*Evidence strong, priority high*)

Recommendation. Within the room of maneuver allowed by the current financial regulation, ECDC should explore all the possible contractual means to make outsourcing more inclusive and broaden the range of expertise available

There are aspects of the decision-making process that remain obscure and poorly intelligible to stakeholders and hinder a judgement on prioritization of activities. This includes better clarity and transparency in the selection of priorities proposed to the AF for scoring and the overall readability of the budget, although it also seems there is substantial informal communication on the same subjects. (*Evidence medium, priority medium*)

Recommendation. The rationale behind inclusion of an item in the prioritization process should be better explained in a background document. A budget organized along a matrix structure should be replaced by a more intelligible budget highlighting resources allocated to key missions and to the achievements of the MAP /sectoral strategy objectives.

This evaluation did not enter into detail on organisational issues, but the operational efficiency of certain organisational choices is worth further consideration and better scrutiny, as it appears at first as a cause of possible obstacles to performance (*Evidence weak, priority low*)

Recommendation. Future organisational reviews of ECDC should consider whether the administration and communication units should be streamlined and some of their functions and staff reallocated elsewhere. In particular, certain administrative functions appear more of a governance nature and communication staff could be better integrated into the disease programmes

9. GOVERNANCE

9.1 Overview

According to its founding regulation, ECDC governance comprises three different layers, i.e. the Management Board (MB), the Advisory Forum (AF), and the Competent Bodies (CB) of the Member States, while operational responsibilities are given to the Director and then delegated to his/her hierarchy. In the statutory provisions, the **Management Board** has very broad supervisory functions that is to oversee that the Centre carries out its mission and performs its tasks. The MB also (i) adopts the Centre's work programme for the coming year and also a revisable multiannual programme; (ii) approves the general report on the Centre's activities for the previous year and the financial rules, and (iii) determines by the unanimity of its members the rules governing the language regime of the Centre.

Possibly as a legacy of the old network-based structure, the **Advisory Forum** was expressly conceived as a body composed of the directors of the participating PHI institutes. The implicit assumption was that PHI could work as sufficiently neutral national counterparts to steer ECDC activities in policymaking-related fields. Differently from the Scientific Committees of other similar European agencies, it was given a number of operational tasks that go beyond the traditional mere advisory role to the Director, including (i) ensuring close cooperation between the Centre and the CB, as to the coherence of the Centre's studies with MS priorities and the relevance of scientific and public health priorities in the work programme; (ii) the day-to-day activities of the CB with the ECDC as well as the coordination of communication during an emerging public health threat; and (iii) the setting up of scientific panels by the Centre.

The founding regulation remains particularly vague when it comes to the **Competent Bodies**. It simply states that the ECDC cooperates with the competent bodies recognized by the MS and appointed by the MB in the different areas of work, particularly on preparatory work for scientific opinions, scientific and technical assistance, and collection of data and identification of emerging health threats. Therefore, the very peculiar situation was created, in which the CB were appointed by the MB, but responsibility for their coordination lied with the AF. This spurred the need, very early in the Centre's life, for the creation of documents defining the respective roles and responsibilities of the CB and the AF in different areas of ECDC activity (e.g. surveillance).

As the network of CBs grew in number and size, in order to cope with the increasing complexity in the relations between MS and the ECDC, in 2010 it was decided that the MB representatives were to appoint one single **Coordinating Competent Body (CCB)** per MS, with one **National Coordinator (NC)**, to serve as the point of contact for all communication between ECDC and MS on technical and scientific issues. Thereby, the CCB replaced *de facto* the AF for this task. So far, while all MS have appointed an institution acting as a CCB, not all of them have nominated a NC. Needless to say, there is substantial overlapping in the role the same individual may play within MS bodies and either as MB or AF member or NC or representative of the CCB. In more staff-constrained MS, this overlapping replicates down the various governance levels: the same individual can be nominated in the apical bodies and appointed as national focal point for given areas, and it is not infrequent to find the same individual in charge of several NFP roles.

The CCB reform however changed the governance structure of the Centre, and the NC in the CCB now:

- (i) acts as the main entry point for interactions between the Competent Body/Bodies in the Member States and ECDC;
- (ii) ensures overall coordination of information exchange;
- (iii) nominates National Focal Points (NFPs) and Operational Contact Points (OCPs) instead of the MB, as well as Member State experts for *ad hoc* working groups and other ECDC meetings (although panels are still on paper under the AF responsibility);
- (iv) ensures that the contact details of nominated persons are kept up-to-date in the ECDC rosters;
- (v) handles institutional relations issues between the Member State and ECDC;
- (vi) coordinates in a timely manner the provision and exchange of scientific and technical information;
- (vii) identifies needs for support from ECDC, in terms of scientific and technical assistance, but does not formally take part in the planning of activities that remains an AF responsibility;
- (viii) updates the country information data and associated contacts, organizations and other related information;
- (ix) supports the dissemination of ECDC publications in the country;
- (x) assists ECDC within its operational areas (disease work and public health functions) when requested.

At the time of writing, the process has not been completed yet. The formal nomination of operational contact points (OCP) was still ongoing and that of the NFP had just been completed in certain areas. Due to the range of activities delegated to the CCB/NC, the issue was soon arisen of whether understaffed or resource-constrained MS needed financial compensation to perform these tasks, although this was not originally envisaged in the Founding Regulation, as it is the case, for instance, with EMCDDA. A number of discussions were then held in more recent years on whether support as a grant had to be given on a voluntary basis to those who required it and how this could be compatible with the EU financial regulation. In addition, the selection of the working language required long discussions within the MB until a temporary compromise approved by majority vote was finally found, given the impossibility of reaching a unanimous solution.

9.2 Main findings

9.2.1 Fulfilment of Mandates

Management Board and Advisory Forum members are generally happy with the way they can implement their mandate as defined in the Founding Regulation, as also confirmed by the survey results reported in the Figure 9.1.a below. Those in the MB who are relatively less satisfied, or at any rate would like to see improvements, mention the need to have stronger focus on budgetary allocations, and a better management of time and logistical issues and less attention paid to micromanagement. They particularly mention the need to improve procedures for agenda setting in order to avoid the too frequent occurrences of items postponed to the following meeting¹³⁰ and leave more time for discussion on crucial points. The main reported issue is that, until recently, difficulties

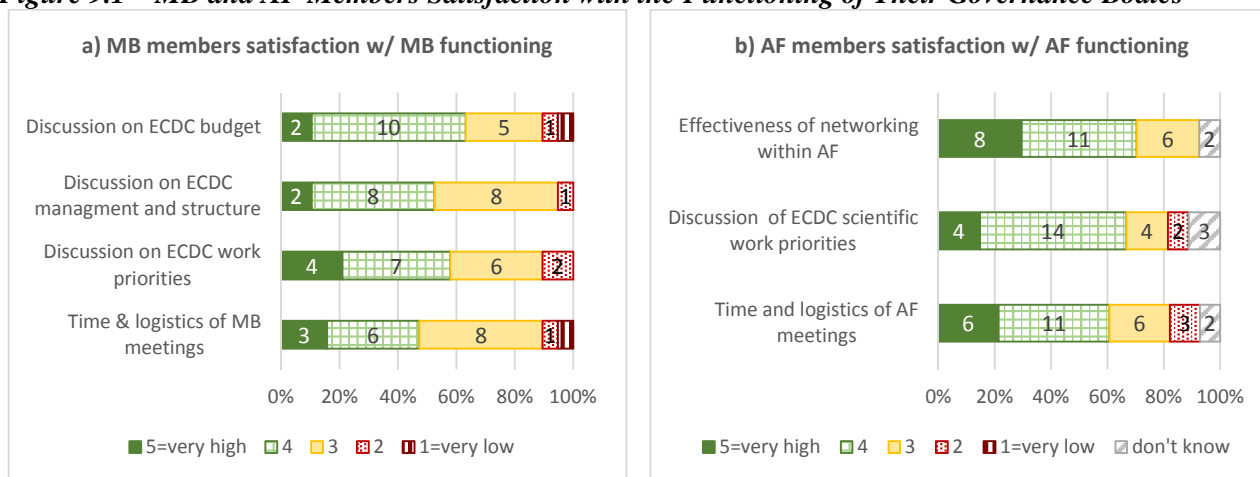
¹³⁰ Even at the time of ECDC establishment, there were discussions on the optimal size of the MB to ensure smooth management of operations. Proposals were also discussed in the past to create a steering committee of the MB to facilitate consensus on decisions but this was rejected in favour of having appointed members of the MB to follow up on specific topics with ECDC staff between two meetings and report back to the MB. According to some stakeholders, the result is that items often remain on the agenda for too long and issues tend to be debated in several meetings in a row before coming to a final conclusion.

were experienced with the late reception of background preparatory documents. This was particularly a matter of concern for large or federal Countries where a long internal consultation process is to be made in order to decide positions to be taken and the reaction time left from reception of documents was far too short. Instances have also been reported of documents received at the meetings, which hindered any possibility of discussing them at the informal pre-meetings. Since 2012, ECDC has routinely monitored these delays as a part of its performance indicators and as a result, the situation has started improving¹³¹.

There are, however, diverging interpretations of how far the MB is to enter into the so-called micromanagement issues, i.e. operational and organizational details that are under the remit of the Director. Some say it is excessive and probably an inefficient way of proceeding, as strategic focus is lost in the process. Others maintain that this level of involvement is necessitated by ECDC’s insufficient appreciation of the implications of its activities at the national level.

Also at the Advisory Forum level, there is a good level of satisfaction with the way their mandate is operationally fulfilled. As shown in the Figure 9.1.b below, the contribution to networking among members is particularly appreciated, while some more reservations are voiced on how meetings are organized. Some, for instance, would like to see a lower number of meetings (down from four to two a year but lasting longer - possibly 2-3 days - with much more possibility given to members of discussing the current priorities and activities at the MS level in order to inform ECDC staff about developments there. Others, conversely, complain that AF members tend, too often, to voice their own national interest with not very much considering the EU perspective and have too little say in setting the agenda, in spite of some attempts made in the past by ECDC to take their opinion into more consideration.

Figure 9.1 – MB and AF Members Satisfaction with the Functioning of Their Governance Bodies



Note: Total headcount (a)=19; (b)=27. Respondents include both actual and former members.

9.2.2 Governance Bodies Composition, Participation and Language Regime

Differently from what reported in the previous external evaluation, there now seems to be a fairly good – although admittedly far from enthusiastic - level of satisfaction with the actual involvement and active participation of all the Countries represented in the MB into its activities, and the steps

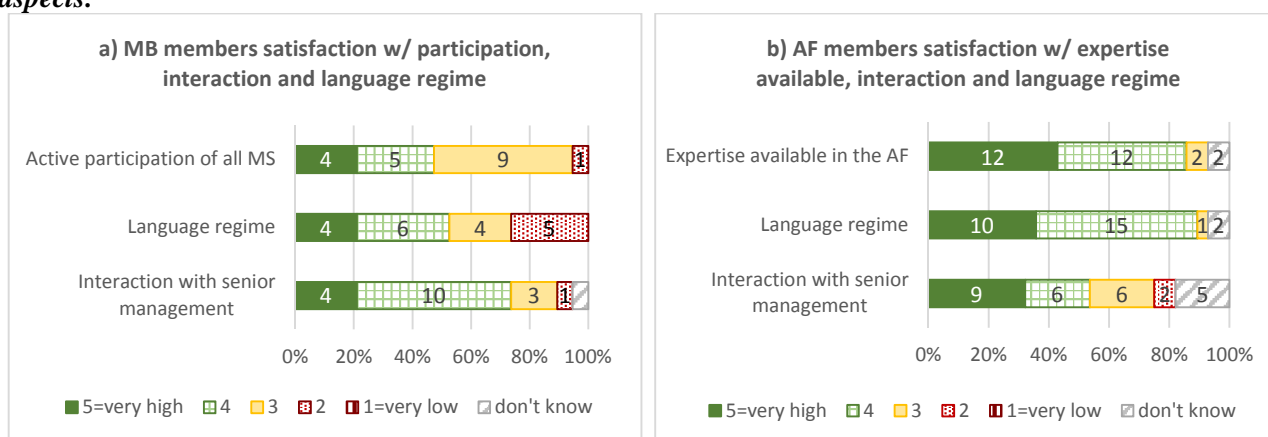
¹³¹ This is not always true however for all the stakeholders concerned. Some AF members for instance noted that invitation for AF meeting now come at much shorter notice than in the past, and also availability of documents has worsened in comparison with the previous situation.

undertaken to facilitate this process have therefore proven somehow effective (Figure 9.2)¹³². Some regret that the one-day gathering session of the MB has now been replaced by a short welcome, as in the past this allowed informal meetings and exchange of views among all MB members and a good interaction with the entire ECDC senior management team. At any rate, the overall satisfaction with dialogue and interaction with the ECDC senior management staff remains very high by all standards as also the figures from the survey below demonstrate.

The language regime remains deeply controversial for some one-quarter of respondents who feel there is really no need for translation into three other working languages and deem that further simplification could bring substantial savings, although all working materials are already prepared in English only. It is worth reminding that the operations of the MB have long been fraught with the issue of the working languages but no unanimous solution could be found¹³³. Most interviewees have agreed that probably this is not the best possible solution, but have also remarked that this appeared the only reasonable compromise that could be reached in given cost conditions to avoid that the issue would further drag on.

The Advisory Forum members also appear generally quite happy with both the extensiveness and comprehensiveness of the scientific expertise available among them, as well as of the language regime for their meetings, although slightly a bit less so in their dialogue with senior management for the abovementioned reasons (Figure 9.2.b).

Figure 9.2 – MB and AF Members Satisfaction with Participation, Interaction and Language Regime aspects.



Note: Total headcount (a)=19; (b)=28. Respondents include both actual and former members.

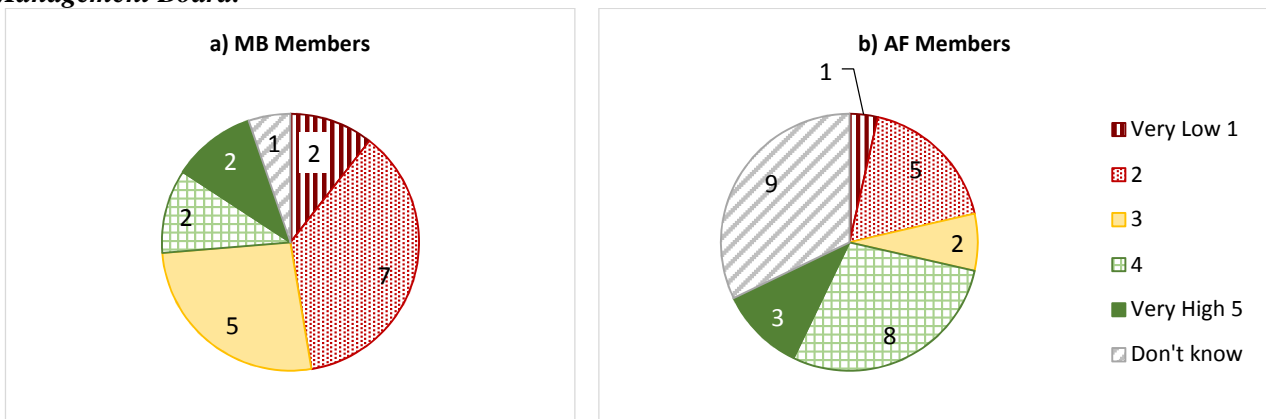
9.2.3 Complementarity of Activities between AF and MB

Complementarity of activities between the AF and the MB is considered by far the most problematic area, as far as ECDC governance is concerned. As high as half of MB respondents and one fifth of AF ones do not appear satisfied with the level of complementarity and synergy in activities reached between them (see fig. 9.3) and several instances of overlapping between the two bodies have been reported in the interview programme and can be noticed in the minutes of the two bodies.

¹³² Actually, in this respect, improvements are recorded since other ways of eliciting participants' views have been introduced in the way the MB meetings are run and this has represented a welcome innovation. However there would remain differences in the actual input from MB members (f.i. response to items, time used), that would require a diplomatic effort in order to see to stimulate eliciting views.

¹³³ A temporary decision was therefore taken with a majority vote in 2011, with three members against - Czech Republic, Greece and Portugal - and two abstentions - European Parliament and Italy.

Figure 9.3 - Satisfaction with Complementarity and Synergy between the Advisory Forum and the Management Board.



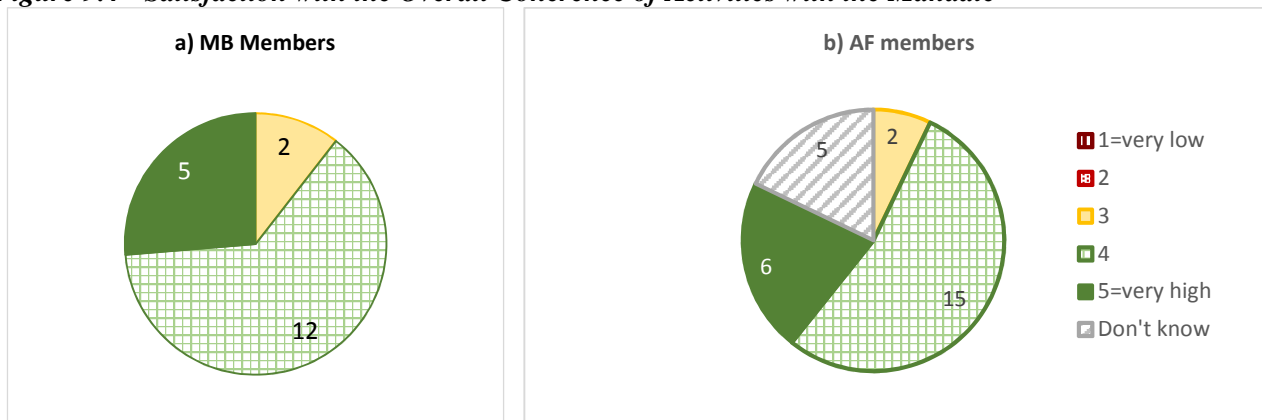
Note: Headcounts (a)=19, (b)=28

The founding regulation envisages some degree of overlapping between the AF and the MB, e.g. when it comes to the annual programming process but in line of principle, the two roles are kept distinct and separate. The prevailing operational practice, however, seems to be different and both the AF and the MB often end up discussing the same issues. There is actually plenty of evidence from the interview programme that patterns of mutual consultation and exchange of information based on personal relations between AF and MB members are a well-established practice within ECDC, which further points to substantial overlapping, and a need for synergy between the two bodies in their day-to-day activities. Proposals were formulated in the past about joint AF and MB meetings, or about improving information sharing by means of cross participation of an AF representative to MB meetings. Actually, one of the issues raised both in the interviews and in the survey was the possibility of having mutual access to each other intranet, in order to be better constantly updated about developments and be in a better position to coordinate positions with their sister representatives. Others say, to this aim, that it would be useful to have formal conclusions of the AF on work priorities and strategic choices prior to the discussion in the MB, in order to avoid the discussion to further drag on.

9.2.4 Quality, Type and Appropriateness of Roles

All the stakeholders consulted are generally happy with the quality of their roles (see Figure 9.4). However, some of them, particularly in the AF, report some ebbs and flows in their past level of satisfaction also depending of the various interpretations that were given to their mandate at different points in time.

Figure 9.4 - Satisfaction with the Overall Coherence of Activities with the Mandate



Note: Headcounts (a)=19, (b)=28

Some would even like the AF to become a scientific committee with a chair that is independent of ECDC, in charge of giving advice to the Director and the MB on the priorities, annual programme and strategic planning without any ECDC interference in their activities. Other AF members have also noted that, at the beginning of the period under consideration, before the CCB reform was defined, the AF had to play an operational supplementary role that went beyond its capacities, including establishing links at the Country level for pandemic emergency management issues and getting therefore too heavily involved into the day-to-day activities of the Centre. To more adequately reflect the complexities and scope of AF scientific support activities, sub-working groups have been created on specific issues. Some, however, complain that AF members should have an option to choose the working group where they would like to participate and not to be placed in working group by an ECDC decision. However, this relates more generally to the apparent contradiction some find between the broad governance functions attributed to the AF and the perceived lack of autonomy, given by the fact it remains an advisory body to the Director who chairs its activities.

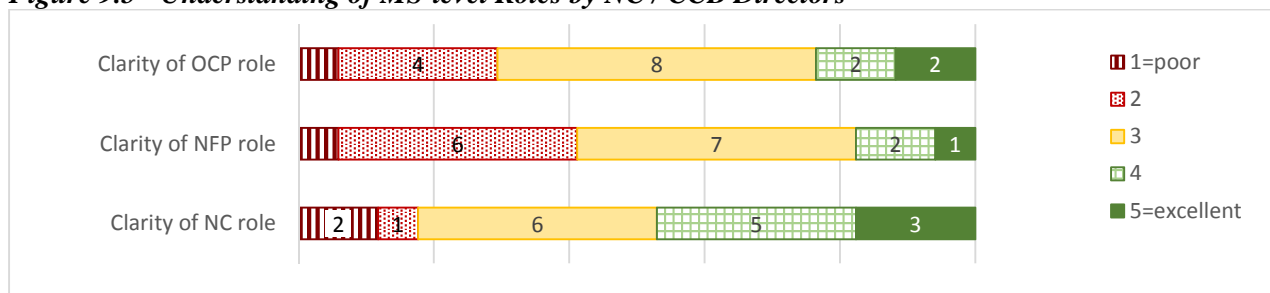
At the MB level some stakeholders are skeptical about the role attributed to AF in deciding priorities for programming purposes and question the pretended independent European viewpoint they would provide and tend to see the process within the broader framework of balancing PHI and Ministerial priorities at the national level. Their conclusion is that, if the system is to be client-oriented in policy terms and serve to the needs of the MS, then the allocation of responsibilities is basically to be redressed by giving more weight to policy counterparts either through the CCB or also by means of a more detailed flow of consultations at the Country level and a programme of Country visits and give a clearer mandate to the AF to focus on truly horizontal horizon-scanning or frontier issues.

9.2.5 Level of Understanding of ECDC Expectations among CCB

Among CCB and NC, there appears to be a quite good level of understanding of the ECDC expectations as far as their own roles and functions are concerned (with some more reservations on the subtle distinction between the NC as an individual and the CCB as an organization). On the contrary, the expectations about the National Focal Points' and the Operating Contact Points' roles and their interaction with the CCB still seem to many respondents insufficiently clear and poorly defined (Figure 9.5). As mentioned before, this is partly due to the fact that the related reform is still ongoing, but some have also voiced more structural reservations on related division of responsibilities and information flows. For instance, some would like to know more about what is done at the DP level and think that a better coordination should be created between the national coordinators and OCPs, by means of biannual meetings to update each other about progress of activities. Generally

speaking, the CCB reform overlaps with an organizational model giving substantial degree of freedom to the former DSN Members, without clarifying how this should eventually change in the light of the CCB establishment and make provisions for that purpose. For this reason, some would even deem it useful to have a coordination/focal point function established at the ECDC itself to better enable the NC to coordinate and develop a real strategy about the development of the various NFP relationships with the Centre.

Figure 9.5 - Understanding of MS-level Roles by NC / CCB Directors



Note: Headcounts=17.

CCB are particularly satisfied of the possibility they have been given of coordinating together and contributing to define their own mandate. The main limitations appear related to resource constraints. On average, respondents have estimated that their NC activities require some total 80 man/days, 40% of which just to respond to ECDC requests and another 40% spent in various forms of exchange of communication with Stockholm. This can represent a real burden for the most understaffed MS. There were proposals in the period considered to provide a small grant on a voluntary basis to any of the Coordinating Competent Bodies that opted to ask it, as partial compensation for the services they provided, but the MB could not find agreement on it also because of uncertainties on the legal basis for such grant¹³⁴. The provision was then reintroduced in the current work programme. In spite of the burden required in terms of person/days, the overall efficiency of communication with the ECDC is deemed as fairly good by the majority of respondents. Conversely, some one fifth of respondents mention as a particular problem area the lack of coherence and coordination structures with in their own Countries, which further reinforce the message that relations with the NFPs and the OCPs do represent a problem in many MS.

9.2.6 Impact of Governance on Close, Effective and Productive Cooperation

The functioning of the ECDC Governance bodies is probably the costliest among similar EU agencies (more than 1% of total budgeted costs, as against 0.1-0.3%), because of the dual governance provisions, the number of meetings and the language regime. To this aim some members have proposed more extended recourse to e-mail communications and simpler mutual access to the intranets as a practical step to streamline functioning. So far, close cooperation between the various Governance bodies has been rated by NC as reasonably good (7 out of 17 NC surveyed qualified it as good or excellent), with limited instances of conflicting views between NC and AF members on some specific activities. Some stakeholders are concerned that such instances could increase in the future as the new organization structure consolidates, and it is unclear to them if procedures to deal with such matters exist. This mirrors the more fundamental dilemma at the root of ECDC functioning. The right counterparts at the MS level to technically act on surveillance systems and play the risk assessors are not necessarily the same to establish a dialogue on policymaking or setting the policy

¹³⁴ Financing of NFP is expressly envisaged in the ECCDDA regulation and managed by means of a contract-based grant. Such compensatory financing is reportedly being considered for possible discontinuation.

agenda, and this creates a tension into the system that can be roughly simplified as one ‘between the PHI and their Ministries’. The box 9.1 below provides a living example drawn from a case study of the problems this can create in practice.

Box 9.1- Example of Conflict Between the Policymaking and Epidemiological Dimensions of NFP and CCB Activities (excerpt from a case-study).

“The new system can become very complicated to manage at the MS level and can paradoxically become less transparent and more time-consuming and prone to mistakes.

If the NC is the state chief epidemiologist, most of the diseases under surveillance are somehow covered and we know each other. If it comes from the Government, they usually don’t know anything about the subject matter, and often don’t even personally know the epidemiologists in charge. This bears the risk that important mails are not forwarded to the right counterpart.

For instance, the NC didn’t feel he had the competence to nominate the country representatives for the Network Meeting - and quite rightly so, as he had no idea of who we are - so nobody got nominated to start with, and I had to do a lot of work to get myself and the OCP nominated.

I am responsible for the national surveillance of all the network-related diseases in my Country but, for some reason, I was not appointed as NFP, and therefore another person is on the mailing list for “everything”. Unfortunately, this person has nothing to do neither with surveillance nor with the daily laboratory work, but is only involved in policymaking.

Had I had any say, I would have appointed my OCP at least as secondary NFP to keep us in the loop.

If I go through the formal procedure, names on mailing lists are near impossible to change, even though the people involved in the surveillance work change fairly often. This is so annoying, both for the people who should not get the mails anymore, and – especially – for the people who don’t get the mails pertaining to their functions. I have tried several times to have changes made, but it is as if the system were impenetrable”

9.3 Conclusions and Recommendations

Evidence	Main Findings
<p>Degree of Fulfilment of Statutory Mandate</p> <ul style="list-style-type: none"> • High level of satisfaction reported by Members of Governance Bodies with the degree of fulfilment of their mandate; • Degree of involvement in micromanagement issues reported as controversial, although diverging views among respondents; • Delays in receiving preparatory documents improved, although also here with some limited instances of complaints at the AF level; • Management of time and agenda setting reported as the weakest operational areas. 	<p>ECDC Governance Bodies can reasonably fulfil their mandate as defined by the ECDC Founding Regulation. The main limitation in this respect is that there can be different understandings of the mandate itself, and therefore lack of coherence in behaviours at the individual level. The management of the agenda is confirmed as an area where the functioning of both the MB and the AF appear more critical</p>
<p>MB Structure and Satisfaction with the Language Regime</p> <ul style="list-style-type: none"> • Members generally happy with the overall level of participation and involvement into MB activities and of the range of expertise available in the AF; • High level of satisfaction with the interaction with ECDC senior management staff; • One fourth of respondents still unsatisfied with the current language regime, but majority deems it the least possible evil. 	<p>Improvements in MB participation and involvement into MB activities reported, particularly as compared to the previous evaluation. Interaction with EFSA management appears very satisfactory. Although it is acknowledged that the situation is far from ideal, there is strong consensus that the language regime issue should not be reopened.</p>

<p>Complementarity of Activities between AF and MB</p> <ul style="list-style-type: none"> • Considered by respondents as by far the most important problem area; • Instances of overlapping already considered as routine practice requiring constant coordination between Members of the two bodies; • Several proposals formulated in the past to improve complementarity have hardly materialised. 	<p>The peculiar dual governance system of ECDC still leaves room for improvements as far as complementarity between AF and MB is concerned, but also appears deeply entrenched in the operating practices of the two bodies almost to be taken as a given..</p>
<p>Satisfaction with Quality, Type and Appropriateness of Roles</p> <ul style="list-style-type: none"> • Generally good level of satisfaction with the quality, type and appropriateness of the roles played, but less so among AF members; • Some complaints reported at the AF level because of perceived lack of independence. 	<p>The lack of independence of the AF from the Director and the complex link between the AF prioritisation exercise and the budgetary allocation mechanism appears as the most controversial areas</p>
<p>Level of Understanding of ECDC Expectations Among CCB</p> <ul style="list-style-type: none"> • Deemed generally good as far as CCB themselves and their functions are concerned; • Reported as much more problematic in CCB relations with NFP and OCP. 	<p>The CCB reform appears relatively well understood and shared, although not necessarily supported by adequate institutional and governance mechanisms at the MS level. It appears as relatively costly in terms of person/days effort.</p>
<p>Impact of Governance Provisions on Cooperation between the Various Actors Involved</p> <ul style="list-style-type: none"> • CCB cooperation with AF and NFP as potentially problematic, as reflects dichotomy between PHI and Ministries; • Current Governance arrangements more costly than in other similar EU agencies. 	<p>The Governance reform introducing the CCB was still in the process of being implemented and some limited problems were reported with cooperation between the various bodies yet, although some have concerns this could gain momentum in the future.</p>
<p>Conclusions and Recommendations</p>	
<p>The majority of Governance-related subject matters do not seem to pose any particular concern to stakeholders. The only exception is represented by the perceived overlapping between the AF and the MB activities, which however almost inevitably results by the way allocation of related responsibilities was decided in the founding regulation (<i>Evidence medium, priority medium</i>).</p> <p><i>Recommendation.</i> There can be a number of ways through which the MB and the AF can make their activities more complementary and synergic. These include sharing their agenda setting process, joint sessions, mutual access to the intranets. Both bodies should identify those more feasible and try to explore them on a pilot basis. These could include, among others, joint approaches to programming of activities or tacking outsourcing policy.</p> <p>The degree of satisfaction on the time and logistics of the meetings is marginally lower than in other areas and there seems to be some more room for improvement in this respect (<i>Evidence weak/anecdotal Priority low</i>)</p> <p><i>Recommendation.</i> A number of right steps have already been taken to improve Governance procedures and performance indicators. There is some limited room for streamlining it through enhanced recourse to IT tools (information items attached as links, more extended recourse to e-mails and web-platforms, etc.) that could be eventually explored, if compatible with the current language regime. The possibility of introducing one more indicator on the share of items in the agenda of the Governance fora postponed to/continued in the following meeting should be considered.</p> <p>There are still some grey areas in the way CCB, NFP and OCP cooperate and the potential for further conflict in the future cannot be ruled out (<i>Evidence speculative/anecdotal, priority low</i>)</p> <p><i>Recommendation.</i> The CCB coordinating body and ECDC could monitor the process and eventually prepare in case of need some recommendations on how to improve cooperation and, to the extent possible, prevent potentially contentious issues.</p>	

10. THE DISEASE PROGRAMMES

Introduction. The Disease Programmes¹³⁵ (DP) have become an ECDC priority since 2010, when a dedicated multiannual strategy¹³⁶ eventually entered into force. This evaluation exercise has been carried out with reference to three specific diseases as case studies for more in-depth analysis, namely influenza, salmonella and HIV/AIDS. The reason for this is that these diseases cover different features which are considered relevant for assessing ECDC performance, and in particular:

- ***The nature, means of transmission and related epidemiology of the underlying pathogen.*** Influenza is an acute airborne disease with a substantial burden on the population that can substantially increase if a pandemic outbreak arises. Salmonella is also an acute foodborne disease with a much more limited impact in ordinary conditions (although it can be considered more chronic in certain regions) but subject to sudden outbreaks that can also have an international dimension. HIV/AIDS is a sexually-transmitted and a chronic illness with more limited episodes of sudden outbreaks of infections and slower transmission patterns.
- ***EU surveillance data reporting requirements.*** Influenza surveillance data are delivered on a weekly basis (fortnight off-season). Salmonella surveillance data are reported on a quarterly basis, while HIV/AIDS ones are transmitted annually, which also reflects the different nature of the underlying diseases.
- ***Integration with laboratory surveillance.*** Both influenza and salmonella envisage a laboratory data component of enhanced virological and microbiological surveillance, while HIV so far has none. The influenza national reference laboratory network is somehow implicitly recognized in the EU legislation, while the salmonella reference laboratory network is not and remains an ECDC pilot initiative.
- ***Underlying policy framework.*** Salmonella as a foodborne disease is extensively regulated at the EU level as far as controls along the food chain are concerned, while there is no specific policy framework for reference as relates the human health aspects only. Conversely, disease-specific policies inclusive of targets for the reduction of the related burden of disease are implemented by means of soft-law instruments (Communications and Recommendations) both in the case of influenza and HIV/AIDS.
- ***Policy counterparts.*** At the Member State level, the bodies responsible for salmonella are often to be found in veterinary offices and there is no official EU counterpart committee in the public health field to coordinate policymaking in ordinary conditions, but the health security committee when an outbreak arises. There is a dedicated HSC subcommittee specifically on influenza, while European policy on HIV/AIDS is steered by means of a parallel ad hoc HIV Think Tank. Policy interventions in the field of HIV/AIDS for certain marginalized groups include social interventions. As far as prevention is concerned responsibilities are often scattered among different bodies often outside the public health sphere, including the Prime Minister offices and the Ministries for Social Affairs.
- ***Management Features.*** The influenza DP activities are run by means of a heavy involvement of the underlying networks, particularly the laboratory network, and have envisaged a policy component also run by separate networks. HIV/AIDS mainly relies on subcontracted work through a framework programme. Salmonella also relies on network activities, but make a more extensive use of ordinary tendering procedures.

¹³⁵ There are seven disease programmes running in the period under consideration, and namely: 1) influenza; 2) tuberculosis (later joined in a common programme on respiratory tract infections); 3) STI, blood-borne diseases and HIV; 4) food & water-borne diseases; 5) emerging and vector-borne diseases; 6) vaccine-preventable diseases and 7) antimicrobial resistance and healthcare-associated infections. An eighth programme on health inequalities and migrant health has just been introduced.

¹³⁶ See *ECDC Strategies for disease-specific programmes 2010-2013*

ECDC activities in these fields have resulted from the inheritance of previous European DSN that have been incorporated within the Centre after an evaluation and validation process. Although this has resulted in some limited degree of harmonization among the different practices prevailing therein, there is a general consensus that legacy factors still influence strongly the DP's management practices and overall performance.

I - INFLUENZA

10.1 Overview

ECDC activities in the field of influenza have been aimed at: 1) monitoring seasonal influenza and supporting the implementation of the EU policy on vaccination; 2) enhancing preparedness to pandemics with particular reference to the A (H1N1) pandemics; 3) monitoring the health threat posed by avian influenza, and 4) assessing the potential use of antivirals for public health purposes, as well as the risks posed by antiviral resistance. ECDC coordinates the activities of the **European Influenza Surveillance Network (EISN)** – one of the oldest disease networks in Europe - which also includes the virological surveillance of the **ERLI-Net**¹³⁷, a sub-network within EISN. Originally limited to influenza, the influenza disease programme has then expanded its activities to cover other respiratory diseases. The core of the influenza programme is to maintain and improve influenza surveillance, allowing access to the Los Alamos laboratories influenza sequence database, and ensuring the coordination of the ERLI-Net that substantially - but not entirely - overlaps with the parallel WHO's NIC network.

Most of 2008-2009 ECDC activities in the field of influenza focused on the A (H1N1) pandemic and related preparedness and support¹³⁸ first, and risk assessment then. Influenza surveillance data are reported weekly to ECDC to be published on-season in the Weekly Influenza Surveillance Overview bulletin (WISO) (off-season on a fortnightly basis). Since 2011, a Europe-wide risk assessment report on influenza has also been produced, to trigger a refinement at the European level of the influenza severity concept. In the 2008-12 period, guidance work has been mainly focused on complementing the EU Recommendation with advice on seasonal influenza immunization in children and pregnant women, while other works on prevention and control have focused on vaccine effectiveness and exploration of the behavioural aspects of vaccination compliance.

Work on **strengthening programmes** has mainly materialized in supporting the Commission in updating its 2005 Communication on pandemic preparedness and in preparing and implementing the

¹³⁷ ERLI-Net has its roots in the CNRL, which was established in 2003 to formalize support to the European Influenza Surveillance Scheme (EISS). The concept of CNRL under the EISS project was retained in the new EISN. Since 2008, ECDC has outsourced the laboratory activities of the network through a call for tender to a coordination group made up of a consortium representing three European Institutes including the WHO Collaborating Centre (WHO CC) in London. The coordination group relies on the expertise of virology task groups to steer its activities and harmonize technical approaches. The MS laboratories that are members of ERLI-Net now report their surveillance data to the TESSy database and data are then transferred to the WHO EuroFlu database and the global WHO FluNet.

¹³⁸ Most of pandemic-related preparedness and support activities took place before the period considered here when all the 27 Member States and the three EEA/EFTA countries were visited. In the 2008-2009 period preparedness and support activities mainly consisted of country visits to three EU candidate countries: Turkey, Croatia and the Former Yugoslav Republic of Macedonia and the preparation together with WHO/EUROPE and the HSC of a Country Assessment tool composed of some twenty indicators to be used to finalize the 2009 status report on pandemic influenza preparedness in the EU/EEA as an update of a similar 2007 exercise. However, this second report never materialized, as it was superseded by the rapidly evolving events and was replaced by a lessons learnt exercise.

Council Recommendation on seasonal influenza immunization. Other activities were related to determine the lessons learned from the pandemic, in order to provide recommendations on the future strategy for preparedness activities and developing the means to support the communication of key public health messages, including a toolkit on influenza vaccination. Influenza-related activities were often run by means of external projects inherited from the PHP and running beyond the scope of influenza proper and even jointly managed with other units within ECDC. For instance, together with EMA and through the VAESCO II project, ECDC funded the monitoring and assessment of influenza pandemic vaccine safety¹³⁹. Through the VENICE II project¹⁴⁰, ECDC funded the monitoring of national seasonal influenza vaccine policies, practices and coverage as expressly requested by the related Council Recommendation¹⁴¹. Finally, ECDC more specifically funded the external I-MOVE project to monitor the effectiveness of seasonal and pandemic influenza vaccines in an area also covered by EMA.

10.2 Main Findings

10.2.1 Enhanced Coherence

The widespread use of ECDC risk assessments in the field of influenza certainly contributes to enhanced coherence with risk management. The survey results show that the majority (52%) of respondents rate ‘good or excellent’ the contribution of the DP to country-level integration of risk assessment, risk management and risk communication aspects, and this percentage further increases if only respondents with a significant knowledge of the DP are considered (63%) (but respondents from Southern countries appear on average more sceptical).

There is overwhelming consensus among interviewees that the WISO and the RRA in the field of influenza are regularly used as a prime source of reference. Concrete modalities of use may vary from Country to Country, but a growing positive trend is clearly there. Data on WISO and RRA downloads and widespread circulation can be further used as supportive evidence. Coherence in risk communication is reported as slightly more problematic by stakeholders, possibly also because influenza-related RRAs mainly concern relations with third countries and therefore potentially sensitive external relations issues. If one takes the delay between RRA report posting in the EWRS and its publication or lack thereof in the ECDC website, for the years where data are available, i.e. 2011 and 2012, as a rough indicator of potentially controversial risk communication aspects it can be noted that of the seven RAs / RRAs carried out in the field of influenza in 2011, two were published without delay, another two were remained embargoed in the EWRS before publication for five and eleven days respectively and another three – mainly concerning third countries – were never actually published. Conversely, the three influenza-related such documents released in 2012 were all published without delays. However, the finding that overall coherence has improved mainly applies to ordinary conditions and external threats and is subject to three main qualifications, and namely:

¹³⁹ The study investigated the relation between A(H1N1) immunization and Guillain-Barré Syndrome.

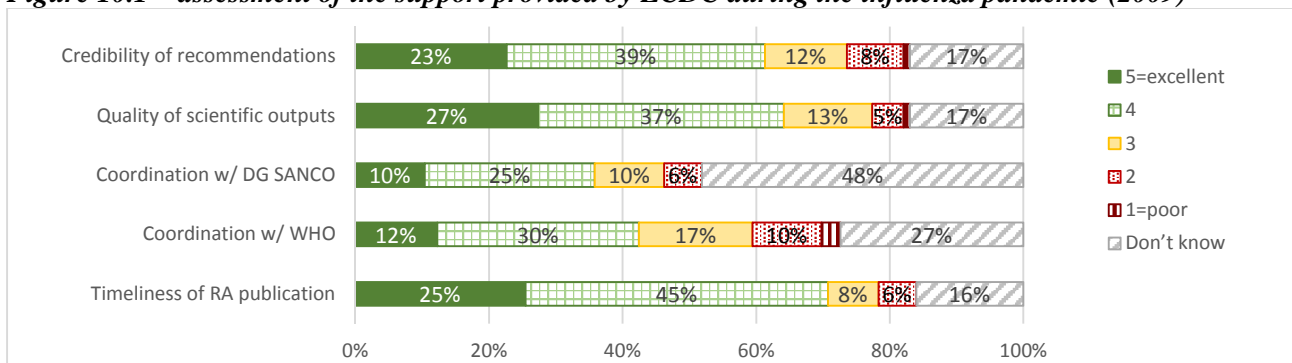
¹⁴⁰ VENICE II is the continuation of VENICE I (2006-2008) sponsored by DG SANCO and supporting a collaborative European network of experts working in all immunization programmes. The VENICE network has migrated into a separate official ECDC Vaccine Preventable Diseases network, with experts appointed by the CCB of each MS

¹⁴¹ In December 2009 the Council recommended that MS should adopt and implement national action plans to achieve 75% vaccination coverage in all at risk groups by the winter season of 2014-15. The selection of risk groups followed guidance from ECDC and WHO. MSs were also to measure uptake in all risk groups and encouraged to report on a voluntary basis to the Commission. With some augmentation, ECDC supported the VENICE surveys as the most effective way of doing this without placing additional reporting burdens on MS.

- instances have been reported of MS having to base their risk management decisions on seasonal influenza mainly or exclusively on national sources, because the ECDC RA report would appear sometimes too late during the season to be of real use for decision-making purposes;
- also related to that, the need to have as the single most important piece of information for risk management purposes reliable data on vaccine efficacy early during the season as part of the RA report and the difficulties created by the discontinuation of I-MOVE and the lack of clarity on possible sources of reliable data, as stakeholders have diverging views on this;
- the inability of ECDC rapid risk assessment reports to avoid extreme positions in many MS risk management approaches and among the media at the time of the A (H1N1) pandemic. This was also partly attributed to a failure in risk communication on the part of ECDC¹⁴². However, interviewees have generally agreed they had been adequately briefed during the daily teleconferences held at that time and therefore attribute divergences in risk management decisions more to the very likely extreme political pressure of the moment¹⁴³.

With more particular reference to the pandemic, the timeliness, quality and credibility of ECDC contributions are generally appreciated (see Figure 10.1 below), and the main reported problem area remains poor coordination with WHO as better detailed in the box 4.1 in Section 4 (Early Warning, Preparedness and Response).

Figure 10.1 – assessment of the support provided by ECDC during the influenza pandemic (2009)



Note: Headcount=138

10.2.2 The General Level of Satisfaction

The contents of the Disease Programme are very well known by about one-third of the self-reported influenza experts surveyed - a figure that does not significantly change between respondents recruited through the ECDC CRM database and external experts. The general level of satisfaction with the Programme is positive across several policy-related and management-related dimensions (see Figure 10.2), ranging from the relevance of the topics chosen to the quality of the data provided to the usefulness and added value of the activities undertaken under the three main domains of (i) the risk assessment of seasonal influenza, (ii) the risk assessments of pandemic and animal influenza and (iii) scientific advice on vaccination. As can be seen, while broadly positive across the board, there are

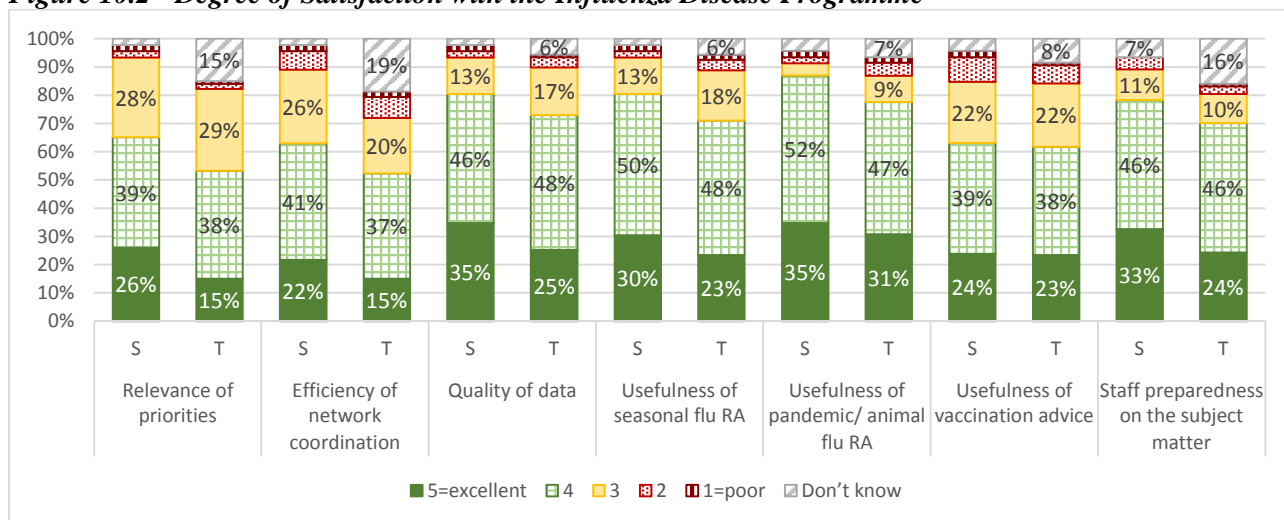
¹⁴² In particular, to the lack of a clear severity index that could have helped MS to better evaluate the severity of the pandemic and respond accordingly. The CDC had developed a similar tool for the local communities in the US in 2007. See http://www.flu.gov/plan/community/community_mitigation.pdf. ECDC has since then developed such an index.

¹⁴³ When criticism is voiced, this generally refers to the excessive emphasis and overreaction ECDC would have shared – with the benefit of hindsight - with other international organizations at the beginning of the pandemic including a certain media hype. In some MS the fact that ECDC experts were aired giving messages apparently conflicting with domestic risk communication strategy is still considered a serious coordination problem.

huge variations in the degree of satisfaction between the various areas considered. So the added value of activities related to the pandemic or the animal flu risk assessments is much more clearly perceived than that of scientific advice on vaccination where some 30% of respondents do not appear as particularly persuaded, or of that of the seasonal flu risk assessment that lies somewhere in between.

As far as management-related aspects are concerned satisfaction with the overall level of staff preparedness is much higher than that of efficiency of coordination of activities or that of the relevance of the selected priorities. To this aim, it can be noted that a number of comments were made on its alleged lack of transparency or the limited weight attached to MS contributions before these are brought before the AF for the IRIS scoring procedure and are therefore not captured by the proposed ECDC monitoring indicator.

Figure 10.2 - Degree of Satisfaction with the Influenza Disease Programme



Note: S= respondents significantly familiar with the DP; T = total respondents. Headcount=138.

There is a general consensus (some 80% of respondents in the survey) that the surveillance data on influenza are probably the best available in the EU in terms of harmonization and reliability for comparison purposes and they have also improved over time. In addition, the WISO represents a relevant activity and a good sources of added value per se. The role played by ECDC in coordinating networks and organizing meetings is also perceived as an added value, although negative comments were reported on insufficient inclusiveness and limited coordination with MS during the pandemic emergency particularly in terms of risk communication. There are more diverging opinions on the ECDC involvement in the VAESCO and I-MOVE project activities that according to some should never have been left to existing networks without a stronger ECDC involvement and supervision and about the importance and added value of communication support activities in general. Comments on the relevance of scientific advice and guidance documents are more nuanced and Country specific. Some stakeholders believe the WHO still has a leading role in this as well as in classification issues (e.g. severity). Guidance and capacity building for pandemic preparedness purposes also vary a lot among interviewees in their perceived added value. Those who are closer to policymaking and more openly committed to the achievement of vaccination policy targets often complain about the too limited importance attached to vaccination behavioural aspects¹⁴⁴ and the need to receive much

¹⁴⁴ It is noted that stakeholders particularly keen on the subject of behavioural advice to increase vaccination compliance, define the problem in terms of misinformed general public and need for professional advice on “myth busting”. Conversely, relatively little attention is paid in their narrative to the parallel issue of convincing the community of health practitioners – that, at least in the case of the pandemics is reported among the originators of scepticism on vaccination policy and at any rate remain key mediators of information with their patients - about the soundness of the scientific

stronger support in this area to steer their activities. Others are more sceptical and maintain that these behaviours largely remain country-specific and too dependent on local cultural factors to make any meaningful generalization at the EU level possible.

Detailed figures on the allocation of resources between the various components of the programme are partly available for 2011 and 2012 (see Table 10.1) only and are so poorly known and understood among stakeholders to have elicited hardly any comment but that of an overall sense of obscurity. The amount of resources devoted to influenza in the period have slightly decreased from 4.9% to 3.7% of Title 3 budget, but with switches in budgetary allocations that can be understood only by insiders. So the amount allocated to surveillance jumps from €49,000 in 2011 to over € 400,000 the following year, while, conversely, resources devoted to scientific advice suddenly drop from €600,000 to € 90,000 which can be explained only by a diverse allocation of responsibilities for specific projects within ECDC itself. The weight of laboratory-related expenditure is massive and reaches as high as over 80% of reported procurement expenses in 2012. This triggered some comments among respondents on the fact that only with the inclusion of a microbiologist in its staff ECDC could have some control on expenditure and take more realistic decision on its efficiency. This also because of the total lack of indicators on intended achievements in that area.

Table 10.1 Budgetary Allocations of the Influenza DP by Area of Activity (2011-2012)

Area of Activity	2011	2012
Surveillance	49 000	42 4075
Preparedness and Response		
Scientific Advice	602 850	90 000
Training	10 000	10 000
Communication	138 729	
ICT		
Crisis Centre		
Translations		
Meetings	274 450	216 980
Country Cooperation		
Library		
TOTAL	1 075 029	741 055
<i>As a % of Title 3 budget</i>	<i>4,9%</i>	<i>3,7%</i>

Operationally-speaking the influenza DB was particularly fraught over the period by the need to cancel or postpone activities or to implement them partially and has therefore contributed more than proportionally to overall ECDC performance in work programme implementation and to decrease overall ECDC operational efficiency measured in terms of completed activities on the total as demonstrated in the Table 10.2 below

Table 10.2 - Implementation of the Influenza Work Programme in the 2008-2012 Period

Year	Total	Completed	Delayed	Postponed	Cancelled	Partially
2008	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
2009	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
2010	13 (6%)	11 (6%)	0	1 (12%)	1 (25%)	0
2011	10 (6%)	7 (4%)	1 (17%)	1 (25%)	1 (33%)	0
2012	14 (6%)	11 (5%)	0	0	0	3 (19%)

Note: absolute number of activities and () share of the total.

advice given by PHI and international organizations as well as the best ways and means to increase confidence among this group. This compounds with the fact that while ECDC is reported as well known among public health practitioners in a given Country it is also less so among healthcare practitioners and the public at large

10.2.3 Evidence of Contribution to Strengthening Programmes

In the 2007-2013 SMAP, the ECDC contribution to strengthening programmes for CD prevention and at the EU level and (upon request) in individual MS was phrased in terms of:

- 1) promoting the interchange among MS of their experience with national CD prevention and control programmes;
- 2) developing a set of recommended minimum standards that MS could use to improve the quality and cost-effectiveness of their own programmes which would contribute to enhancing the protection against CDs for the entire EU;
- 3) identifying which elements in European Commission programmes pertaining to health and other sectors could have a significant influence on CD determinants, and
- 4) engaging the relevant EU structures in discussions to advocate for and contribute support to such change.

There is little consistency on how specific project activities have been classified and reported over the years and instances can be found of the same project considered as contribution to strengthening programmes one year or improvement of scientific understanding the following year and so on. Anyway, in 2008 the bulk of ECDC contribution can be classified under point 3) and 4) above and consisted of providing advice on seasonal influenza and immunization to support the European Commission's initiative to produce the related recommendation, as well as technical support over the issue of sharing virus specimens ('virus sharing'). In 2009, ECDC briefed the EU Health Council on the Recommendation and undertook a series of related dissemination guidance, training and communication activities. In 2011, the annual ECDC Influenza Spotlight was developed and the case for an annual European Influenza Immunisation Day explored. Finally, in 2012, in preparation for the progress report by the Commission to the Council the VENICE project undertook monitoring and support work on Council Recommendation on influenza immunisation including the production of a guidance document on its monitoring. Activities under point 2) were first envisaged in 2010 but then postponed to the following year and consisted of a pilot monitoring and evaluation tool for seasonal influenza vaccination programmes in the Member States and providing EU - wide action guides to monitor influenza prevention and control public health programmes. Activities under point 1) almost exclusively consisted all over the period of the monitoring of the EU seasonal influenza vaccine policies, practices & coverage under the VENICE project.

As can be seen the bulk of ECDC activities in this area has been skewed and related to assisting the Commission and the Council in policymaking preparation. At the MS level it is recognized an ECDC institutional and networking role and some more limited evidence of specific concrete impact on vaccination programmes, their monitoring systems and the related decision making process is reported. Reports are deemed as moderately effective per se as a tool for change if not followed up by the provision of technical assistance and/or accompanied by training and dissemination events (workshops, etc.) - a weakness only recently partly addressed by the DP. For instance, a couple of MS have reported to VENICE of having taken into consideration the European guidelines on coverage data collection and assessment for their vaccination monitoring system but need technical assistance to implement them. The VENICE reports on the follow-up surveys have been used for information purposes but hardly as a tool to influence programming of activities also because comparative information on the contents of the action plans is missing in the reports and these are published with substantial delays as compared to the timing of the survey that can reach as long as two years.

10.2.4 Evidence of Improved Scientific Understanding

In the 2007-2013 SMAP, the ECDC contribution to improving scientific understanding of communicable diseases and their determinants grouped several different activities, and namely:

- 1) mapping the present, and estimate future forecasts of incidence, prevalence and threat potential of a specific CD or group of CDs;
- 2) developing a methodology for, and undertake assessment of current and future forecasts of the economic impact of individual CDs, selected groups of CDs, as well as the totality of CDs;
- 3) developing a methodology for measuring other societal impacts of CDs and undertake current assessments and future forecasts of these;
- 4) mapping existing science-based knowledge regarding CD determinants for individual or groups of CDs;
- 5) promoting and support studies to enhance the priority areas of public health need;
- 6) analysing the relative public health importance of individual determinants and ways to deal with them;
- 7) promoting and supporting further studies to enhance the scientific basis for such knowledge in priority areas of public health need.

Also in this case little consistency can be found in how specific project activities have been classified¹⁴⁵ over time because some of these definitions are so generic to partly overlap with those used for defining improved capacity to prevent and control diseases. In particular, a subtle distinction is to be found between the technical reports mapping the knowledge available on a certain subject and the related guidance documents in which information is then validated by a panel and conclusions and recommendations are drawn. Although very close in nature and often preparatory to one another, the first were classified here, while the second more properly belonged to capacity to prevent and control diseases. However, stakeholders are not necessarily familiar with this subtle distinction and tend to classify everything in the second group. So, specific activities¹⁴⁶ that can clearly be classified in this area are mainly related to point 4) above and include:

- an “interim” guidance on the public health use of antivirals during the pandemic (which is however a kind of hybrid document between a technical report and a guidance);
- the 2010 report on systematic literature review on seasonal influenza immunization in children and pregnant women across the EU;
- the science watch activity of relevant publications on influenza that was first included in the Influenza News bulletin, then in the Influenza Digest and then regularly published in the ECDC website.

There were plans to make a study on scientifically determining risk groups for influenza immunization, but these never materialized as they were first postponed to 2012 then abandoned because of the loss of the relevant staff who should have followed it.

Given the paucity of activities and the fact that most of the areas originally envisaged were never covered, it is little surprise this is generally considered by interviewees as the weakest area of ECDC contribution among those considered here. In particular, some stakeholders would have liked to see

¹⁴⁵ Starting from 2011 ECDC classifies as improved scientific understanding also ordinary surveillance and RA activities, which further adds confusion to confusion.

¹⁴⁶ Differently from ECDC 2012 Annual Report we do not consider here the Venice Report on Influenza immunisation evaluation and monitoring, because already classified as a contribution to strengthening programmes.

more in the field of estimating the actual burden of influenza under different scenarios. However, the document on public health use of antivirals during pandemics is reported as widely used as a point of reference at that time, although overcome by subsequent scientific developments. ECDC scientific advice on seasonal influenza vaccination of children and pregnant women largely overlaps in terms of informational contents with the WHO guidelines. European added value is more perceived as related to the underlying consensus building process, while the existence of European specificities deserving a separate scientific document appears as much more controversial.

10.2.5 Evidence of Improved Capacity to Prevent and Control Diseases

In the ECDC 2007-2013 SMAP, the definition the improved capacity to prevent and control diseases includes in order of priority:

- 1) mapping the current range of prevention methods and control of individuals and groups of CDs, assessing the current scientific evidence base for their effectiveness and cost; and promoting and supporting studies to further enhance such an evidence base in priority areas of public health need;
- 2) identifying areas where new and improved methods and technologies of CD prevention are needed and promoting and supporting the search for and development of such methods and technologies.
- 3) undertaking similar action (as in the two points above) with regard to treatment methods for individual or groups of CDs in priority areas of public health need.

Work in this area mainly consisted of support to the I MOVE project on providing data on seasonal and pandemic vaccine effectiveness and to the VAESCO epidemiological study on pandemic vaccine safety for narcolepsy and GBS purposes. Support to the I Move project was then discontinued due to an unclear ECDC mandate and lack of financing.

In 2010 a research seminar on the behavioural aspects of influenza control relevant to both the A(H1N1) 2009 pandemic and improving seasonal influenza control was organised and in 2011 a communication toolkit on how to communicate with public and healthcare workers to improve vaccination coverage was prepared with a view for its partial dissemination in 2012 due to contractual problems with copyright issues. In 2012, training courses in influenza prevention focusing on influenza immunization were also held.

There are strongly diverging views among stakeholders on the added value of both I-MOVE and VAESCO and some wish in retrospect these had never been funded as external network activities not fully controlled by ECDC. Supporters of the I-MOVE initiative report extensive use of related results although more for information purposes than for concrete decision-making due to delayed reporting during the season. Similar considerations also apply to the VAESCO results generally appreciated from the scientific viewpoint rather than translated into concrete capacity. Patterns of use of advice on behavioural aspects and the risk communication toolkit are very Country-specific and, particularly for the latter, extremely divergent in their perceived usefulness.

10.2.6 - Evidence of Improved Preparedness against Outbreaks

As reported in the Table 10.1 above, the Influenza DP had no dedicated budget for capacity building activities in this area, neither in 2011 nor in 2012. Activities were put on hold, while waiting for the regulatory developments related to the new Common Health Threat Regulation and joint procurement

of vaccines. So, for instance, the 2012 pandemic preparedness procurement workshops were postponed. The bulk of the output here is therefore represented by the 2010 report on the lessons learnt from the pandemic, aimed at providing recommendations on the future strategy for pandemic preparedness activities in the EU Member States, including a participatory "witness symposium" and on the contribution ECDC gave to similar reports prepared by the Belgian presidency or the EU Parliament.

Although marginal in terms of number of activities undertaken, the report on the lessons learnt from the pandemic stands out among the most frequently quoted ECDC deliverables deemed to have had a concrete impact on the domestic policymaking process by survey respondents.

Most of the comments received during the interview programme therefore predate the period under consideration and very divergent and Country-specific patterns of impact appear also depending on the underlying need for technical assistance and capacity building. The provision of guidance documents was more frequently mentioned than other activities including training (which was reportedly subcontracted with all the related perceived quality problems), but enabling of networking per se is generally considered the most important source of added value in this field.

II - HIV/AIDS

10.3 Overview

Since 2008, ECDC has inherited the activities of the EUROHIV disease surveillance network¹⁴⁷ covering 53 European countries and therefore representing one of the first instances of joint partnership with WHO/Europe that predates the establishment of the Centre. Together with the collection of surveillance data that remained its primary mission, the EUROHIV network was also to make international comparisons, assess trends, characterize affected populations and predict burden of disease. After its activities were transferred to ECDC these core tasks were also extended to more directly policymaking-related activities including the joint monitoring of the Dublin Declaration on the one hand and of the Communication on HIV/AIDS and the related action plan in the other hand¹⁴⁸. The publication of joint annual surveillance report with WHO/Europe was also continued. As a consequence of incorporation into ECDC, HIV/AIDS activities then became a component of the broader ECDC's disease programme for sexually transmitted infections (STI).

Given the current chronic nature of the disease, there are not so many HIV-related outputs that qualify as risk assessments and some have atypical features. A risk assessment on HIV transmittal in tissue/cell transplantation involved the establishment of an *ad hoc* panel and was the subject of discussions because the mandate of ECDC in the field of tissues and cells was not apparent to some MS. Another risk assessment on a HIV epidemic among injecting drug users (IDU) in Greece and Romania was carried out jointly with the EMCDDA. The programmes has also supported MS to implement behavioural surveillance on a voluntary basis, by developing a dedicated toolkit to this

¹⁴⁷ The first report on the surveillance of AIDS in Europe was issued in April 1984 by the forerunner of EuroHIV – the WHO Collaborating Centre on AIDS – presented information on AIDS cases reported in 11 countries. The topics covered include the estimation of AIDS under-reporting, mortality data, analysis of reporting delays, European AIDS surveillance case definition, estimates of HIV cumulative incidence and prevalence, HIV testing and HIV prevalence in specific populations. Results from studies included in the European HIV Prevalence Database have been presented regularly since 1991. The European HIV case reporting system was set up in 1999 with most countries participating.

¹⁴⁸ These new activities include improving the completeness and accuracy of reporting and developing a comparable system for the monitoring of prevention policies at the European level, as well as in supporting capacity building, through Country visits.

aim. Guidance work has focused on HIV testing, prevention in men who have sex with men (MSM) and IDU and related control of hepatitis. This has materialized also in the preparation of a joint guidance document with the EMCDDA on HIV management in IDU. Most of remaining activities aimed at strengthening national programmes have focused in assessing in detail the content of the programmes themselves and particularly in developing a flexible monitoring system to monitor political commitments at the national and international level. A relatively minor role has been played so far by coordination of support laboratory activities, which are still at a very early explorative stage and by the provision of support to the communication of key public health messages.

10.4 Main Findings

10.4.1 - Enhanced Coherence

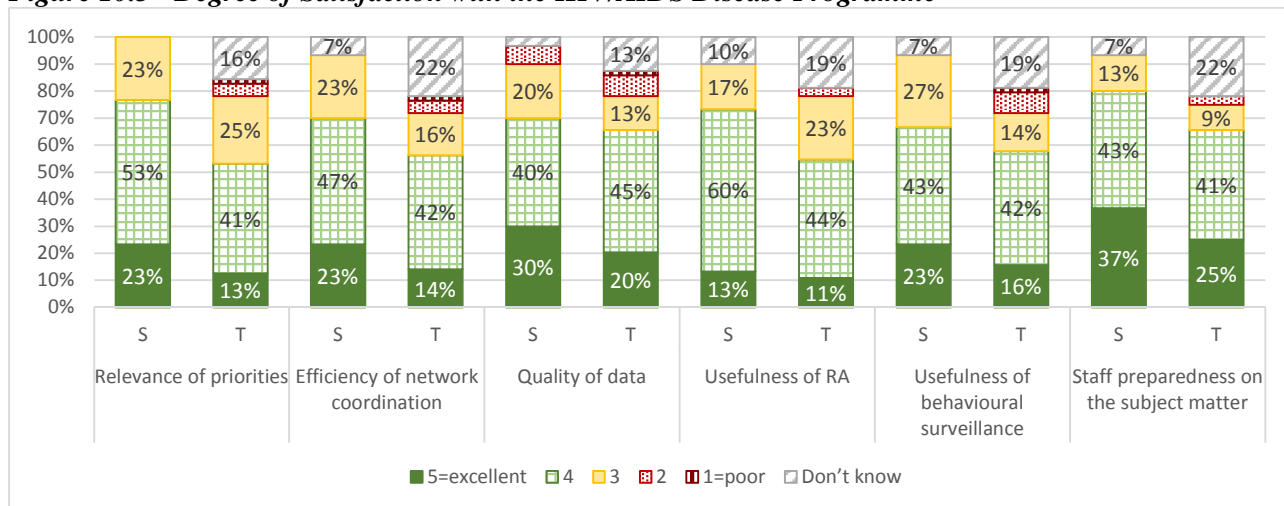
Risk assessments in the field of HIV have been a relatively minor output and often focused on particular Countries (although the risk assessment on reports of HIV outbreaks among IDUs in Greece and Romania also identified a number of other countries at risk) thereby with little anticipated impact on overall coherence. This is somehow recognized also by survey respondents who assess the DP contribution to this aspect less significant than in the case of influenza reported above (only 37% of positive feedbacks, which increase to 47% if only experts very familiar with the DP are considered).

There is strong consensus among interviewees that data from surveillance reports are regularly used as a prime source of reference and that the inclusion of WHO/Europe countries also greatly helps in this respect. However, also in this field there is preliminary evidence of the inability of ECDC risk assessment reports to avoid that MS, when subject to extreme political pressure, can take risk management decisions at a variance with ECDC risk assessment conclusions. Risk communication aspects appear slightly less controversial when compared to the other disease programmes reviewed in this Study. Actually, since reports are often used for advocacy purposes, requests that they should go even more in-depth into possible risk management recommendations are voiced more frequently than in other areas. As it will be better described below, disagreement with ECDC involvement is phrased more in terms of perceived outright lack of mandate in certain areas than in terms of overstepping on risk management aspects.

10.4.2 The General Level of Satisfaction

The contents of the Disease Programme are reported as very well known by some one third of respondents who declared themselves HIV experts, however differently from influenza the programme appears as rather poorly known by experts who are outside of ECDC loop (half of them declared no familiarity at all with it). The satisfaction with the Programme is fairly high across several dimensions and relatively homogeneous among the various areas considered (Figure 10.3). So, the added value of activities related to risk assessment or behavioural surveillance is recognised by some 65% of well-informed respondents. Satisfaction with the quality of the data provided is also good, although lower than for influenza. As far as management-related aspects are concerned the satisfaction with staff preparedness is higher than with the efficiency of activity coordination or that of with the relevance of the selected priorities. To this aim, it can be noted that a number of comments were made on its alleged lack of transparency or the limited weight attached to MS contributions before these are brought before the AF for the IRIS scoring procedure and are therefore not captured by the proposed ECDC indicator.

Figure 10.3 - Degree of Satisfaction with the HIV/AIDS Disease Programme



Note: S= respondents significantly familiar with the DP; T = total respondents. Headcount=91.

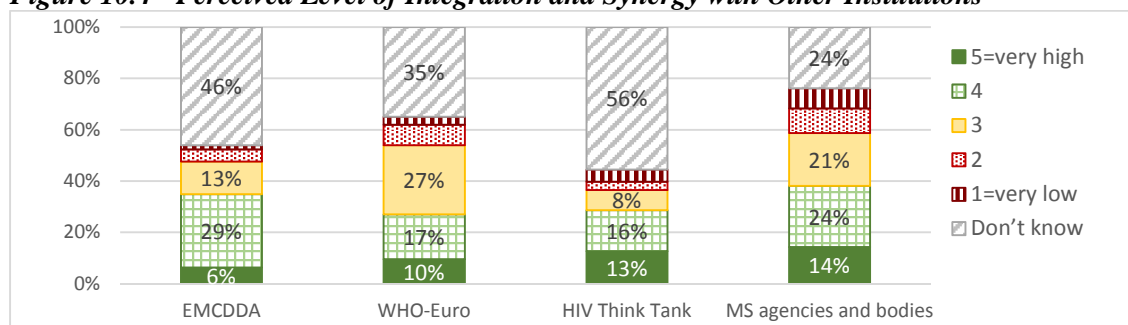
Relevance of the broad areas covered by the programme is hardly controversial, but for work on social prevention aspects and tissues. Reservations are made on the detailed contents of the specific projects (an aspect which might border quality aspects) and above all their number. Their identification and selection, in fact, appears exceedingly top down and not clear, transparent and participative enough. The delay between the period when projects are “announced”, the data “gathered” and the results finally “published” would further compound to the problem and contribute to reduce added value for final users. This would result into too many documents and consultations that would exceed the absorption capacity even of the better-equipped Countries and often a bit too outdated to be of real use, or, at any rate poorly synchronized with the underlying policymaking process.

The DP capacity to accompany reports with ad hoc targeted dissemination and communication events would reportedly appear relatively stronger than in other DPs¹⁴⁹. A certain confusion on who does what was also reported and the level of integration and synergy between the activities of the various bodies involved is often not clear to most respondents (see Figure 10.4). The fact that ECDC is responsible for the Dublin Declaration and Commission Communication monitoring but not evaluation is a source of confusion together with division of roles with WHO/Europe in the provision of technical assistance at the Country level. Relations with the HIV Think Tank are also very poorly understood. It is regretted that the network had little links with the underlying laboratories, which is not always the case with the other STI¹⁵⁰.

¹⁴⁹ For instance, the European Parliament has been used as a forum to highlight the HIV prevention needs of MSM (2009), to launch the HIV testing guidance (2010) and to hold a seminar on HIV prevention among IDUs (2011).

¹⁵⁰ It is only in 2012 that ECDC started a project to revise HIV/AIDS surveillance including more information on the route of transmission variables and the feasibility of clinical data at time of diagnosis (e.g. CD4 count and viral load) order to capture links to HIV treatment.

Figure 10.4 - Perceived Level of Integration and Synergy with Other Institutions



Note: Headcount=91

The perceived added value of HIV/AIDS activities tends to vary with the level of capacity existing in a Country and the perceived need for advocacy support. So instances can be found of high added value perceived from guidance documents particularly in the Mediterranean and most (but not all) Eastern European Countries (where it is particularly perceived when ad hoc Country visits or RA reports were received), together with others where added value mainly lies in networking with peers or in cross-border issues (e.g. migrants). The annual report and guidance on HIV testing are the items where interviewees more frequently recognize added value while opinions are more divergent in the other areas also depending on differences in the underlying epidemiology. Quality of data although far from ideal according to scientific standards is recognized fit for policy purposes. Cooperation with EMCCDA has also been highly appreciated. The role played by ECDC in coordinating networks and organizing meetings is also an added value, although relations with relevant national agencies and bodies are deemed not fully satisfactory by some 40% of respondents. Country visits and country assessments are also generally recognized as highly appreciated sources of added value.

Detailed figures on the *allocation of resources* are not available because reported together with those of the other sexually transmitted diseases (Table 10.3). The amount of resources devoted to STI in the period have slightly increased in relative terms from 4.3% to 4.6% of Title 3 budget but decreased in absolute figures. The bulk of expenditure is represented by surveillance and scientific advice activities, but communication receives a small but constant € 30,000 budget. In particular, resource allocated to surveillance activities have decreased from €430,000 to € 340,000, while those for scientific advice increased correspondingly from €307,000 to € 475,000. Differently from influenza that mainly funds ad hoc tenders, over 80% of HIV procurement is managed by means of a framework contract, a share that remains however slightly lower than that of other similar ECDC disease programmes. The HIV/AIDS DP is characterized by a heavy reliance on multiannual projects.

Table 10.3 - HASH Disease Programme. Budgetary Allocations by Area

Area of Activity	2011	2012
Surveillance	430 000	340 000
Preparedness and Response		
Scientific Advice	307 000	475 000
Training		
Communication	30 000	30 000
ICT		
Crisis Centre		
Translations		
Meetings	180 000	88 000
Country Cooperation		
Library		
TOTAL	947 000	933 000
<i>As a % of Title 3 budget</i>	<i>4,3%</i>	<i>4,6%</i>

Operationally speaking the HIV/AIDS component of the HASH programme did not particularly contribute to reduce overall ECDC operational efficiency through cancellation or postponement of activities as demonstrated in the Table 10.4 below, because the only such instances recorded in 2010 were related to hepatitis.

Table 10.4 - Implementation of the Sexually Transmitted Disease Blood Borne Diseases and HIV AIDS Work Programme in the 2008-2012 Period

Year	Total	Completed	Delayed	Postponed	Canceled	Partially
2008	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
2009	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
2010	11 (5%)	9 (4%)	0	2 (25%)	0	0
2011	12 (7%)	12 (7%)	0	0	0	0
2012	15 (7%)	15 (7%)	0	0	0	0

Note: absolute number of activities and () share of the total.

10.4.3 Evidence of Contribution to Strengthening Programmes

By far the bulk of ECDC contribution was instrumental to monitoring the implementation of the Dublin Declaration and of the related Council Recommendation. Activities started in 2009 with the development of a questionnaire and related training sessions and the first monitoring report was finalized in 2010 when a flexible monitoring and evaluation (M&E) system to monitor political commitments at (inter)national level with respect to the HIV/AIDS epidemics was also developed. After consultations with MS in 2011, it then restarted in 2012 with the HIV monitoring and evaluation of Dublin declaration and the more specific monitoring of EU and EU country responses.

Throughout the 2008-2011 period a programmes of Country visits to assess and evaluate national prevention and control programmes for HIV was also run under point 1) above including Country visits to Estonia in 2010; Finland, Romania and Latvia in 2011.

Therefore, much of the impact has been skewed and related to assisting the Commission in policymaking preparation. At the MS level, it is mainly of an indirect nature or Country-specific and related to either the risk assessment reports contributing to maintain programmes in place or the results of Country visits and assessment reports. It is noted that hardly any follow-up was made by ECDC on whether the results of given projects have contributed to shaping programming in the MS also as a feedback for steering of activities. The monitoring report on the implementation of the Communication and Action Plan for combating HIV/AIDS in the European Union and neighbouring countries 2009–2013 has reportedly been well received by the HIV Think Tank and deemed useful *per se* but was not a document expressly conceived to compare performances at the MS level and allow cross-fertilization of experiences. More detailed reports were published the following year and fall outside the scope of this exercise. So little impact on programming could be reported.

There is clearer evidence of ECDC strengthening of programme monitoring itself across Europe, as patterns of reporting on the implementation of the Dublin Declaration on the partnership to fight HIV/AIDS in Europe and Central Asia have improved together with UNGASS reporting. ECDC work is now focusing on improving the usefulness of indicators for regional monitoring. The 2011 ECDC consultations with the MS on a set of regionally specific and harmonized indicators to monitor the HIV response in Europe was actually used for data collection during the 2012 Dublin/Global AIDS Response Progress and Universal Access (UNGASS) reporting round. It helped somehow to reduce the reporting burden on countries and as such considered an important contribution by some MS,

although others reported that their information system had not been adapted in due time and therefore data had often to be collected on an *ad hoc* basis with notable effort.

10.4.4 Evidence of Improved Scientific Understanding

This appears an area where ECDC heavily invested in the period and financed activities over and above those specifically requested as RA. This includes:

- 1) forecasting and modelling exercises of the HIV/AIDS epidemic (including national HIV prevalence estimates, undiagnosed fraction of HIV and life expectancy and burden of disease);
- 2) a systematic review updating the current knowledge about HIV/STI preventive interventions targeted at MSM in Europe, summarising the effectiveness of interventions as well as gaps in the evidence base and the need for better outcome evaluations;
- 3) studies on burden and prevention among PWID (in cooperation with EMCDDA) and migrants;
- 4) study on the public health benefit of partner notification;
- 5) study on feasibility and EU added value of HIV ARV monitoring;
- 6) studies on HIV testing policies, practices, outcomes and barriers in the EU.

Despite the heavy effort, some limitations have been reported in the impact of some of these activities. It is noted that other international organizations cover extensively the field of estimating burden of disease, taking the leadership in that area. Another ECDC project on a more accurate picture of HIV prevalence in Europe was launched in December 2012¹⁵¹ and, therefore according to some, a reliable model of prevalence rates is still missing at the European level. Conversely, others more policy-oriented were better received: it has been reported that activities on MSM, migrants and to more limited extent PWID have had some impact for advocacy purposes in Northern and Central Europe, while those on testing mainly in the Mediterranean. However, only in a very few cases this could be traced back to ECDC by means of quotations or other forms of hard evidence.

10.4.5 Evidence of Improved Capacity to Prevent and Control Diseases

In the field of HIV this has mainly materialised in guidance on HIV Testing, prevention policies for IDU in cooperation with EMCDDA. Support to MS has also included behavioural surveillance related to HIV and STI in epidemiologically relevant sub-populations through the development of a toolkit and related pilot studies.

The release of a standardized protocol for behavioural surveillance and the development of a web-based toolkit and a self-assessment tool was piloted in several MS and twelve of them participated to a follow-up initiative to assess implementation of behavioral surveillance in their countries. However, there remain 13 Countries in the whole WHO/Europe region constantly reporting behavioral surveillance since 2006 and another seven - of which three under ECDC coverage - having intermittently done so in the period considered here, also because of reported resource constraints. There is more limited information on the level of uptake of the collection of scientific advice on options for key infectious disease prevention among IDUs, because final user organizations are often social services. Those who reported some forms of uptake are located in the Mediterranean where the problem is more acutely perceived. This apparently applies also to testing.

¹⁵¹ The development and implementation of a user-friendly model for HIV national prevalence estimates in Member States (including country support and training) was postponed due to an unsuccessful tender: no offer received

III - SALMONELLA

10.5 Overview

Salmonella surveillance is carried out as a part of the Food and water-borne diseases (FWD) programmes set up in 2006 and that has incorporated since 2007 – but with a wider scope¹⁵² - the activities of the Enter-net network that used to cover Salmonella, verocytotoxin-producing *Escherichia coli* (VTEC/STEC) and *Campylobacter* infections only. ECDC complements mandatory food and animal surveillance along the food chain with data from human surveillance. The programmes has been publishing - jointly with EFSA - an annual report on zoonoses (Community Summary Report on Trends and Sources of Zoonoses and Zoonotic Agents in the European Union).

After the transfer of the coordination of the Enter-net network to ECDC, the main priority in 2008 and 2009 was to consolidate, improve and harmonize surveillance and to develop a specific epidemiological platform (EPIS) for information exchange and sending out urgent inquiries. Only starting with 2010 the other key priorities, such as the improvement of laboratory diagnostics and data quality (improved standardization with animal data, external quality assurance, etc.) have entered the agenda. EPIS also went eventually live in March 2010. The DP has then focused its activities in improving the quality of laboratory data, by managing the activities of a molecular surveillance platform¹⁵³ that absorbs a substantial share of its resources. It also involved further strengthening of collaboration with the veterinary stakeholders for animal health¹⁵⁴ and overall laboratory capacity in the Member States by means of external quality assurance (EQA) exercises for serotyping and antimicrobial resistance testing. Other capacity building activities have focused on the provision of specific trainings on particular needs identified in the MS, again mostly to support the development of the molecular surveillance platform. As part of its routine activities since 2007, ECDC has been coordinating the urgent inquiries between Member States for detecting outbreaks of enteric diseases including multinational outbreaks in close collaboration with the FWD members and the other food safety stakeholders like RASFF, EFSA and INFOSAN. In particular, two outbreaks of salmonella were investigated by means of rapid risk assessments in the period under consideration: one of *Salmonella* Stanley (2012) and another of *Salmonella* Agona (2008). Salmonella as such has not been the subject of any specific guidance document or communication tools, but the FWD programmes has contributed to the preparation of a communication toolkit on the prevention of gastrointestinal diseases.

¹⁵² The programme at present covers anthrax, botulism, brucellosis, campylobacteriosis, cholera, cryptosporidiosis, echinococcosis, giardiasis, hepatitis A, legionellosis, leptospirosis, listeriosis, norovirus infection, salmonellosis, shigellosis, toxoplasmosis, trichinellosis, tularaemia, typhoid and paratyphoid fever, variant Creutzfeldt-Jakob disease (subcontracted) , verotoxigenic *Escherichia coli* infection, and yersiniosis.

¹⁵³ A pulsenet-type platform is a centralised tool to collect and analyse pulsed field gel electrophoresis (PFGE) data for *Salmonella* and other FWD. It is based on an accreditation system and on standardized protocols and databases. The system ensures that the same profiles from different countries have the same name. This is to help real time detection of international clusters by linking cases from different countries and also provides information on trends. It basically works as a fast alert system to highlight events deserving further investigation among European food producers.

¹⁵⁴ In April 2008, ECDC and EFSA signed a Memorandum of Understanding. The programme also assigns a great importance to its collaboration with the Rapid Alert System for Food and Feed (RASFF, part of the European Commission), with the European Reference Laboratories for VTEC, *Salmonella* and *Listeria*. EURL-Salmonella was established in 1992 according to the EU Directive 92/117/EC. Since 2006, Regulation (EC) 882/2004 has formed the legal basis for the EURL. Its activities include the organization of annual interlaboratory comparison studies among the National Reference Laboratories (NRLs) for *Salmonella* on the bacteriological detection of *Salmonella* in the presence of competitive microorganisms; the organization of annual inter-laboratory comparison studies on serotyping and phage typing of *Salmonella*; the organization of an annual workshop; the development and standardization of methods; supplying scientific and technical support to the DG-Sanco, the NRLs-Salmonella, as well as third parties.

10.6 Main Findings

10.6.1 Enhanced Coherence between Risk Assessment and Risk Management

The foodborne disease area is mainly regulated at the European level through veterinary measures, an eradication programme and mechanisms for trade bans of food products. Related counterparts at the national level are food safety authorities or veterinary services, and public health authorities take care of risk management decisions typically in case of large salmonella outbreaks affecting the population. This means that ECDC support to coherence can mainly be seen in the area of multi-Country outbreaks and in the identification of the common source of clusters. However, trace-back investigations are mainly the responsibility of food safety authorities and detailed procedures to coordinate investigations between the two branches at the EU level have been missing until the latest Salmonella outbreak. For this reason, concrete operational results in this area are still very partial and substantially untested. So far, the ultimate origin of the outbreak could not be identified with certainty or the existence of clusters confirmed. Risk communication aspects are also extremely sensitive as they might relate to trade restrictions or shifting consumers' behaviour. Actually, there is evidence that RRA in this field have remained under embargo in the EWRS for a certain period of time before being published, because of possible misunderstanding or unintended consequences on the public and the media. So improved coherence is mainly to be seen in better information sharing and enhanced networking among the subjects involved, including in certain MS better information sharing with food safety authorities themselves.

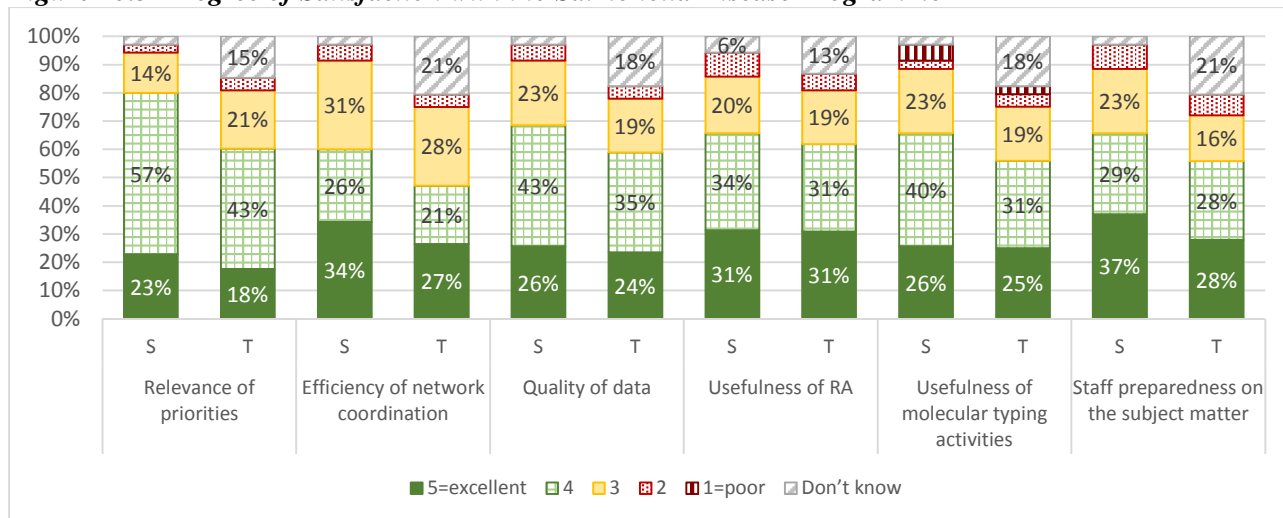
There are diverging opinions on the subject among stakeholders. Some 50% of survey respondents with deep knowledge of the DP think that it has substantially contributed to improve coherence, possibly because of the institutional and operational difficulties mentioned above, and some 40% believe that things have remained more or less unchanged. Those who are more positive on the subject mainly belong to Eastern European Countries, where previous lack of communication between the two branches of Government differently in charge of salmonella was reported as very serious and that ECDC activities during outbreaks has somehow managed to mend.

10.6.2 The General Level of Satisfaction

The contents of the DP are reported as very well known by some 45% of respondents who self-declared salmonella experts, although some one-third of the external experts had no familiarity at all with it. The general level of satisfaction with the Programme is also fairly high, although possibly lower on average than the other DP considered across most (but not all) of the areas analysed. The relevance of the priorities selected is on average rated higher than for the other DPs and the quality of data comparable to that of HIV/AIDS. However, the added value of activities related to risk assessment or molecular typing is not fully acknowledged by some 30% of well-informed respondents, and molecular typing in particular seems to elicit fairly diverging views. Also management-related aspects score relatively lower both in terms of staff preparedness and of efficiency of activity coordination. To this aim, it can be noted that the DP is reported as professionally managed, although stronger in epidemiological aspects than in microbiological ones. This is bound to become a growing gap as the technical complexity of molecular surveillance is projected to increase dramatically over the next few years. Coordination of activities suffer from being perceived as rather top-down and not really participative as it used to be with the Enter-net network. The fact that the DP now has a much wider scope, also contributes to dilute the added value

of discussions, as participants have different backgrounds and not always a common language in terms of interests and priorities among them.

Figure 10.5 - Degree of Satisfaction with the Salmonella Disease Programme



Note: S= respondents significantly familiar with the DP; T = total respondents. Headcount=81.

As far as relevance of priorities is concerned it is worth noting that not all stakeholders agree with the appropriateness of this broader EU policy approach and perceive a lack of appropriate ECDC support instruments in Countries where salmonella is a sub-endemic infection widespread in the population. Apart from these more structural reservations, issues of relevance boil down to the usefulness and added value of the different instruments put in place to that aim. In essence, issues of prioritization are not that much content-wise but more of a budgetary nature and relate to the balancing of resources between aiming at the technological frontier in molecular surveillance or conversely investing more on the Countries lagging behind in more fundamental skills, by devoting more resources in assistance.

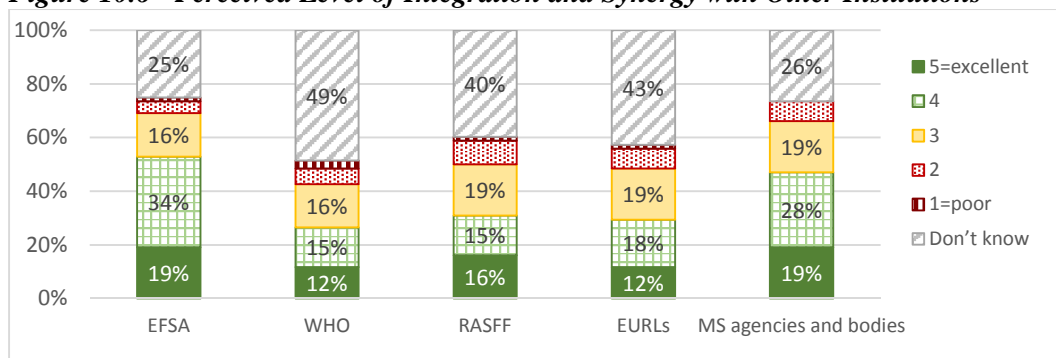
The EPIS platform is frequently mentioned as a fairly good source of added value. It is deemed useful for coordination of online investigations and it has solved some of the problems of the previous Enter-net more informal e-mail-based mechanism that was comparatively understaffed and much less coordinated. The quality of related reporting has also improved as compared to the past, when it was unclear how many notifications on the total were actually posted by the MS, and ECDC acts to complement information coming from RASFF (but integration between the two systems is still considered sub-optimal by some 30% of respondents as reported in the Figure 10.6 below), although as a side effect of lower chaos, participation is possibly less proactive than in the past. However, there is also evidence that EPIS has been used as a benchmark to improve parallel national detecting systems and it is considered for replication at the national level and it had a reportedly lighthouse effect in letting stakeholders understand the importance of data sharing data and cross-access to specific information. Its main shortcoming – of course according to the specialists involved - would be that it is not really conceived for risk managers and related access is not restricted to specialists in the field. So, signals can be misunderstood as threats by over-reactive participants and absent any validation process can rapidly escalate to the EWRS without any real need. Some risk managers have actually reported they purposefully do not want to have access to EPIS exactly for the same reason. Access is also reported as difficult in contexts of low IT capacity.

ECDC RRA reports are considered as valuable secondary sources of information depending on the cases and the level of involvement. Generally speaking, risk management and risk communication decisions are based on national sources because European data in the FWD field have always some

delays as compared to national ones. Since salmonella outbreaks are often self-contained, it is only sporadically that the RRA can contribute some added value in collating the information from several countries. The added value attached to communication toolkits appears to be very Country-specific and limited to low capacity environments.

Integration and synergy with WHO and with relevant national agencies and bodies is deemed less problematic than in other areas, but that with EFSA remains perceived as slightly more complicated than with EMCDDA in the field of HIV/AIDS (tab. 10.13)

Figure 10.6 - Perceived Level of Integration and Synergy with Other Institutions



Note: Headcount=81

Detailed figures on the *allocation of resources* are available for the FWD programme as a whole (tab.10.5). The amount of resources devoted to FWD in the period have slightly increased in relative terms from 4.2% to 4.5% of Title 3 budget but slightly decreased in absolute figures. There are huge shifts in the allocation of resources between the different areas likely to depend on internal allocation of responsibilities within the ECDC matrix structure. In particular, resource allocated to surveillance activities have decreased from € 640,000 to € 270,00, while those for scientific advice increased correspondingly from € 90,000 to € 450,000. As was the case with HIV AIDS communication receives a small but constant € 30,000 budget. Some 70% of procurement expenditure is laboratory related and contracts represent some 30% of the total. According to 2012 budgetary figures, the average tender would be particularly low in size and worth less than € 30,000, which appears hardly efficient administratively-speaking.

Table 10.5 - FWD Disease Programme. Budgetary Allocations by Area

Area of Activity	2011	2012
Surveillance	643 266	267 000
Preparedness and Response		
Scientific Advice	90 000	453 900
Training		35 000
Communication	30 000	30 000
ICT		
Crisis Centre		
Translations		
Meetings	149 400	126 200
Country Cooperation		
Library		
TOTAL	912 666	912100
<i>As a % of Title 3 budget</i>	<i>4,2%</i>	<i>4,5%</i>

Operationally-speaking the FWD programme has been one of the major contributors to reduce overall ECDC operational efficiency through cancellation or postponement of activities as demonstrated in the table 10.6 below, although this is not specifically referred to salmonella in particular, but to

general FWD reports and surveys of which salmonella was a component and to activities related to listeria.

Table 10.6 - Implementation of the FWD Work Programme in the 2008-2012 Period

Year	Total	Completed	Delayed	Postponed	Canceled	Partially
2008	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
2009	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
2010	17 (8%)	11 (6%)	4(50%)	0	2(50%)	0
2011	9 (5%)	7 (4%)	0	1(25%)	0	1(20%)
2012	18 (8%)	17 (8%)	0	1(14%)	0	0

Note: absolute number of activities and () share of the total.

10.6.3 Evidence of Improved Scientific Understanding

The seroepidemiological study on salmonella was still ongoing at the end of 2012 so it is unfit for use in this evaluation.

10.6.4 Evidence of Improved Capacity to Prevent and Control Diseases

Improved capacity to prevent and control diseases is tantamount in the case of salmonella to assessing the specific usefulness of laboratory molecular typing methods and techniques and of EPIS. Molecular surveillance can be considered as a best practice methodology but presupposes an even and comparable level of underlying surveillance data to be really effective. The quality of molecular surveillance has certainly improved across Europe over time. However, if a capillary surveillance network is not really in place at the national level, the methodology can be misleading and cluster identification can become controversial to the specialists involved, as related baseline data for reference are missing. In other words, under these conditions the information provided by molecular surveillance would be a necessary but not sufficient condition to draw conclusions (e.g. Salmonella Stanley), which would decrease its added value for investigating cross-country outbreaks, as compared to other more homogenous surveillance contexts. So, any vision of making molecular surveillance more sophisticated and close to the technological frontier (e.g. genomics, genome subtyping, etc.) would clash against the fact that the current TESSy data are not really conducive to clustering because of the intrinsic limitations of the underlying national surveillance systems. As long as these constraints are not removed and many MS will continue to have a weak infrastructure for surveillance, there is the risk that these activities are de facto outweighed in its impact on cross-border investigations when compared to their real practical added value is apparent.

Actually the bulk of the added value reported by survey respondents is related to the fact that the combination of molecular surveillance and EPIS have made them aware of national outbreaks they were unaware before, when cases reported in other Countries of serologically rare types were also tested domestically and discovered in small clusters.

10.7 Conclusions and Recommendations

Evidence	Findings
<p>Enhanced Coherence between Risk management and Risk assessment</p> <ul style="list-style-type: none"> ECDC risk assessments confirmed as a widely used source of information for risk management across Europe although more so for influenza than salmonella. Recourse to risk assessment for HIV is a residual activity; 	<p>The coherence between risk assessment and risk management has increased overall during the period, while risk communication aspects</p>

<ul style="list-style-type: none"> • No instance of disagreements on contents reported. Risk management at a variance with risk assessment attributed to political pressure; • Timeliness reported as the main factor hindering further coherence; • Risk communication aspects more controversial as also witnessed by some instances of embargo before publication. 	<p>remain more controversial in areas with potential consequences on restriction to travel and trade. Impact on salmonella was hindered by the lack of a clear procedure to coordinate with EFSA and remains to be tested.</p>
<p>The General Satisfaction with the Disease Programmes</p> <ul style="list-style-type: none"> • General satisfaction with the disease programmes positive although with notable variations across DP and by subject area; • Available information does not put stakeholders in a position to judge on the appropriateness of allocation of resources; • Dissatisfaction with prioritisation of activities is not captured by the IRIS system, but relates to how priorities are identified and proposed at the DP level; • Overall satisfaction with staff skills and coordination of activities is fairly high, but appears more problematic the more specialised a field becomes in terms of laboratory and microbiological surveillance; • Problems with tendering and availability of staff are the most frequent cause of delay in programme implementation and operational efficiency. 	<p>The outputs of the disease programmes are generally recognised a good added value, although this can vary from case to case and the DP programmes themselves considered as well managed. Issues of insufficient synergy and integration with other international organisations appear as the outstanding problem.</p>
<p>Evidence of Strengthening Programming</p> <ul style="list-style-type: none"> • Inconsistencies in ECDC classification of activities and little evident link with strategic objectives. Activities are undertaken on a need basis upon request and justified and rationalised ex post; • Use of outputs mainly to be found at the European level; • Evidence of impact on the policy programming process mostly at the European level. Some more impact on MS monitoring practices; • Level of effort highly variable by DP and almost nil in some areas. 	<p>Most ECDC activities in this area have been geared towards the European Commission that appears as ECDC main client in this respect. To this aim some stakeholders voice the need to further strengthening the networking component by giving more emphasis to sharing of policy experiences.</p>
<p>Evidence of Improved Scientific Understanding</p> <ul style="list-style-type: none"> • By far the weakest area in terms of initiatives launched, but for the HIV AIDS DP where most of them were concentrated; • Impact of more theoretical initiatives hardly reported at the MS level, more visible for more policy-oriented ones that however represent a peculiar ECDC definition of scientific understanding. 	<p>The lack of any objective criteria or pre-allocation of funds by strategic objective have left the improvement of the scientific understanding of the disease determinants as the area deserving more strengthening in most of the DP considered. However, the relevance of such activities could also appear potentially contentious to some stakeholder.</p>
<p>Evidence of Improved Capacity to Prevent and Control Diseases and Improved Preparedness and Support Against Outbreaks</p> <ul style="list-style-type: none"> • Level of effort variable by DP; • Patterns of use highly diversified on a geographical basis and more evident in the Mediterranean and in Eastern European countries; • Activities related to Improved Preparedness and Support discontinued over time. 	<p>The capacity of preventing and controlling diseases would increase if ECDC outputs were accompanied by strengthened parallel technical assistance activities and more on-hands support.</p>
<p>Conclusion and Recommendations</p>	
<p>The coherence between risk assessment and risk management has improved, but remains politically controversial in areas with potential consequences on restriction to travel and trade. (<i>Evidence medium, priority medium</i>)</p> <p><i>Recommendation.</i> There is little ECDC can do to further improve overall coherence between RA, RM and RC, but marginal improvements on specific deliverables such as for instance the timeliness of the influenza seasonal risk assessment. Effectiveness of procedural agreements with EFSA to be monitored in the future</p>	

Most ECDC policy-related activities appear heavily geared towards the European Commission that appears as ECDC main client in this respect. To this aim some stakeholders voice the need to further strengthening the networking component by giving more emphasis to sharing of policy experiences. (*Evidence medium, priority medium*)

Recommendation. The establishment as part of the ECDC intranet of a sort of repository where all those concerned can share documents, analysis, etc. could be considered. That would allow a smoother exchange of information between countries, but it is unclear the extent to which this would overlap with already existing tools and, most importantly, it is unclear to stakeholders themselves what role should eventually ECDC play in removing the language barrier to cross-fertilisation of experiences

ECDC advocacy role in steering surveillance activities appears relatively stronger than in strengthening programming. This also appears to be a sub-product of a mandate more widely recognized as more fully legitimate in one area than in the other. The improvement of the scientific understanding of the disease determinants remains the most underdeveloped area in most of the DP considered. However, the relevance of such activities could also appear potentially contentious to some stakeholder. (*Evidence medium, priority medium*)

Recommendation. It is worth exploring whether more extensive recourse to MS-commissioned mandates could represent a way to improve orientation to client needs. And strengthen impact on policymaking. The capacity of preventing and controlling diseases would probably increase if ECDC outputs were accompanied by strengthened parallel technical assistance activities and more on-hands support at the Country level.

11.MANDATE AND ADDED VALUE

11.1 Overview of Past Recommendations

The previous *external evaluation*¹⁵⁵ of ECDC, carried out in 2008, made a number of recommendations, in particular:

1. develop a sharper *vision and articulate related priorities* that are increasingly driven by stakeholder expectations and needs;
2. translate priorities into a more limited *set of performance indicators* that can be easily monitored and evaluated against the objectives of the ECDC Strategy;
3. *deepen activities* to maintain its sound scientific reputation and provide important services to stakeholders;
4. develop *guidelines* for providing scientific advice *that can be adapted to the national policy context*;
5. clarifying the roles and responsibilities of the European Commission, the ECDC (and other EU agencies) and the Member States with regard to *risk assessment and risk management*;
6. *improve efficiency by establishing more coordination between the functional units* and horizontal disease specific programmes based on a more cohesive approach;
7. continue to *improve management information systems*, project management systems and supporting work flow tools to support the efficiency of working processes and implementation of operational activities;
8. continue the ongoing process of *formally delegating some of the daily management activities* of the Director to a lower level in the organization;
9. further improve a *well-balanced input from all members in the Management Board* and its focus on strategic issues;
10. provide continuous attention to the necessary support from the counterparts (in particular the Government of Sweden) to *make Sweden an easier and better place to work and live* for staff of the ECDC;
11. keep *building on the cooperation with all relevant stakeholders* (e.g., regarding risk communication)
12. clearly define the *responsibilities and the tasks of collaborating partners*, for example by preparing joint work plans;
13. legislation should clearly define the terms “*scientific advice*” and “*competent body*” in the Founding Regulation;
14. consolidate and build on *existing activities within the remit of ECDC’s current mandate* in the coming five years.

In response to the evaluation report, the MB approved a document endorsing most of the related conclusions and formally addressing the related recommendations with the notable exception of that on the functioning of the management board itself because it had revealed a lack of understanding on how the Board worked in practice. In particular, it was commented that the composition of the MB was determined through political decisions in the MS. The comments on MB need to focus on strategic rather than operational issues were also only tentatively addressed. As mentioned elsewhere in this report an attempt was made at creating a steering committee within the MB itself, but the proposals was subsequently rejected because of insufficient consensus among members and concerns about insufficient participation. Due to the heavy organisational restructuring in 2010-11, the mid-

¹⁵⁵ ECORYS Nederland BV, “External Evaluation of the ECDC”, 15 August 2008. http://www.ecdc.europa.eu/en/aboutus/key%20documents/0808_kd_external_evaluation.pdf

term external evaluation exercise was not carried out and was replaced by an internal organisational review exercise aimed at eliciting views to support restructuring.

11.2 Degree of Uptake of Past Recommendations

The current evaluation takes place after ECDC has approved its next multiannual programming document. A strategic vision for the steering of the Centre activities in the next few years was developed in that occasion with an extensive debate also with the contribution of external experts. During the rest of the evaluation period considered here a number of sectorial strategies were approved, articulating a more detailed (but also inevitably partial) *vision* of the ECDC that was not always possible to be found clearly described in the first SMAP. A number of strategic decisions (e.g. the decision of heavily investing into laboratory support) with significant impact on the life of the Centre were well known only within restricted ‘circles’, but remained somehow ‘hidden’ in budgetary allocations and poorly formulated in terms of clear, quantifiable objectives understandable also by outsiders.

Better mechanisms to *incorporate stakeholders’ expectations and needs* into the prioritisation process have been introduced and mainly consisted of the successful IRIS scoring initiative. Other forms are, however, still underdeveloped. Formal public consultations of strategic documents, for instance, have only recently been introduced – also in line with greater recourse to public consultations in general. ‘Customer satisfaction’-like surveys aimed at gathering operational feedback on quality features are foreseen starting from 2015. While the findings of this evaluation exercise show an overall good level of satisfaction among stakeholders with the relevance of ECDC priorities, this does not necessarily apply to the transparency of the underlying mechanism, and it can therefore be concluded that stakeholders would still like to have a greater say in the way these are formed.

It is only with the new multiannual programming document that the issue of *linking priorities with a set of underlying performance indicators* has been more convincingly addressed than it was in the past. The process still has to be extended to the various sectorial strategies underneath. In this respect attention should be paid to avoid unnecessary proliferation of indicators and to keep the core set of figures to be monitored as small and concise as possible. Apart from these new developments the way the previous indicators were monitored and reported in the period evaluated here can be considered as far from best practice. Related figures were never included in the ECDC annual reports and indicators found impossible or too difficult to calculate never proposed for revision. This contributes to create the overall impression of an activity undertaken for formal purposes only, with little traction on the concrete strategic steering of activities, and without a deep conviction of its usefulness. The decision not to have a mid-term evaluation should be understood also in the light of this, because such exercises can help foster reflection when a strategic monitoring system is in place, but their value becomes less apparent when these systems are not there.

ECDC has certainly *deepened its activities* and further built its scientific reputation among stakeholders, as discussed in Section 3 (on Scientific Advice), but the provision of services and quality contents to its stakeholders is not always strictly in line with their operational needs. The guidelines for the provision of scientific advice to the *national policy contexts* has not particularly improved over the period and remains a problem - pending, among others, a clarification on the role of the external experts in the preparation of these guidelines. There continue to be requests that these guidelines should be better adapted to the local contexts also eventually by means of technical assistance, and other on-the-field activities. A certain resistance can still be noted among stakeholders

as to ECDC issuing guidance documents out of concern that local conditions are not sufficiently taken into consideration.

According to some, progress in the clarification of roles and responsibilities of the various stakeholders involved with regard to **risk assessment and risk management** can be found in the new Regulation on Cross Border Threats. In the period reviewed here, there remained different views on the ultimate relevance of the subject also based on the features of the different national institutional models and on how such distinction should be practically framed. There is a broad agreement on the principle that ECDC should leave decision makers and risk managers with a set of available options and refrain from indicating any such thing like the only possible solution, but how this broad principle materializes in concrete situations is still subject to different and ‘case-by-case’ interpretations. It remains to be seen whether the new Regulation will bring about some more clarity and consensus or ways should be found to exploit the room of flexibility available to accommodate the different stakeholders’ needs.

By establishing a matrix structure ECDC certainly followed up the recommendation of establishing more **coordination between the functional units and horizontal disease specific programmes** based on a more cohesive approach, although this also had unexpected consequences and created side-problems. However, impact on operational efficiency and overall cohesiveness has been hindered by problems with internal communications that have not been fully addressed yet.

Much in the same vein, ECDC has recently started prioritizing the improvement of the **management information systems and of the project management systems** and supporting workflow tools to increase the efficiency of working processes and of operational activities, and many important developments are already in the pipeline. That this happened relatively late in the evaluation period can be partly explained by the overall rescheduling and postponement of planned work caused by the organizational turnaround and by the impact of the pandemic. Substantial work was also devoted to providing continuous attention to the necessary support from the Government of Sweden to make **Sweden an easier and better place to work** and live for staff of the ECDC and most, although not all, of the problems reported at the time can be considered as solved.

Possibly, the area where recommendations have been followed up the least so far regards the process of **formally delegating some of the daily management activities of the Director** to lower level in the organizations, because there still remains substantial centralization of operational decision-making at the level of senior management staff and, as anticipated in the paragraph above, the matrix reform could have even contributed to make things worse in this respect. However, also in this area, possible redressing measures are already being considered by ECDC.

ECDC has certainly kept building on the **cooperation with all relevant stakeholders** and notable improvements have been reported in this respect. Some progress was also achieved in defining the responsibilities and the tasks of collaborating partners, although preparation of joint work plans can be reported only with a few international/European partners. Substantial effort has been devoted to better defining the concept of **competent body** to improve cooperation at the national level.

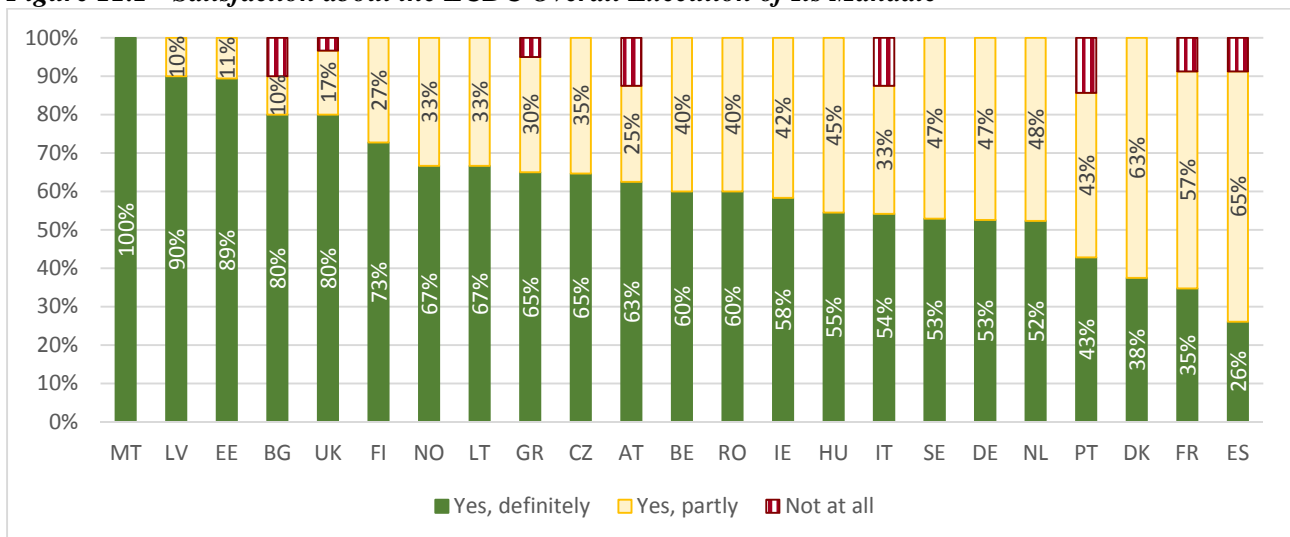
Finally ECDC has certainly abode to the recommendation of **consolidating existing activities within the remit of its mandate** although there have been sporadic instances of work in more controversial areas (e.g. on tissues), to cope with unforeseen information needs.

11.3 Degree of Fulfilment of Mandate and Need for Change

Since different stakeholders have different interpretations of the ECDC mandate also based on the specific needs of their MS and the role they play in the ECDC governance system, it is hardly possible to give a unanimous answer to the question whether ECDC’s current mission, tasks and activities are still regarded as relevant to the needs, or conversely would have to be changed in line with new needs. When asked whether ECDC is interpreting and executing its mandate all in all in a way that is consistent with their expectations, more than half of stakeholders provided a strongly affirmative answer. Positive ratings seem increasing with the respondents familiarity with ECDC. Within this group, lower-than-average appreciation was given by CB representatives. The possible reasons range from the fact that ECDC would not sufficiently take into account the vast differences across Member States in terms of professional, technical and financial resources, to the need to organize workshops, meetings and training courses to a much wider scale, to increase financing for research grants, as well as funding for the different EU reference labs, to the fact that ECDC should have a much stricter cooperation with medical practitioners in the field of communicable diseases - just to mention a few of those voiced by CB representatives.

There are notable geographical variations in the degree of satisfaction among the expert community at large across the different European countries (see Figure 11.1). The degree to which the ECDC mandate fulfilment is perceived in line with expectations is highest among respondents in several new MS as well as in the UK and some Nordic countries (FI, NO). Instead, it reaches quite overt levels of scepticism in Denmark, France and Spain where the relative majority of experts deem it only partially in line with their expectations. The box 11.1 below reports some of the comments made on the reasons behind dissatisfaction (or partial satisfaction). As can be seen, they summarise many of the issues highlighted in this report and often point to insufficiently developed partnership relationships

Figure 11.1 - Satisfaction about the ECDC Overall Execution of Its Mandate



Note: Only MS with more than ten respondents are shown. Total headcount: 441, of which 43 ‘don’t know’ answers (not displayed).

Box 11.1 – Issues with the Execution of Mandate. Comments of Dissatisfied Experts

- *Interaction with countries very remains poor, lack of information in countries about ECDC activities, total absence of ECDC networking activities at the national level, lack of a clear link with improvement of the national surveillance strategy*
- *There is not enough exchange of information on the priorities of the MS to build a workable workplan for all - Work in the area of immunisation, for instance, could be discussed more in details also in the light of national budgetary constraints. There is a need for improved coordination with the MS, specially through the competent bodies and NC.*
- *ECDC does not support sufficiently exchange of information with the national experts. Data reporting via Tessy is disappointing in this respect, as there is no interactive exchange allowing meaningful interpretation of the data reported. Outsourced projects have done better on this point.*
- *ECDC devotes too much effort to standardize procedures and promote QA studies. However, we need first to improve the “science” and gather evidence before establishing procedures and QA.*
- *More resources should be put in surveillance and networking activities;*
- *More active involvement of MS outside Northern and Central Europe.*
- *ECDC needs to be closer to the reality of each MS, of which they have a totally insufficient understanding.*
- *They had better consider the needs of the MS, as in recent years they only see their agenda and expect MS to agree with what they have on their agenda which is not necessarily of importance to the MS.*

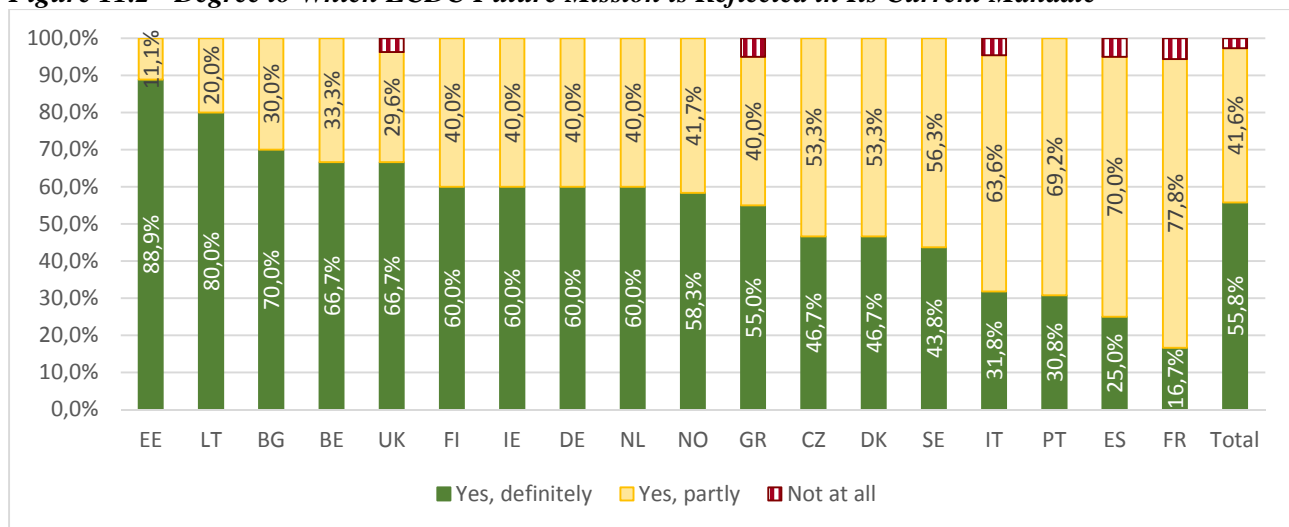
There is much more uncertainty on whether the mission and tasks of the ECDC as currently designed are still in line with future stakeholders’ needs, or should be changed. Differently from the question above the number of respondents who are totally positive on ECDC responsiveness to needs and challenges is roughly equal to that of those who think it is but only in part, and those who have doubts about it, although there is a somewhat clearer positive view in this respect among those who claim to have a high level of knowledge about ECDC and among those with a long familiarity with ECDC. This “*constituency effect*” was also found in the interview programme where the majority of interviewees were against the idea of expanding ECDC mandate towards the surveillance of non-communicable diseases, variously pointing to the need to avoid another ‘public health elephant’ or to leave time to ECDC to consolidate its activities without further major disruptions.

However, the subset of high level respondents whose institutional responsibilities went beyond the field of communicable diseases were much more positive on the idea of expanding ECDC mandate, and found it hard to justify a Centre to cover just 2% of the actual burden of disease across Europe and therefore bound to find itself disproportionately involved with potential “catastrophic” health threats only to justify its existence. They also noted that once the window of opportunity created by the need to institutionalise the ECHI network activities expires and a permanent solution is found to the continuation of its activities, the likelihood ECDC could one day accomplish its original mandate would decrease practically to nil and the alleged disruption of activities would be more than compensated by the fact that the Centre already has a valuable expertise in incorporating networks. Moreover, in their view the main benefit is that this would result in an overall more balanced institution than it currently is.

The patterns already highlighted for the question above are confirmed, and AF members are much more positive than CB on the fact that ECDC mission is still in line with needs. Moreover, there remain huge geographical variations across the expert communities of the different countries as reported in the Figure 11.2 below. While respondents from the UK, Belgium and some new MS appear persuaded overall that ECDC mission should remain as it is, because broadly in line with needs, more need for a change is voiced by France, in other Mediterranean countries (IT, ES, PT), and in some Nordic countries (SE, DK) where the majority of respondents see a clear need at least for a partial change in ECDC mission. The driving forces behind these requests for change are however different: while in the Nordic Countries respondents would like to see stronger provisions

to have less duplications of work and build stronger synergies with WHO and national bodies alike to cope with budgetary constraints, and call for a substantial strengthening of the vaccine effectiveness assessment component and a much clearer ECDC mandate in this field, in the Mediterranean and in France prevail the requests for a stronger mandatory harmonisation of surveillance systems to increase their comparability and for expanding the mandate of ECDC to non-communicable diseases (see Box 11.2). It is worth noting that the issue of ECDC involvement in preparedness and response activities in the light of the recently approved EU Regulation on common threats was spontaneously raised mainly in Southern Europe. However, during the interview programme, interviewees, while having different opinions on the overall political opportunity of regularly involving ECDC in this area, had a fairly open attitude on the fact that that ECDC could represent one of the several bodies the HSC committee could turn to in case of need for technical assistance as was sporadically done in the past and that this therefore represented a non-issue in terms of ECDC future mission.

Figure 11.2 - Degree to Which ECDC Future Mission is Reflected in Its Current Mandate



Note: Only MS with more than ten respondents are shown. Total headcount: 435, of which 62 ‘don’t know’ answers (not displayed).

Box.11.2 - Need to Update ECDC Mandate. Comments of Experts

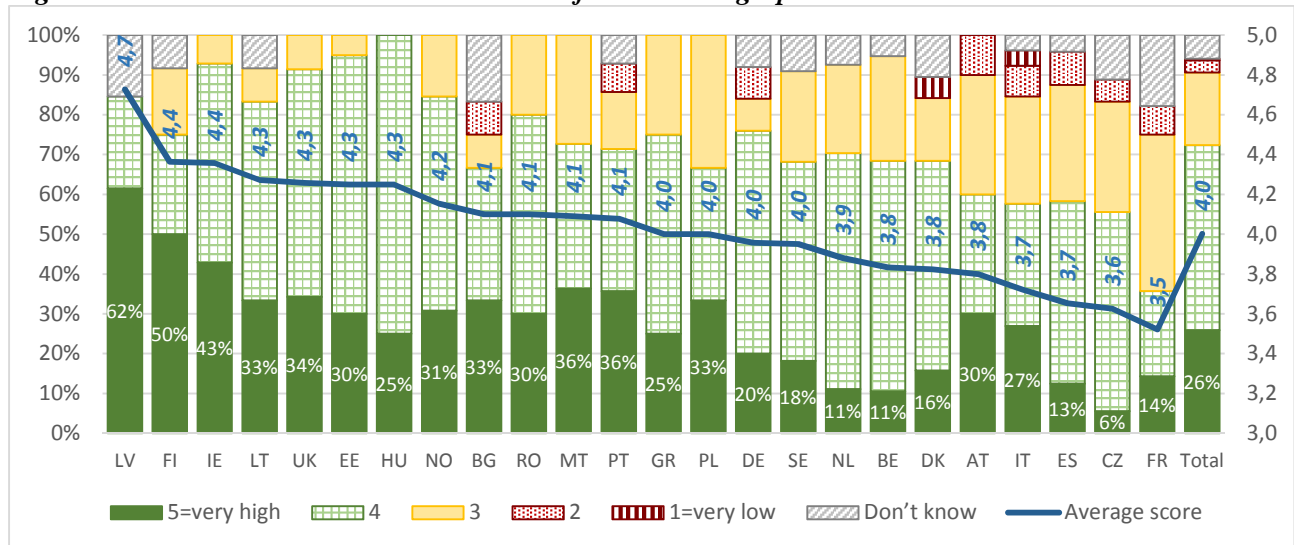
- *Surveillance and reporting: less duplicate work (Nordic Country);*
- *Vaccine impact and safety evaluation should be high on the ECDC mandate. Now they are not. What do we need surveillance for if we do not understand what the intervention in place produce? (Nordic Country);*
- *Vaccine effectiveness studies should be more clearly supported by ECDC (Nordic Country)*
- *Much clearer coordination with WHO to reduce overlapping tasks (Nordic Country).*
- *ECDC should also work in the field of non-communicable diseases. (Southern Europe)*
- *Other health risks, in addition to infectious, should be included in ECDC mission (Southern Europe)*
- *ECDC contribution need not to be limited to infectious diseases only (France)*

11.4 Perceived Sources of Added Value and Trade-Off with Workload

The degree of consensus that ECDC’s current mission, tasks and activities creates added value for national stakeholders and other international bodies is fairly high (average score 4 out of 5), and appears even higher among those who claim to have a good knowledge of the Centre (where it reaches as high as some 90% of respondents). Stakeholders generally believe that added value has steadily

increased over time and this belief is more deeply entrenched (over 80% of positive feedback) among those who have a longer experience with the Centre and therefore should be in a better position to judge. However, also in this case the feedback collected is fairly diversified on a geographical basis and unevenly distributed across Europe. As can be seen in Figure 11.3 below, the extent to which ECDC work is perceived to have added value to the national stakeholders and international partners is highest among the expert community the New MS (especially the Baltic region) in UK and Ireland and in , and then slowly decreases until reaching its lowest point in certain Mediterranean Countries, the Czech Republic and France, where respondents' consensus on the fact that ECDC represents a source of added value reaches roughly half of the average.

Figure 11.3 - Perceived Overall Added-Value of ECDC. Geographical Breakdown



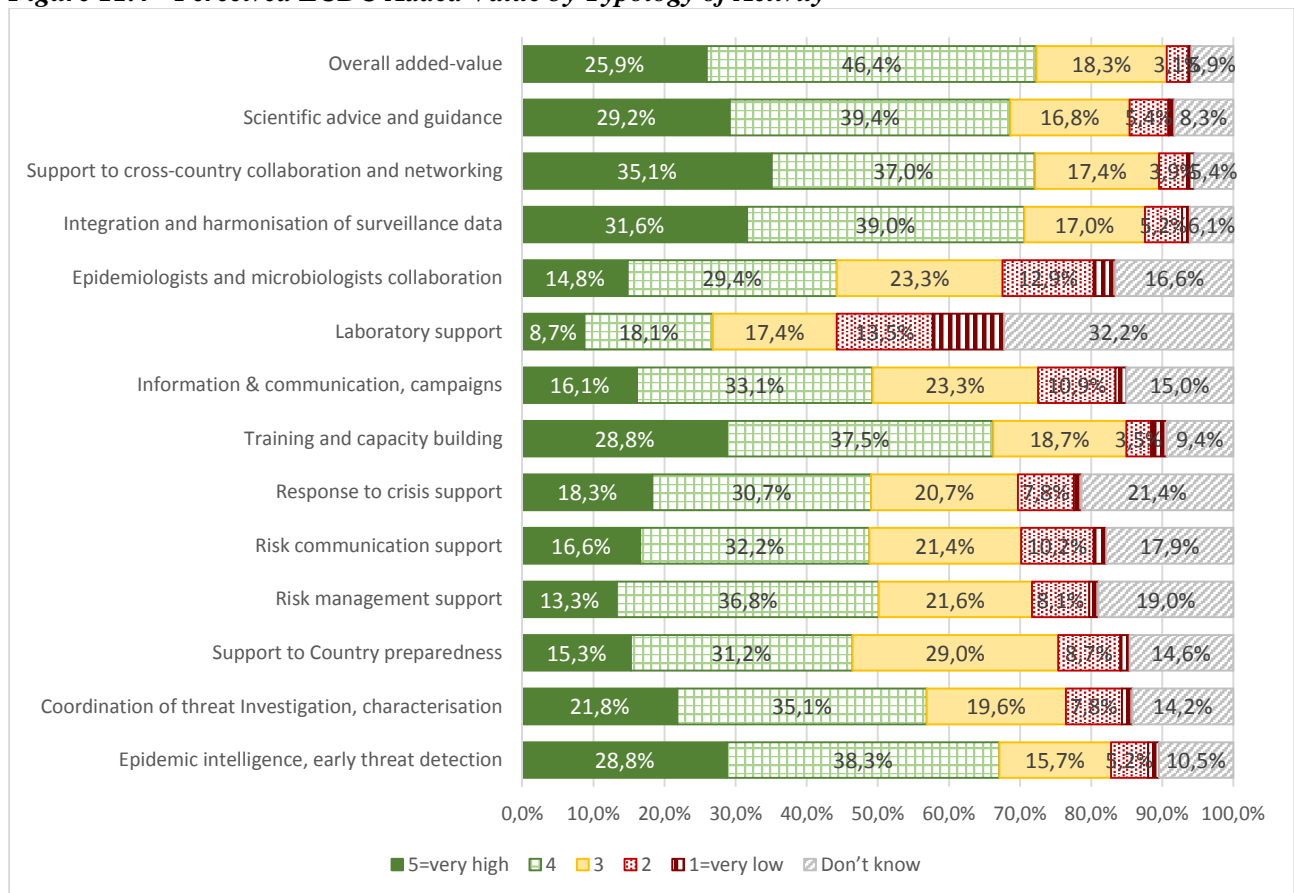
Note: Only MS with ten respondents or more are shown. Total headcount: 59. The average score is calculated on non-agnostic answers (headcount: 432).

In fact, there can be several different reasons behind this different perception across Europe:

- *Economies of scale:* small countries are more likely to perceive added-value from ECDC activities because these replace the economies of scale they cannot benefit from internally. Also low capacity Countries tend to value ECDC activities comparatively more for the same reason;
- *The point of view:* respondents in certain Countries (notably the UK and Ireland) tend to judge ECDC performance and added value from a broad European perspective and with reference to impact on the EU as a whole rather than as the benefit they directly draw from ECDC activities, so for instance, Countries particularly keen to attach importance to networking and liaising with colleagues abroad tend to give a higher score to added value than other interviewees based elsewhere who appeared more focused on their own domestic impact and added value.
- *The different assessment given to specific components of added value.* As will be better explained in the paragraphs below certain ECDC activities are generally considered good source of added value, but some specific Countries have more reservations on them So for instance, the added value provided by the integration and harmonization of surveillance data is poorly perceived in France where they would prefer a much stronger legal harmonisation framework. Other Countries particularly in Southern Europe have a less favourable opinion on the added value provided by partnership and cross-country cooperation or by information and communication activities that can often appear as out of context in local conditions. Others, particularly in Northern Europe still have strong reservations on the relevance of support to risk management or support to risk communication activities as sources of added value.

As the figure 11.4 below demonstrates, there are ECDC activities more clearly perceived as sources of added value than others because of the wider consensus on them both in geographic terms across Countries and outside the inner circles of related experts within Countries whose opinions are summarised in the relevant chapters. So it can happen that the average perception of added value in a given activity (e.g. information and communication and support to campaigns) is not outstanding, but nothing hinders the same single to be scored with the highest added value in a given MS. So, generally speaking, networking per se as well as of all activities related to the provision of scientific advice, the harmonization of surveillance data, training and capacity building, and epidemiological investigation and early threat detection. The added value of preparedness and support activities is less apparent to stakeholders in certain MS and that of communication and information and of support to risk communication is also more variable and less apparent outside the restricted circle of specialists. By far the most problematic area appears that of support to laboratory activities, where both the share of respondents not sufficiently informed to reply is very high (including those with a long familiarity with ECDC) and where those who do, appear much more sceptical about its added value than in other areas. However, also in this case there is clearly a professional bias in these replies because the survey sample is skewed towards public health specialists and epidemiologists, but even when the responses of microbiologists are extrapolated from the rest for comparison purposes their expert opinion on the added value of ECDC activities in this area remains comparatively low (43% of positive feedbacks, overall) when compared to other areas of activity.

Figure 11.4 - Perceived ECDC Added Value by Typology of Activity

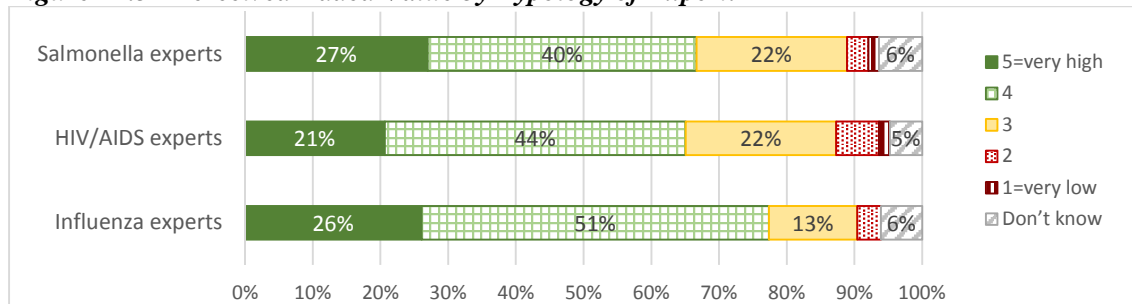


Note: headcount=459

The perception of added value tends to vary also by disease programme and area of specialization of respondents, broadly reflecting the perceived quality of underlying surveillance data. So it appears

higher among influenza specialists (see Figure 11.5) than among HIV/AIDS or salmonella ones. The heavy polarization of the latter result, however, depends also on sample composition, and, again, reflects the fairly diverging views that epidemiologists and policymakers on the one hand and microbiologists on the other hand have of the added value of laboratory support activities and molecular typing for salmonella. The Box 11.3 below summarizes evidence gathered from the case studies.

Figure 11.5 - Perceived Added Value by Typology of Expert.



Note: headcount HIV=63; Influenza=115; Salmonella=63.

Box.11.3 - Perceived Elements of Added Value. Evidence from the Case Studies

Influenza. There is a general consensus that the surveillance data on influenza are probably the best available in the EU in terms of harmonization and reliability for comparison purposes and they have also improved over time. In addition, RRA and the WISO represent relevant activities and good sources of added value. The role played by ECDC in coordinating networks and facilitating networking and organizing meetings is also perceived as an added value *per se*. There are more diverging opinions on the ECDC involvement in the I-MOVE project activities and about the importance and added value of communication support activities in general. Provision of guidance and capacity building for pandemic preparedness purposes also vary a lot among interviewees in their perceived added value.

HIV. The perceived added value of HIV/AIDS activities tends to vary with the level of capacity existing in a Country and the perceived need for advocacy support. So instances can be found of extremely high added value reported (particularly when ad hoc deliverables Country visits or RA reports were received) together with others where added value mainly lies in networking with peers. The annual report and guidance on HIV testing are the items where interviewees more frequently recognize added value, while opinions are more divergent in the other areas also depending on differences in the underlying epidemiology. Cooperation with EMCCDA has also been highly appreciated. Also as a result of the perceived lack of a clear focus of activities the role played by ECDC in coordinating networks and organizing meetings is less of an added value than in other areas irrespective of the good quality of the underlying day-to-day management. Country visits and country assessments are also generally recognized as highly appreciated sources of added value.

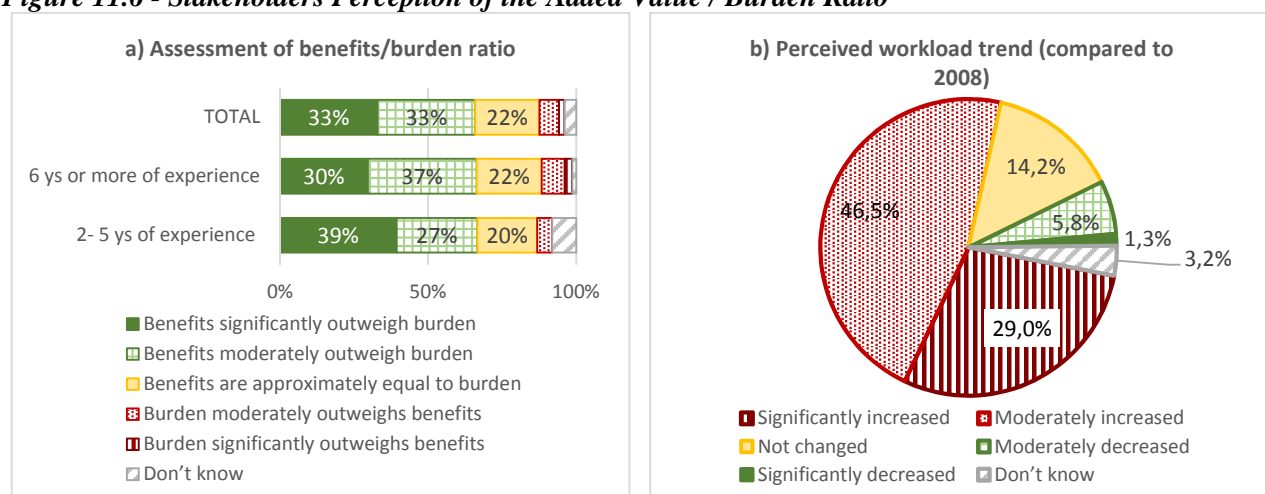
Salmonella. The networking process is often reported as top down and not really participative as it used to be with the Enter-net network. The fact that the DP now has a much wider scope, also contributes to dilute the added value of discussions on the programming of activities, as participants with different backgrounds cannot always find a common language. The EPIS¹⁵⁶ platform is the most frequently quoted source of added value and even considered among the best ECDC products overall. It is deemed useful for coordination of online investigations and it has solved some of the problems of the previous Enter-net more informal e-mail-based mechanism that was comparatively understaffed and much less coordinated. Generally speaking, risk management and risk communication decisions are based on national sources because European data in the FWD field have always some delays as compared to national ones. Since salmonella outbreaks are often self-contained, it is only sporadically that the RRA can contribute some added value in collating the

¹⁵⁶ EPIS has been used as a benchmark to improve parallel national detecting systems and it is considered for replication at the national level and it had a reported lighthouse effect in letting stakeholders understand the importance of data sharing and cross-access to specific information. Its main shortcoming would be that it is not really conceived for risk managers and related access is not restricted to specialists in the field. So signals can be misunderstood as threats by over-reactive participants and absent any validation process can rapidly escalate to the EWRS without any real need. Some risk managers have actually reported they purposefully do not want to have access to EPIS exactly for that.

information from several countries. The added value attached to communication toolkits appears to be very Country-specific and limited to low capacity environments.

The added value generated by ECDC is generally recognized as outweighing the *workload requested on stakeholders* and partners, although also in this case with notable geographical variations among respondents but with broadly similar patterns across the DP¹⁵⁷. This perception is stronger among those who have established a recent working relationship with ECDC, while those with a longer experience are still influenced by the comparison with the more informal and less burdensome procedures of the Disease Surveillance Networks (see Figure 11.6.a below). In fact, there is overwhelming consensus among those who have a longer experience with the Centre that the burden of cooperating with ECDC has somehow increased over time (Figure 11.6.b).

Figure 11.6 - Stakeholders Perception of the Added Value / Burden Ratio

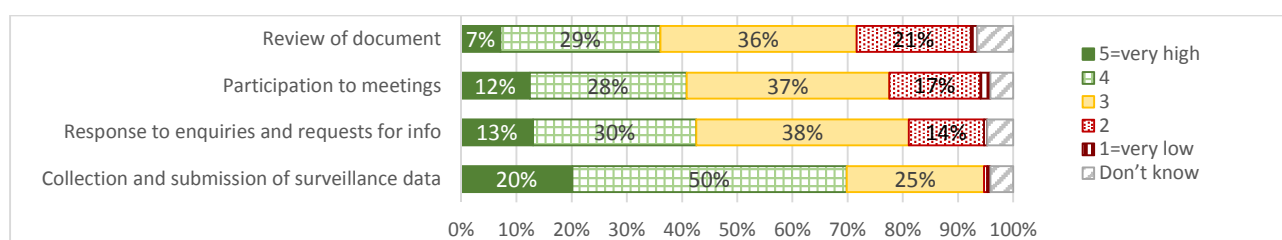


Note: (a) total headcount=258; (b) only answers from experts whose work experience with ECDC dates back to 2008 or earlier. Headcount=155.

The burden of cooperating with ECDC for an average competent body / member of a governance body has been estimated on average in some 33 person days, but again with huge geographical variations and a substantially higher incidence in the Mediterranean where figures can reach also twice the average EU value. The collection of and submission of surveillance data is reported as very burdensome task by some 70% of respondents, while response to enquiries and requests for information and participation to meetings follow in order of importance (42,6 and 40,8% respectively). It is mainly members of the Advisory Forum and the Management Board, as well as the National Coordinators who report considerable time spent in reviewing documents (see Figure 11.7 below). However, burden tends to vary also based on the specific features of the different DP (Box 11.4).

¹⁵⁷ In particular the Influenza experts that find the ratio broadly equivalent are 24% of the total, as against a 28% and 35% who report benefits outweighing burden respectively moderately and significantly. For HIV/AIDS the same shares are 18%, 39%, and 26% and 25, 28% and 40%. Both HIV/AIDS and Salmonella include cases of burden outweighing benefits for respectively 13 and 3% of respondents.

Figure 11.7 - Amount of Work Implied by Collaboration with ECDC



Note: Headcount=260

Box 11.4 - The Burden Required by Cooperation with ECDC. Evidence from the Case Studies

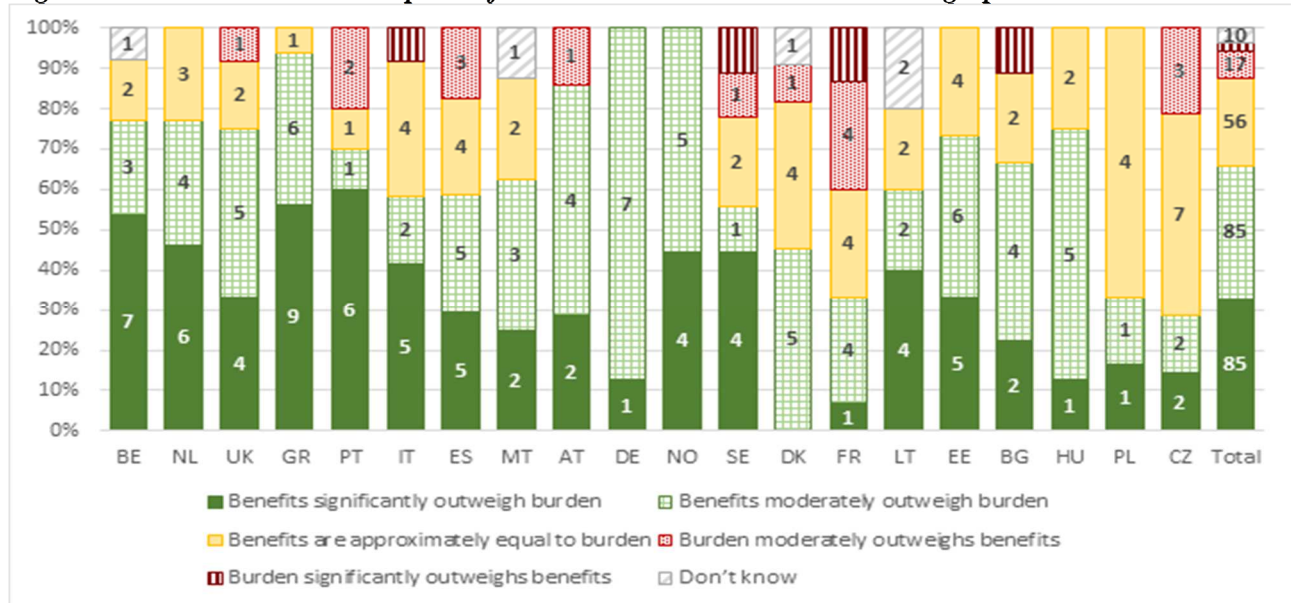
Influenza. Given the frequent reporting requirements, it can reportedly reach 15% of a full staff time. Virology subtyping reporting - although voluntary - is considered very time-consuming. The main cause of concern - double reporting of surveillance data with WHO - was eventually sorted out although with some delay as respect expectations. This temporary double data reporting apart, a positive balance is generally acknowledged between the effort devoted to and the added value received from the DP.

HIV/AIDS. Given the less stringent reporting requirements than in influenza, it can reportedly reach some 5% to 10% of a full staff time and be as high as 15% only for those who are more heavily involved also into parallel subcontracted project-related activities. Surveillance *per se* is not the main cause of concern, but rather the number of questionnaires to be filled in, sometimes with substantial overlapping between different international organizations including UNAIDS/UNGASS. The recent introduction of an ECDC internal procedure to reduce the number of requests for participation to surveys is a welcome although much delayed innovation still deemed insufficient to tackle the full extent of the problem that also draws from proliferation of activities and initiatives not always deemed strictly necessary. However, all in all the added value of the DP is always deemed positive either in terms of net balance from the specific MS perspective or in terms of overall contribution to improving dialogue in the field of HIV in Europe.

Salmonella. Given the quarterly reporting requirements and consultation of EPIS, it can reportedly reach some 5% of a full staff time, plus another 5% for purely FP-related activities. The effort devoted to data inputting and provision of information is not the main cause of complaints, but rather the feedback received in terms of quality of the underlying surveillance data. Only recently, these would have reportedly become if not really comparable at least not fraught with major statistical errors as was reportedly the case in the past. This would have finally contributed to make the resources invested into supporting surveillance at least sufficiently justified by the results achieved. Generally speaking, the participation into ECDC activities is judged worth the effort mainly because of the added value provided by networking (including first and foremost EPIS). A very particular source of added value for participating laboratories is represented by participation to EQA as this can also be used for their ISO or EU certification purposes.

As can be seen in Figure 11.8 below the extent to which it is perceived that ECDC added value more than outweighs the related burden on participants is highest among respondents in Southern Europe, UK, and the Benelux, and then slowly decreases in the other regions until reaching its lowest point in Denmark or France where a majority of respondents report that in their opinion the burden outweighs the benefits. It is interesting to note that the Countries where the physical burden in terms of person time is reported as the highest, such as in the Mediterranean, value its cost the less, while Countries with a high perception of ECDC added value – like in Eastern Europe – also have an acute perception of related financial costs and overall burden. There are very preliminary elements to presume that the complexity of the regional / federal nature of the State and its surveillance information system might work as a burden amplifier and this has been expressed differently in the various relevant MS (which could also justify the very high percentage of respondents that in German-speaking countries believe that benefits only moderately outweigh burden), but no firm conclusion can be drawn from available data.

Figure 11.8 - Stakeholders Perception of the Added Value/Burden Ratio. Geographical Breakdown

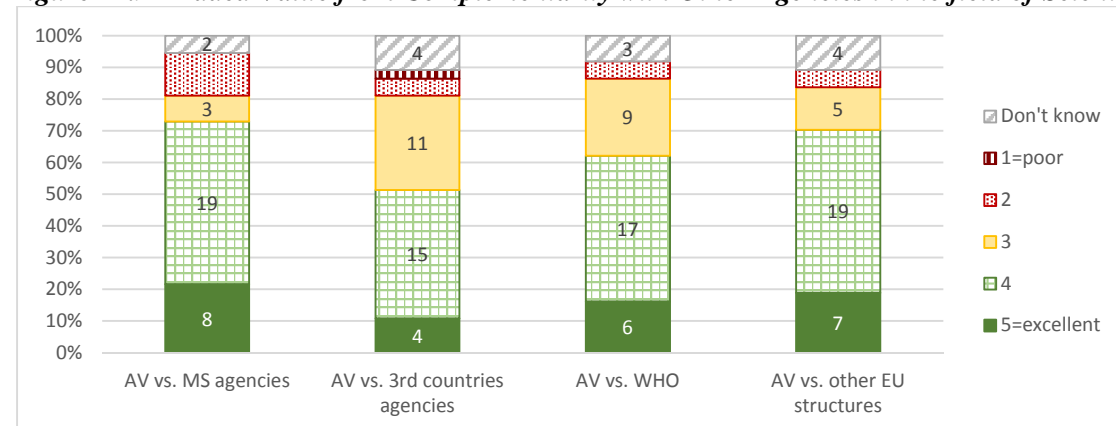


Note: Only MS with more than five respondents are shown. Headcount=258

As an additional rough indicator of the perceived ratio between ECDC added value and related burden on participants, the frequency of attendance to meetings has been considered (as also suggested by some interviewees). The results indicate a certain ‘fatigue’ with attendance of meetings especially among German respondents, and to a lesser extent – and for reasons possibly due to cost considerations - among MS experts in Eastern Europe. As to the rest, data do not particularly correlate with the abovementioned perceived added value / burden ratio indicator.

The added value of ECDC can also be seen in reaching synergies and complementarities with the activities of the relevant national agencies, and other peer agencies at the regional and global level including the European agencies. The obvious example frequently mentioned by interviewees is that of cost savings due to avoided duplication of activities. This added value from complementarity is generally recognised at the national level (although with some notable exceptions), and in ECDC relations with the other European Agencies, but a bit less so in the other cases (Figure 11.9).

Figure 11.9 - Added Value from Complementarity with Other Agencies in the field of Scientific Advice.



Note: this question was addressed only to NFP for scientific advice and AF members. Headcount=37

The matrix organisation and the paucity of information available on *allocation of resources* by area of activities makes it very difficult to draw conclusions on ECDC “value for money” and overall efficiency of operations in terms of perceived added value. The Table 11.1 below reports the

breakdown of expenditure available for 2012 including the number of full time equivalent (FTE) staff allocated to the different areas. As reported elsewhere in this report the amount of expenditure for laboratory support can be roughly estimated in some one-third of the overall expenditure for scientific advice and the disease programmes.

Table 11.1 - Breakdown of ECDC Budget by Area of Activity (amounts in €)

	FTE	Title 1	Title 2	Title 3	Total
Antimicrobial Resistance	12	1 320 528	222 618	1 573 075	3 116 221
Emerging and Vector-borne Diseases	5	514 369	98 990	866 000	1 479 359
Food and Waterborne Diseases	10	1 090 601	184 742	912 100	2 187 443
Influenza	8	848 814	145 677	741 055	1 735 546
Tuberculosis	6	565 128	114 211	647 770	1 327 109
Sexually Transmitted Infections HIV	8	770 995	154 744	933 000	1 858 739
Vaccine Preventable Diseases	11	1 194 513	207 071	1 498 000	2 899 584
Surveillance	23	2 495 023	437 241	1 553 000	4 485 264
Scientific Advice	28	3 054 787	544 053	1 944 000	5 542 840
Preparedness and Response	26	2 692 689	495 116	798 000	3 985 805
Training	13	1 367 753	249 492	4 000 000	5 617 245
Health Communication	43	3 675 355	796 492	1 760 000	6 231 847
Partnerships	8	896 209	154 767	655 000	1 705 976
Leadership	19	1 789 410	1 024 963	15 000	2 829 373
Administration	79	6 632 449	1 834 545	2 365 000	10 831 994
Trainees and Interim		1 344 258			1 344 258
TOTAL	299	30 252 881	6 664 722	20 261 000	57 178 603

Apart from the very special case of partnership, which is not comparable here, expenditure on surveillance appears to be the most efficient area of expenditure in eliciting perception of added value, together with preparedness and response (early threats), scientific advice and training. The amount of resources devoted to health communication (the second most important item in the list and the second largest employer within ECDC) conversely appears disproportionately on the high range when assessed against the added value perceived, together with laboratory support, for which however a distinction should be made between categories of respondent, as it is better perceived by microbiologists. No such ranking is possible for the disease programmes, because HIV/AIDS and Salmonella are component thereof and no budgetary breakdown exists at the level of analysis.

11.5 Conclusions and Recommendations

Evidence	Findings
<p>Degree of Uptake of Past Recommendations</p> <ul style="list-style-type: none"> Evidence could be found of actions taken and changes implemented as a result of most of the past recommendations. 	<p>The current process of MB uptake of evaluation recommendations has proven reasonably effective, although some recommendations have been implemented only at the end of the period considered.</p>

<p>Relevance of Mandate to Stakeholders' Needs</p> <ul style="list-style-type: none"> • ECDC are still generally regarded as relevant but with requests for a much stronger Country partnership component; • Weak consensus that ECDC mission should remain the same; • Requests for change are however divergent in nature and vary also based on geographical area. 	<p>Some of the requests for mission change can be achieved by means other than a regulatory intervention and have already been addressed or are being discussed these days. The main problem is that given their very different nature compromises tend to be made on a minimum common denominator and those who are dissatisfied – for different or even opposite reasons – remain high.</p>
<p>ECDC Activities as a Source of Added Value Outweighing Related Burden</p> <ul style="list-style-type: none"> • ECDC generally perceived as a source of added value although with notable geographical disparities; • Added value perceived on an increasing trend; • ECDC added value generally perceived as more than outweighing benefits although again with notable geographical disparities. 	<p>Communication and support to laboratory activities are those for which evidence of added value is less convincing or at any rate are more controversial among stakeholders.</p>
<p>Complementarities in the Mission with Other Agencies</p> <ul style="list-style-type: none"> • Complementarity with national and European agencies stronger than with international ones. 	<p>There is scope for increasing added value from better synergy and collaboration with WHO. This should not be seen in negative terms of duplication, but also in terms of increased added value from synergy</p>

Conclusion and Recommendations

ECDC appears as particularly inclined to learn from past experiences and has in place adequate provisions to incorporate lessons learnt and recommendations from external evaluations but feedback on progress made is delayed or poorly communicated (*Evidence strong, priority high*)

Recommendation. If mid-term evaluations of ECDC activities are not carried out as was the case in the period evaluated here, then some kind of regular reporting on the progress achieved in the implementation of recommendation could be introduced. This also covers lessons learnt from the pandemics and other more operationally-oriented evaluation exercises.

Stakeholders have often very different understandings of what ECDC mandate should consist of and of the Centre's future mission. This makes it difficult to create any consensus among them. (*Evidence strong, priority high*)

Recommendation Different interpretations of the ECDC mandate and of the need for its expansion are issues political in nature on which an evaluation cannot make a recommendation. What can be said is that for the time being there seems to be no sufficient consensus for any of the proposals made to be fruitfully discussed at the ECDC level within the current constituency, but this might change depending on the level of the decision making process.

There are a number of ECDC activities whose perceived added value is below average. This partly depends on their variable responsiveness to needs across the different MS, on the limited level of effort devoted by ECDC itself in the period, on a priori reservations on their appropriateness or a combination thereof. While most of them have been pursued with limited financial effort, laboratory support and communication in general can be singled out as those where the cost – added value ratio is less apparent to stakeholders (*Evidence high, priority high*).

The ECDC new MAP has already made provisions to scale down risk communication activities while support to laboratories remain a strong priority. It is recommended that both these subjects are closely monitored and possibly evaluated in the next mid-term evaluation.

12. CONCLUSIONS AND RECOMMENDATIONS

12.1 SWOT Analysis

This section summarises the findings of the previous chapters in a final SWOT analysis that could serve as a basis for the subsequent conclusions and recommendations. According to the usual terminology, strengths are defined here as the positive features under control of the ECDC, in other words the areas of positive performance influenced by internal factors. Weaknesses highlight the areas of more negative performance that should be redressed to better align results of activities with expectations. Opportunities and threats represent environmental or regulatory factors outside of ECDC control that can have an impact on its overall performance, respectively as potential drivers for future increased added value of ECDC activities, or as structural triggers of operational inefficiencies. These are first exposed in a summary format in the SWOT diagram below (Figure 12.1), then briefly commented in the light of the findings of the Study.

Figure 12.1 - SWOT Analysis

<p style="text-align: center;">STRENGTHS</p> <ul style="list-style-type: none"> • Good reputation and scientific credibility among peers in core activities. • Products of good professional quality in all areas. • A learning-oriented organization very active in addressing shortcomings and improving performance. • Already quite Internet-oriented and open to the information society. • Good capacity of quickly reacting to health threats and performing in crisis conditions. • Good human capital potential and capacity to deliver. • Good visibility among peers. • Strong attention to inclusiveness and networking aspects. • Clear focus on system rationalization and sustainability. • Successful ‘catalyst’ role in supporting MS surveillance systems overhaul • Fairly recognized independence. 	<p style="text-align: center;">WEAKNESSES</p> <ul style="list-style-type: none"> • Lack of a clear strategic focus with shifting priorities over time. • Complex governance structure poorly conducive to strategic focus • Not fully recognized as a credible or legitimate player in the fields of microbiology and risk communication. • Extremely slow and burdensome management of ordinary activities. • Excessive reliance on informal processes. • Limited overall transparency of functioning, and intelligibility to outsiders. • Poor translation of the appreciation voiced by decision-makers into tangible change. • Limited first-hand intelligence of MS conditions and needs. • Underutilisation of internal expertise. • Uneven recruitment of available expertise across Europe.
<p style="text-align: center;">OPPORTUNITIES</p> <ul style="list-style-type: none"> • Strong demand for networking and partnership at the national level. • Growing need for evidence-based sources for policymaking and policy implementation. • Room to strengthen synergies with European and International organizations. 	<p style="text-align: center;">THREATS</p> <ul style="list-style-type: none"> • Fast technological change hard to cope with. • Risk that ECDC deliverables are used in conflicts on agenda setting at the national level. • Poorly defined boundaries with neighbouring International and European organizations.

<ul style="list-style-type: none"> • Demand for more interactive and internet-oriented deliverables. • Strong demand for technical assistance, capacity building and training activities. • Increased capability of staff to play a more direct role in the production of knowledge. 	<ul style="list-style-type: none"> • Imbalances in the support to policymaking activities, too much driven by Commission needs and too little by MS needs. • Little MS willingness to invest in improving and harmonizing surveillance systems and conducting campaigns. • Increasing budgetary pressures.
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12.1 Strengths

Good reputation and scientific credibility among peers in core activities. There is evidence of ECDC good reputation and credibility among peers in core activities, ranging from the assessment given to scientific advice, the perceived scientific relevance of capacity building activities and the standing of the rapid risk assessments.

Products of good professional quality in all areas. The good quality of ECDC products – professionally speaking - is recognized across the board, even in more controversial areas such as laboratory support (e.g. the EQA) or health communication.

A learning-oriented organization very active in addressing shortcomings and improving performance. ECDC appears strongly oriented to learning by doing. Recommendations from external evaluations are taken into consideration and followed up (e.g. capacity building), improvements in performance are acknowledged by stakeholders in practically all areas of activity. Improvements were also recently made in management process and procedures and others are in the pipeline. Strong willingness to import processes and procedures from peer European agencies and align with recognized best practice in the field (e.g. conflict of interest, product terminology, etc.).

Already quite Internet-oriented and open to the information society. ECDC has already invested in its internet strategy and extensively uses the internet as a dissemination tool. It has ensured management of complex IT tools such as EWRS, EPIS, TESSy that are at the frontier of public health institutes' practice.

Good capacity of quickly reacting to health threats and performing in crisis conditions. ECDC can produce rapid risk assessment at a very short notice and is generally recognized as one of the organizations with the quickest reaction time. Also ECDC support to response during major crises is rated positively, even in the highly controversial field of risk communication. Good general capacity of ensuring quick response to urgent needs.

Good human capital potential and capacity to deliver. Staff skills and knowledge of the subject matter generally deemed adequate to needs although requiring some strengthening in some specific areas. Good capacity of interacting with peers on content issues and coordinating their activities. Good interaction of governance bodies with ECDC senior management staff. Management of scientific processes deemed adequate to needs.

Good visibility among peers. ECDC products widely circulated in its peer community, also thanks to the good visibility and wide echo of *Eurosurveillance* in the scientific community. Visibility and attendance rate of ESCAIDE very high.

Strong attention to inclusiveness and networking aspects. Increased participation and even active participation ‘from low capacity’ countries into ECDC activities. Benefits of ECDC activities more often reported from “low capacity” environments.

Clear Focus on system rationalization and sustainability. Improvements in system rationalization, harmonization and overall sustainability (surveillance, capacity building, EWRS) generally recognized.

Successful ‘catalyst’ role in supporting MS surveillance systems overhaul. Surveillance datasets are still largely incomplete although positive trends are registered thanks to ECDC advocacy role.

Fairly recognized independence. Perception of independence fairly high. Conflict of interest policy deemed definitely adequate. Perceived balanced relationship with scientific societies and NGOs.

12.2 Weaknesses

Lack of a clear strategic focus with shifting priorities over time. Strategic roles envisaged in the 2007-2013 SMAP such as that of initiator of studies or catalyst for research never convincingly implemented. Level of effort highly in achieving strategic objectives highly variable by DP and almost nil in some areas. Activities appear sometimes undertaken on a need basis upon request and justified and rationalized ex post, which led to inconsistencies in their classification and little evident link with strategic objectives. Allocations to certain areas (e.g. preparedness and support) suddenly discontinued, others (laboratory support) boosted on pilot basis without clear benchmarks to be achieved. The drafting of a definitive PH microbiology work plan is quite recent (2012) the same apply to the roadmap for molecular typing integration (2013). Sudden budgetary shifts in the allocation of resources (e.g. capacity building and health communication).

Complex governance structure poorly conducive to strategic focus. Very lengthy governance processes (discussion on language regime lasted several years) and instances of overlapping between governance bodies together with reported involvement in micromanagement issues point to lack of focus on strategic issues, including budgetary allocations and staff development strategy.

Not fully recognized as a credible or legitimate player in the fields of microbiology and risk communication. Overall ECDC credibility and visibility in the field of laboratory support much lower than in other areas and conflicting views on related added value. ECDC not recognised yet as a prime referent at the national level for risk communication and very mixed patterns of partnership in health communication in general.

Extremely slow and burdensome management of ordinary activities. Excessive centralization often reported as a cause of operational delays (even in submitting documents to governance bodies before meetings). Timeliness of scientific advice reports often suboptimal and late compared to needs, surveillance reports published with huge delays, delays in disbursing funds and implementing activities have often fraught overall operational efficiency. Indicators to monitor length of processes only recently and partially introduced.

Excessive reliance on informal processes. Procedures poorly formalized during the period without clear mechanisms in place to check compliance and activities often run on a customary or informal basis. Past sectoral strategies typically lacked indicators and previous SMAP indicators not always gathered and reported, but nevertheless high level satisfaction among ECDC governance bodies with

such weak monitoring and reporting practices. Current organizational arrangements would require more formal information sharing procedures across units that is reportedly the case today. Instances of conflicting instructions received by ECDC and DG SANCO on certain operational issues related to cross-border investigations reported as confusing.

Limited overall transparency of functioning, and intelligibility to outsiders. Decision-making processes not always transparent to outsiders and staff (including, among others, rationale behind outsourcing). Widespread uncertainties about division of labour at ECDC, related allocation of responsibilities among staff and related coordination mechanisms. Difficulties reported in identifying ECDC contact persons for risk communication or external partnership purposes. Confusion made worse by frequent turnover among staff. Consistency of programming with parallel allocation of resources not entirely clear to many stakeholders. Information on how priorities are originated is missing and this is compounded by persisting difficulties in synchronisation with Commission programming.

Poor translation of the appreciation voiced by decision-makers into tangible change. While generally appreciated, ECDC products are not often used by policy makers or necessarily considered useful for policymaking purposes. Attendance of ESCAIDE relatively low among policymakers. Surveillance reports are mostly appreciated for their data quality, much less for their utility for decision-making. Selection of experts for guidance document sometimes counterproductive to increase impact of use.

Limited first-hand intelligence of MS conditions and needs. Too limited first-hand knowledge among staff of MS working environments and needs. On the field missions were very few, especially in recent years, although they are considered useful for policy-making purposes. AF members complaining about the limited possibility given to explain developments at the MS and emerging needs.

Underutilisation of internal expertise. Relatively high staff turnover, reported high levels of dissatisfaction among staff.

Uneven recruitment of available expertise across Europe. MS complain that their PHI and laboratory capacity of networking with peers is hindered by current contractual procedures, so that access to a diversified range of expertise would be suboptimal.

12.3 Opportunities

Strong demand for networking and partnership at the national level. Support to networking and cross-country collaboration is the Centre's work area with the highest perceived added-value, but substantial share of stakeholders moderately satisfied with partnership at the national level. Support to collaboration between epidemiologists and microbiologists is perceived as important and in need for expansion also at the national level.

Growing need for evidence-based sources for policymaking and policy implementation. Requests to broaden the range of sources considered for scientific advice and invest in the gathering of evidence including for cost-effectiveness aspects.

Room to strengthen synergies with European and International organizations. Partnership usually substantially increase the added value of the output for the final users. ECDC materials often used in synergy with European campaigns.

Demand for more interactive and internet-oriented deliverables. Frequently mentioned requests to move from paper reports to more interactive and more frequently updated deliverables.

Strong demand for technical assistance, capacity building and training activities. Demand for capacity building is high, and various MS are also willing to cover costs. Requests to have a more direct hands-on approach in implementation of advice in certain Countries. Demand for simulation exercises also partly unmet.

Increased capability of staff to play a more direct role in the production of knowledge. Strong consensus the current weight of outsourcing should be reduced and in-house expertise strengthened

12.4 Threats

Very fast technological change hard to cope with. Anticipated developments in microbiology represent a challenge for ECDC to keep staff skills updated.

Poorly defined boundaries with neighbouring International and European organizations. Instances of overlapping and duplication still reported by national stakeholders as the main problem area in relations with other International and European organisations.

Imbalances in the support to policymaking activities, too much driven by Commission needs and too little by MS needs. European Commission confirmed as the single largest user of ECDC scientific advice products which might contribute to the perception of ECDC as exceedingly Commission-focused institution.

Little MS willingness to invest in improving and harmonizing surveillance systems and conducting campaigns unless return of investment is demonstrated. The overall burden for furthering molecular surveillance seems beyond what MS are willing to invest unless clear benefits are demonstrated. Ditto for surveillance systems.

Risk that ECDC deliverables are used in conflicts on agenda setting at the national level. Most ECDC scientific outputs can be used for agenda setting at the national level rather than for informing policy, which makes their prioritisation mechanism and the respective role played by Ministries and Public Health Institutes intrinsically controversial. To this aim preliminary instances of possible conflicting relations between policy-driven CCB and surveillance-driven NFP and of challenges to the AF role in selecting priorities can be noticed.

Increasing budgetary pressures. MS are under heavy budgetary pressures to cut resources and see immediate value for money. Limited mechanisms in place to avoid duplication of scientific advice at the national and European level when budgetary constraints and need for savings are more and more apparent.

12.2 Conclusions and Recommendations

Introduction. There are several factors¹⁵⁸ affecting the drafting of conclusions and recommendations from this evaluation, and namely:

- 1) the existence of disagreements among stakeholders as to the scope of future ECDC mission and the relevance of activities in its current mandate in areas where the overall EU legal basis for reference is relatively weak or lend itself to diverging interpretations. In such cases, there is little room for recommendations of any kind, as there is an underlying political disagreements among the actors involved;
- 2) divergences in the perception of ECDC added value not only across countries, but within different professional communities. So the fact that the added value of a given activity is reported on average as not particularly outstanding, does not rule out the possibility that the same activity can be considered the most important source of added value in a given Country or by a certain group of concerned stakeholders. It frequently happened that experts in a given field gave a slightly different (and generally more positive) assessment about the added value of ECDC activities than that perceived by colleagues active in neighboring areas;
- 3) the existence of differences between the subjective degree of usefulness reported by the stakeholders' themselves and the lack of objective impact or apparent use of ECDC deliverables that can be verified from outside observers;
- 4) the fact that this evaluation refers to the 2008-2012 period, and a number of managerial shortcomings related to that period have been recently addressed or are in the process of being tackled also as a consequence of the recently approved new 2014-2021 MAP and of the new Surveillance Strategy, but it is too early for this evaluation to see the tangible results of these actions.
- 5) finally, with the approval of the next MAP a complete set of indicators has already been approved. So the focus here has been, instead of reviewing the whole set and repeating the exercise once more, to see whether additional improvements can be proposed

The conclusions and recommendations presented here are therefore grouped along three main core themes: 1) the perceived added value of ECDC activities; 2) the usefulness of ECDC outputs and possible ways to improve them; 3) management and governance issues, including processes and procedures. They include only those items highlighted in the chapters above for which supporting evidence was categorized as sufficiently strong. Other more tentative recommendations based on weaker or more anecdotal evidence can be found at the end of each chapter, but have not been reported here.

I. ADDED VALUE

Address Areas where ECDC Added Value is Less Perceived. ECDC is generally perceived as a source of added value although with notable geographical disparities across Europe and among different lines of activity. There is strong consensus that added value has been on an increasing trend and, on average, more than outweighs burden for Member States, although again with notable geographical disparities. However, communication and support to laboratory activities are those for which the cost / added value ratio is less convincing or at any rate are more controversial among stakeholders although for very different reasons.

¹⁵⁸ This evaluation was not to make any assessment of organizational aspects in detail, so, whenever apparently relevant, preliminary suggestions for possible future organizational reviews have been left in the main text and are not reported here.

- *Recommendation.* The ECDC's new MAP has already made provisions to scale down risk communication activities while support to laboratories remain a strong priority. It is therefore generally recommended here that both areas should be closely monitored in the next few years and possibly evaluated in the next mid-term evaluation.

More in particular in the field of laboratory support:

Better Monitorable Laboratory Support Strategy. Confidence in the added value from laboratory support activities appears as a divisive and contentious issue and is not openly acknowledged by a large share of stakeholders, although for different and opposite reasons. While some cannot see much concrete informational return from current activities to outweigh the significant budgetary allocations, others complain that the current level of investment is times below the needs. This debate is not helped by the pilot and often explorative nature of ECDC activities so far, the related lack of clear quantitative benchmarks on the objectives to be achieved¹⁵⁹ and underlying criteria to justify such considerable expenditure.

- *Recommendation.* Therefore, the first very obvious recommendation is that ECDC should be more explicit in the quantification of the concrete objectives it wants to achieve in this area, beyond the generic maintenance of existing capacity often reported by interviewees. Transparency in laboratory support will be also enhanced by a clearer structure of the budget.
- *Recommendation* To be able to quantify objectives, ECDC should strengthen its monitoring of the range of laboratory expertise available across the EU – especially in the light of the rapid changes in the landscape of private services. It has carried out a baseline study but has not put in place yet a monitoring system to report on the progress achieved in microbiology laboratory capabilities EU wide, including first and foremost among the laboratories supported.

Keep a Balanced Double Track for Incorporation of Microbiological Data into Surveillance. At a more strategic level, it can be observed that the next MAP is based on the assumption that laboratory techniques and protocols will change radically in the coming years and inevitably new molecular characterization methods will gain momentum. Interviewees agree that this fast technological progress will be hard to cope with also in terms of staff skills. Whether mechanisms to cope with progress in this area should include consortium agreement between Countries with lower and Countries with higher capacity within the framework of European Reference Laboratory Networks or other means remain among those controversial future development items on which respondents have diverging views and ultimately remains a political decision. While this strategic decision is pending the following recommendation can be made:

- *Recommendation.* On the one hand, this process seems set to dramatically change surveillance systems (at least for certain diseases), on the other hand the uncertainties and the costs of innovation appear significant, so resistances and disparities can be anticipated. ECDC should ensure an adequate balancing between keeping abreast of the technological frontier and avoiding the creation of excessive gaps EU-wide. Any substantial expansion of ECDC activities in this area appears likely to greatly benefit, as a prerequisite, from a carefully designed staff development strategy to cope with potential bottlenecks in internal skills.

¹⁵⁹ Also initiatives and projects in support of more in-depth collaboration between epidemiologists and microbiologists need to become systematic rather than episodic, and to this end ECDC should adopt – as for the other surveillance activities – a clear evidence-based approach demonstrating the usefulness and effects of collaboration to both groups.

Address Difficult Recognition of Added Value from Health Communication Activities and Switch Focus of Activities. ECDC now has a strong communication capacity which has translated in high quality outputs and in a particular in a well appreciated website. However, there remains the widespread feeling that too many resources have been invested in this line of activity and deliverables are not always relevant to the specific Country needs. Moreover, demand for further ECDC support concentrates in the provision of technical advice on new approaches to risk communication together with more practical examples of what works and what does, which could mean a strengthening of the partnership dimension with more sharing of actual practice among Member States.

- *Recommendation.* To increase its perceived added value ECDC can either more clearly focus on activities with a European dimension and invest more in synergies with the existing campaign events (such as the *Antibiotic Awareness Day* and the like) where demand for support is already high and where there is clear scope for a EU-wide approach, or endeavor into a more differentiated and country-tailored strategy conducting specific research on communication needs and available materials in collaboration with the Communication NFP and targeting specific materials to clusters of Countries sharing similar needs, including enhanced translation of materials. Additionally, it is recommended that ECDC should increasingly become a centre of expertise in assessing the impact of risk communication techniques and tools and facilitating related exchange of experiences and in following the latest technical developments in the field.

Keep the EU Added Value of Capacity Building Activities. There is clear evidence about the widely recognized European added value of capacity building and training activities. Indicators are positive in most of the areas analysed: participation, relevance, quality of outputs, utility and impact. However, interviews show that capacity building activities are subject to a growing request of being fine-tuned to Country specific needs, which could also implicitly mean a lower focus on their European dimension. Since the demographic profile of public health professionals is reported in certain Countries to cause a dramatic need for staff turnover in the next few years in the Consultant's opinion it can be very easily anticipated that demand to complement decreasing national training resources towards "cost-sharing schemes" mainly inspired by national priorities cannot but further increase. In addition, the frequently voiced requests to get back to an itinerant ESCAIDE can also be seen as ways to strengthen national networking and internal visibility of the PHI involved and replace decreasing resources for communication events at the national level.

- *Recommendation.* The sustainability concerns for the training programmes are already being addressed through a policy that promotes EAP instead of ECDC-financed fellowships schemes. This seems an important area of work for future development, since the EU added-value of, for instance, MS-track of the programmes is inevitably limited as compared to real mobility schemes (the measure mostly responded to the need to reduce 'brain-drain' from low capacity MS to high capacity ones under EPIET). The training programmes should not have a substitution effect on national ones.

II. USEFULNESS

Substantially Strengthen the Country Dimension of Partnership. One of the clearest requests stemming out from this evaluation exercise is that in order to increase usefulness of deliverables and impact on policymaking ECDC, knowledge of local conditions should be substantially strengthened together with the the Country partnership component. This includes better on-the-field knowledge through Country visits and other means, enhanced follow-up and accompanying events, and more targeted outputs for instance on communication products as highlighted above.

- *Recommendation.* Increased focus on the Country dimension and better knowledge of local conditions can be achieved as a side effect of measures recommended elsewhere in this report, and in particular, also through broadening of the expert basis that can be mobilised through outsourcing. Other tools include a review of patterns of staff participation to Country visits, a strengthening of the AF role in debriefing about local developments (including the possibility of having a dedicated session on this topic) mechanisms to allow staff to better share their knowledge about MS. Also internal repositories of MS systems, programmes and procedures could help in this respect.
- *Recommendation.* MS should be encouraged to much more proactive approach to the use of mandates either on an individual basis or as groups of Countries sharing the same interest with clear indications on their particular needs and on the level of support needed in the identification of responses and of the pros and cons of concrete practical implementation issues, the comparative impact that different responses have had so far in different contexts so that available options can be better framed and cost and ethical aspects considered when needed. The number of mandates originated by MS can be used to monitor progress in this area.

Focus on Usefulness for Policymakers. While a recognized source of added value a number of ECDC activities have resulted in good quality outputs whose immediate usefulness for policymakers could, however, be further improved if a clearer impact on their day-to-day activities is to be seen. In particular:

Better Demonstration of the Usefulness of Surveillance Results. Surveillance activities lie at the core of ECDC mandate and perceived added value. The discontinuation of seventeen different hubs and their centralization into the ECDC responded to a logic of ‘optimization’ that seemingly none of stakeholders would challenge. On the other hand, there is a widespread consensus on the fact that the above benefits remain largely untapped, and the integration process is far from being concluded. The potential benefits are clear to all, but until an appropriate level of quality and comparability of data is reached, the added-value of most surveillance network remains limited to that of a sunk investment to be mobilised in case of urgent need if a sudden threat appears, rather than as an ordinary source of ‘information for action’, i.e. to support policy analysis and change, especially when compared to the burden imposed on national counterparts.

- *Recommendation:* ECDC should be encouraged to strengthen the provision of scientific evidence from surveillance data (reinforce the ‘evidence-based’ approach¹⁶⁰) by better highlighting the policy-relevant information that can be drawn from them in dedicated sections/chapters of their epidemiological reports and move away from a too descriptive approach. If needed, a dedicated budgetary allocation to fund analytical research on results from the surveillance system can also be considered.

Improve Usability of Scientific Advice. Although a relatively young institution, ECDC is recognized as a leading organization in the provision of scientific advice, with good quality deliverables, and reasonably independent. Its scientific reputation has constantly been increasing over

¹⁶⁰ This not only is more in line with the design of ECDC as a network-of-networks centre but is also considered as more effective by national stakeholders to win the ‘resistances to change’ that ECDC has sometimes encountered in the uptake of common metadata and case-definitions at the national level. The argument is to some extent ‘circular’, as demonstration of the usefulness of improving data quality presupposes that data quality is improved - which is under the responsibility of MS. The establishment of a composite indicator summarizing MS degree of compliance with harmonization requirements to be reported in the annexes could also represent a way to quickly monitor progress in this area

time and has now consolidated at quite high levels in the community of public health practitioners everywhere in Europe. However certain areas of its mandate have been less adequately covered in both scope and depth. This particularly concerns, the provision of new evidence from studies, the inclusion of cost and cost-effectiveness issues in guidance documents. Also the range of sources considered often appears to limited to some stakeholders.

- *Recommendation:* ECDC could consider to have a better formalized procedure for catalysing external research (with an annual description on the action taken annexed to its annual report for instance) and, most importantly, initiating studies gathering new evidence in the different areas of activity including targets in the related allocation of resources. It could also consider broadening – at least on a pilot basis - the ranges of sources used from peer-reviewed literature to cover policy-relevant communications or grey literature coming from MS themselves and enter into the concrete lessons learnt from past implementation experiences including better consideration of cost and cost-effectiveness issues. To this aim since some stakeholders voiced the need to complement the scientific information from ECDC with lessons learnt from more practical experiences, it is worth considering the establishment of a sort of repository where all those concerned can share documents, analyses, etc. to allow a smoother exchange of information between countries.

Improve Dissemination and Targeting of Events to Policymakers and other Target Groups.

ESCAIDE enjoys a very positive reputation in the scientific and PHI peer community. However, its possible impact on policy-makers appears as comparatively more limited. More generally speaking, there might be scope to do more to target activities to policy makers who are looking for succinct analysis of information. Also the level of dissemination and awareness of toolkits and other training materials seems sometimes not optimal among potential target populations.

- *Recommendation:* Event dissemination and communication activities could be more actively targeted and oriented towards policymakers and their needs. For instance, the number of policymakers from Government organizations and policy-NGOs among ESCAIDE attendants could be used to better monitor progress in this area. Finally, certain training ‘products’ such as toolkits, the FEM Wiki etc. seem to suffer from limited awareness among potential stakeholders, and therefore greater dissemination effort would be needed.

Enhance Evidence-based Conclusions in Rapid Risk Assessments. The RRA have emerged as one of the best known and most valued ECDC deliverables. However, since it is not easy to trace clear boundaries between risk assessment and risk management and stakeholders’ views on this point diverge - also because the distinction does not really apply to the reality of some MS and where it applies peculiar implementation modalities exist¹⁶¹. RRA conclusions appear to some stakeholders sometimes influenced by concerns about possible political consequences, which make them exceedingly vague or generic, and that this may also affect timeliness of release. Irrespective of views on how division of roles should look like, there appears to be consensus on the fact that there is room to further expand the usefulness of an instrument that is already perceived as fundamental.

- *Recommendation.* The preparation of the Rapid Risk Assessment is now based on an internal ECDC guideline document but feedback remains informal and not systematized or otherwise codified. Since ECDC already plans to have a “client satisfaction survey” feedback mechanism in place in the next few years it is worth considering whether a specific section on the conclusions

¹⁶¹ For instance in certain MS conclusions and recommendations are reportedly attached as a side letter to the risk assessment report addressed to risk managers in order not to appear that they are overruled by risk assessors..

of the RRA should be added with open qualitative comments to allow an update of this guidance document every two to three years based on a kind of “lessons learnt” approach, by reviewing and incorporating feedback from potentially contentious issues or cases of perceived exceedingly generic conclusions. The document could eventually be discussed with the Commission and the HSC. This might be of some help in aligning expectations with practice and find some common ground among stakeholders themselves.

III. MANAGEMENT AND GOVERNANCE

Turn ECDC into a Leaner and More Transparent Organisation. Although it is widely acknowledged that ECDC management and governance have improved in the period considered there remains three main areas deserving further attention: 1) overall transparency of the organisation to outsiders; 2) a mix of cumbersome and poorly formalised procedures and processes often resulting in very slow reaction times; 3) better operational efficiency through increased inclusiveness and user-friendliness. More in particular:

Improve the Intelligibility of the Organization and Key Decisions to Outsiders. An organizational restructuring along a matrix model is not a unique development among European agencies and MS alike. However, one of the unintended side-effects of the matrix restructuring of ECDC is that the organization has become poorly intelligible to stakeholders who often report difficulties and uncertainties in understanding internal allocation of responsibilities, division of labour across units and sections and related coordination mechanisms. There are aspects of the decision-making process that remain obscure to stakeholders and hinder a well-informed judgement on prioritization of activities. This includes better clarity and transparency in the selection of priorities proposed to the AF for scoring and the overall readability of the budget.

- *Recommendation.* ECDC organisation can be made more intelligible through very simple means such as enhanced use of directories and better explanative organigrams. If dedicated webpages were built on projects or initiatives in the pipeline these should include as a rule references to responsible contact persons within the organisation. The practice of rotating staff responsible for the same project that was sometimes reported by interviewees as an inconvenience and a cause of disruption of activities should be minimised and kept monitored. The rationale behind inclusion of an item in the prioritization process should be better explained in a background document. A budget organized along a matrix structure should be replaced by a more intelligible budget highlighting resources allocated to key missions and to the achievements of the MAP /sectoral strategy objectives.

Streamline Cooperation with WHO-Euro, EFSA, EAHC and EMA and Make the Underlying Process More Transparent to Stakeholders. Improving cooperation with WHO/Europe in particular and the other European Agencies in general has been a frequently mentioned issue of this evaluation. Although cooperation and mutual understanding of roles has increased over time and steps have already undertaken to address areas of overlapping the process is perceived as slow and not participative enough.

- *Recommendation.* Coordination mechanisms to improve cooperation between agencies are often in place but when they are not they should be established or resumed. Ways should be found to make the process more participative and involving also stakeholders at the MS level in the dialogue on identifying areas for streamlining of activities and avoiding duplication of efforts outside of the usual hierarchical channels. For instance, public consultations or restricted public

consultations could be held on draft programmes of activities to allow for comments and make the process more participative, and progress reports published on the progress achieved to give a feedback and inform about developments.

Continue the Effort of Improving Procedures and Management Systems. There is converging evidence from several sides that ECDC has long relied on informal procedures and centralised decision-making and this has negatively impacted on operational and budgetary performance and internal information flows. It appears that the Centre has already taken steps to redress these weaknesses although it is too early to see results.

- *Recommendation.* The process of creating internal procedures should be encouraged and adequately monitored through appropriate mechanisms to control compliance, although we would warn against making procedures necessarily homogeneous across the Centre and would carefully consider the peculiarities of the various functions. Also the current process of administrative decentralisation of decisions is worth encouraging. Indicators to monitor possible problems in processing contracts, disbursing funds and ensuring compliance with procedures should be developed and routinely reported to MB.

Define a Staff and Outsourcing Policy. Several aspects of staff management (lack of mid management, high rotation of staff, insufficient skills in certain area, identification of job profiles) appear suboptimal to stakeholders and would deserve to be redressed in more strategic terms than they are today and also with a clearer vision of the tasks to be developed in-house and those to be contracted out. In fact, there appears to be at the same time excessive recourse to outsourcing and underutilisation of outsourcing as a tool to build more inclusive networks and enhance cooperation and partnership with the MS.

- *Recommendation.* Borrowing from the experience of other European agencies, it is worth considering preparing strategy documents (or a joint strategy document), inclusive of monitoring indicators on staff development and outsourcing policy, whose implementation could be eventually discussed with the Management Board and could also serve as a guide in the future to avoid possible overlapping with EAHC in the financing of projects. Within the room of manoeuvre allowed by the current financial regulation, ECDC should explore all the possible contractual means to make outsourcing more inclusive and broaden the range of expertise available¹⁶².

Address to the Extent Possible Complementarity between AF and MB. ECDC Governance Bodies can reasonably fulfil their mandate as defined by the ECDC Founding Regulation. Limited complementarity between AF and MB can be considered as the most important problem area and a cause of delays in the decision making process as dossiers go through both fora, and instances of overlapping already represent a routine practice to require constant coordination between Members of the two bodies. Several proposals formulated in the past to improve complementarity have hardly materialised

- *Recommendation.* There can be a number of ways through which the MB and the AF can make their activities more complementary and synergic. These include sharing their agenda setting process, joint sessions, mutual access to the intranets. Both bodies should identify those more

¹⁶² Much in the same vein, there seems to be further room to improve the geographic ‘balance’, both in terms of participants (both to ESCAIDE and EPIET/EUPHEM) and of training sites. For EPIET/EUPHEM it is possible to slightly review selection criteria in order not to excessively penalise young, talented experts with limited professional experience (but without relaxing the selection criteria to the point of affecting programmes’ value and reputation).

feasible and try to explore them on a pilot basis. A number of right steps have already been taken to improve Governance procedures and performance indicators. The possibility of introducing one more indicator on the share of items in the agenda of the Governance fora postponed to/continued in the following meeting should be considered.

Increase user-friendliness of ECDC processes. In the evaluation of the different areas of ECDC activity a number of suggestions on how to improve user-friendliness of current processes were formulated also as a way to save time and increase operational efficiency. Some of these technicalities are reported here. For instance:

- *Recommendations.* In the field of surveillance the user-friendliness of the system could also be improved by (i) technical upgrade of TESSy to become a machine-to-machine system (ongoing); (ii) enhanced functionalities for data access and analysis by external users; (iii) rationalisation and better timeliness of reports and other outputs. There is room for better integrating the EPIS and EWRS systems by establishing appropriate linkages between events, which may then facilitate the rapid sharing of materials across platforms. This process may also benefit by the (apparently planned) overhaul of the Threat Tracking Tool, making it available to external users. This might help overcoming the EWRS limited capacity when it comes to PH emergencies. Better integration means also better distinction¹⁶³. The ECDC management of EWRS could better distinguish the information therein that is really confidential from the information that is publicly available from other sources.

¹⁶³ EPIS should more clearly remain a scientific forum for early-stage discussion on emerging threats. Cases were reported where epidemic intelligence signals ‘leaked’ too early at the risk management level, causing undue reaction prior to proper validation. There seems to be room to improve procedures to avoid or mitigate such instances.

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