ECDC DIRECTOR'S PRESENTATION

ECDC's approach to outbreaks with intentional background and cross-border dimension

LÜKEX visitors program, 27–28 November, Bonn, Germany

Dear colleagues,

I would like to start by thanking you for inviting me to this very interesting simulation exercise on bioterrorism.

I am highly impressed with what I have seen and experienced during these two days.

Following you during this exercise has also made me realise that many of the challenges you see here in Germany, regarding multi-state coordination, are similar to those that we also experience in an EU setting with 28 Member States.

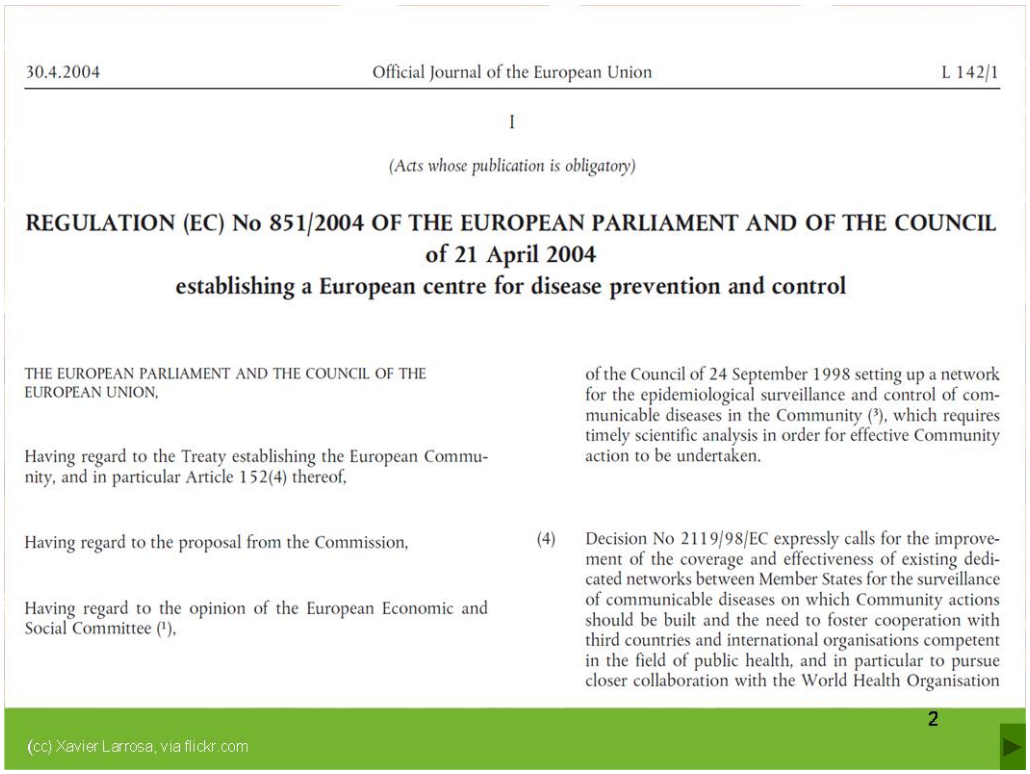
I would now, over the next 20 minutes, like to give you some insights in how EU agencies, and in particular ECDC, would get involved in an emergeny like the one we have just been simulating.

But first of all, allow me to give you a brief introduction to ECDC, to our mandate and to how we work.

ECDC is a fairly young organisation based in Stockholm that became operational in 2005.

As a result of a European Commission proposal, the Council of the European Union and the European Parliament established a new European centre for disease prevention and control.

Our founding regulation, in a nutshell, assigns us to detect, assess, monitor and communicate health risks caused by infectious diseases.



30.4.2004 Official Journal of the European Union L 142/1

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(Acts whose publication is obligatory)

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

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 152(4) thereof,

Having regard to the proposal from the Commission,

Having regard to the opinion of the European Economic and Social Committee (1),

of the Council of 24 September 1998 setting up a network for the epidemiological surveillance and control of communicable diseases in the Community (3), which requires timely scientific analysis in order for effective Community action to be undertaken.

(4) Decision No 2119/98/EC expressly calls for the improvement of the coverage and effectiveness of existing dedicated networks between Member States for the surveillance of communicable diseases on which Community actions should be built and the need to foster cooperation with third countries and international organisations competent in the field of public health, and in particular to pursue closer collaboration with the World Health Organisation

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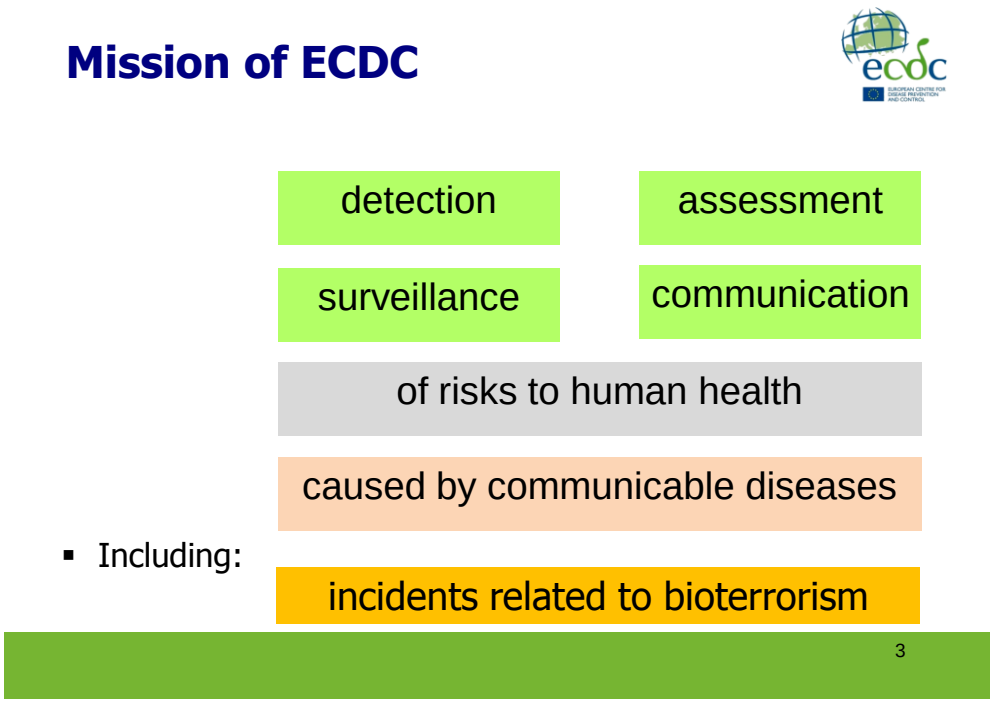
However, our mandate also includes emergencies related to bioterrorism or threats of unknown origin.



Mission of ECDC

detection

assessment

surveillance

communication

of risks to human health

caused by communicable diseases

- Including:

incidents related to bioterrorism

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I will come back to the role of ECDC in emergencies related to bioterrorism or threats of unknown origin very shortly.

But first a few words about our agency, ECDC.

ECDC has just under 300 highly motivated staff members from almost all EU Member States.

We have experts from all public health relevant disciplines, including risk analysis, microbiology and even bioterrorism.

Our scientific advice is centred around 7 disease specific programmes, prepared to address health risks with major impact on the EU.

And one of our 7 programmes is the food- and waterborne diseases and zoonoses programme which deals with all kinds of food-borne outbreaks.

ECDC behind the scenes

- Just under 300 staff members from almost all EU Member States
- Experts in communicable diseases, epidemiology, epidemic intelligence, risk assessment, communication, IT-tools, training, scientific methods, microbiology and bioterrorism
- 7 disease specific programmes addressing health risks with major impact on the EU

As a European Agency, we also rely on different partners and networks in Europe such as the European Commission, the European Parliament and Council, other EU agencies such as EFSA in Parma, EUROPOL in the Hague, EMA in the London, as well as organisations such as CDC in Atlanta and the WHO.

But we in particular rely on our cooperation with the Member States and have members from every EU and EEA country in our Management Board and in our Advisory Forum.

In this 2-day simulation exercise, we have been dealing with an outbreak caused by bio-terrorism.

Biological threats, in general, may be caused either by natural epidemics, by accidental spread, such as in laboratory incidents, or through intentional release, such as in a bioterrorist attack.

And in the perception of the public, bioterrorism continues to be seen as one of the most threatening and disruptive scenarios of a health threat.

You may recognise this pathogen here on this slide.

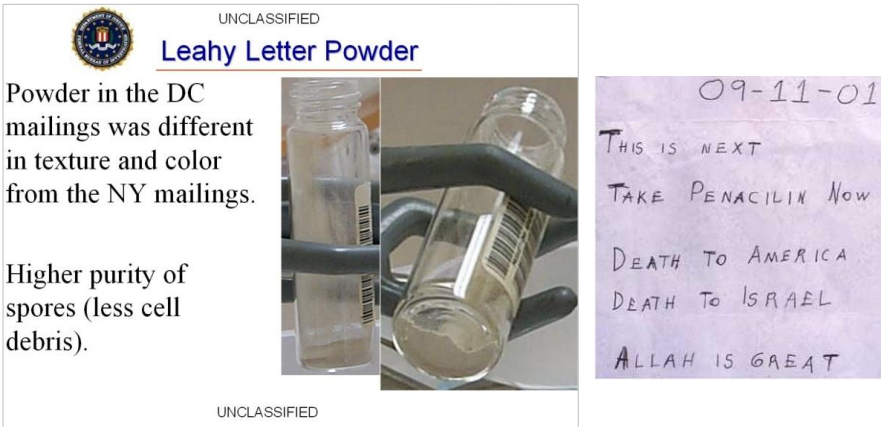
Bacillus Anthracis

It brings us back to over 10-years ago..

Because looking into bio-security from a European perspective means looking back to 2001.

A year that was shaped by 9/11, and shortly afterwards by a series of biological attacks with weaponised anthrax spores.

American anthrax 2001



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It was this incident related to bioterrorism that triggered the establishment of the EU Health Security Committee.

And the reason behind this establishment was the urgent need for a decisive body to support all EU Member States in preparedness and coordinated response to CBRN-threats.

In the beginning the Health Security Committee was mainly focussing on health threats caused by biological and chemical agents.

In 2007, the mandate was extended to generic and pandemic preparedness and to risk communication.

Though the Health Security Committee was mainly set up as an informal advisory group, it has dealt with all kinds of major health threats since 2001.

This includes SARS, the H1N1 pandemic and the on-going outbreak of the MERS Coronavirus.

Health security in the EU

- Oct. 2001: Anthrax attacks in the US
- Dec. 2001: EU Commission "Programme of Cooperation on Preparedness and Response to Biological and Chemical Agent Attacks (Health Security)"

→ **Health Security Committee - HSC**

- 2007: Extension of mandate
- Nov. 2013: New legislation on "serious cross-border threats to health"

And as we have heard this morning from Germain Thinus at the European Commission, the Health Security Committee was recently formalised through a new legislation for serious cross-border health threats.

Here, ECDC as a technical agency supports the health security committee by providing:

- validated data,
- risk assessments, and
- scientific guidance.

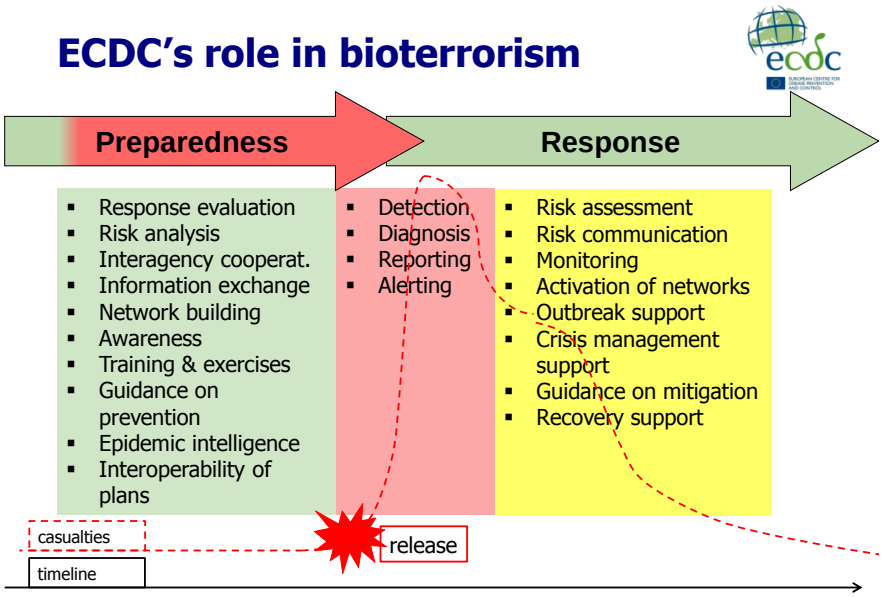
By providing this, we enable decision making on the basis of the best available evidence.

So what would ECDC's support look like in the case of an intentional release of a biological agent?

In a large scale biological attack, we are likely to see a sudden increase in case numbers (as opposed to in a natural outbreak where the number of cases tend to gradually increase).

The reason for this is that, in an intentional release, many people would be infected at the same time. So in the case of a biological attack, with potential mass casualties, preparedness becomes crucial.

What you see here to the left of this slide, in green, is the cornerstone of ECDC's preparedness work.



And ideally solid preparedness leads to rapid detection and effective response, as you see to the right of this slide.

At the end of recovery phase, preparedness planning starts again, incorporating "lessons learned" from the preceding crisis.

So ECDC is involved in the whole 'life cycle' of such an emergency.

What does solid bio-preparedness mean to us?

It first and foremost means building trusted partnerships with relevant agencies in 'peace time'. And here ECDC's cooperation with designated experts in the CBRN counter-terrorism unit at EUROPOL is a good example of such a partnership.

This cooperation is based on a Memorandum of Understanding which includes the possibility to share official information.

Capacity building is also crucial for preparedness. A major initiative for capacity building consisted in the *"bridging security and health*" trainings and regional workshops between 2004 and 2007.

These were carried out jointly between ECDC, the European Commission and EUROPOL.

ECDC has also provided guidance in bio-security, for example on prevention of anthrax in heroin users.

And we are also contributing to the QUANDHIP laboratory network, which is an EU funded project that links together 38 highly specialised and advanced laboratories from 23 European countries.

Bio-preparedness at ECDC

- Interagency agreement with EUROPOL
- Capacity building (e.g. training)
- Providing guidance (e.g. anthrax in heroin users)
- Microbiology coordination (e.g. QUANDHIP)

A few words on incident detection and reporting:

Epidemic intelligence is a structured process for retrieving information from all kinds of web-based sources.

This includes retrieving different types of unofficial information, such as from online news media or from social media.

It also includes information from informal disease specific networks where experts with different backgrounds can share information.

Detection & reporting

- Event based surveillance - "epidemic intelligence"
  - 24/7 duty at ECDC
  - Daily "round table" evaluation
  - Rapid detection
  - Sensitive also to rare events
- Official reporting systems - e.g. EWRS, IHR, former RAS-BICHAT

ECDC is coordinating some of these networks, including the one dedicated to food- and waterborne diseases.

Our official reporting tool, that most of you will know, is the European Early Warning and Response System – EWRS. This is a secure alert system linking the public health authorities at national and EU level, and operated by ECDC.

Our activities in response to biological threats include:

- Preparing, and continuously updating, risk assessments and monitoring cases all over Europe.
- Offering support to outbreak investigation and sometimes dispatching outbreak assistance teams upon request by national authorities.
- Furthermore in long lasting outbreaks, ECDC would develop in-depth guidance, for example on diagnostics or prevention.

Response

- Risk assessment
- Risk communication
- Monitoring
- Activation of networks
- Outbreak support
- Crisis management support
- Guidance on mitigation
- Recovery support

ECDC regularly produces risk assesments on health emergencies, and here below you see the two "classical" columns defining a health risk *(the two green columns on the right hand side).*

What you see is the hazard imposed by a certain pathogen and its impact on human health and health care systems.

Integrated risk assessment

THREAT	HAZARD	IMPACT
CRITERIA ▪ Acquisition ▪ Production ▪ Dispersion Devices ▪ Capabilities ▪ Intention	QUALITY OF AGENT ▪ Identity ▪ Transmissibility ▪ Infectivity ▪ Pathogenicity ▪ Burden of Disease ▪ Case fatality ▪ Out of reservoir resistance	CRITERIA ▪ Exposure ▪ Susceptibility ▪ Treatment options ▪ Prophylaxis options ▪ Ease of detection ▪ Diagnostic capabilities ▪ Decontamination options ▪ Scale of incident
CRUCIAL INPUT ▪ EUROPOL ▪ Complementary institutions		

In bioterrorism we have to integrate an additional quality – Threat.
(seen in the red column to your left)

This describes the grade of capability and intention of a terrorist or criminal groups to use biological agents.

This type of information is normally unavailable for public health institutions. Therefore it is crucial to have exchange mechanisms with law enforcement agencies in place to enable a full picture assessment.

Law enforcement agencies also benefit from this exchange as they obtain scientific assessment regarding feasibility and potential impact in bioterrorist plots.

I would now like to use the example of the EHEC outbreak in Germany a couple of years ago.

This is an outbreak you are all familiar with, but I would like to use this example from a slightly different perspective.

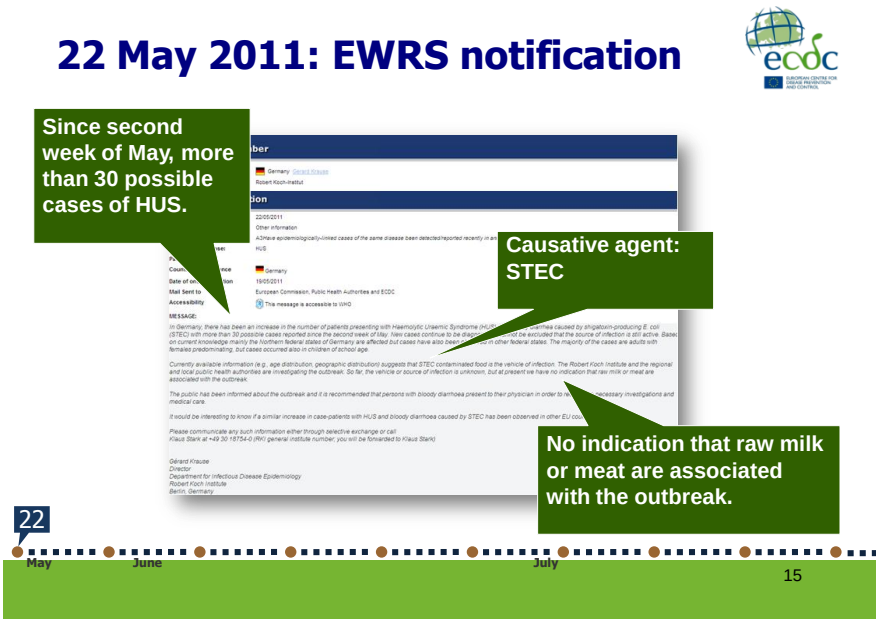
You may recall that at the beginning of the EHEC outbreak, some media were actually speculating about an intentional release.

Even an accidental release from a military research laboratory site in Northern Germany was shortly discussed in some blogs.

The EHEC outbreak in 2011, did indeed show some initial signs pointing towards an intentional or accidental release of a toxin in the food chain. In other words: Very similar to the simulation exercise we have been following during these two days.

That is why I would like to use this outbreak as an example for ECDC's interventions in the case of a biological attack.

It started on Sunday 22 May, when Germany issued an alert on EHEC to its EU partners via the Early Warning and Response System.

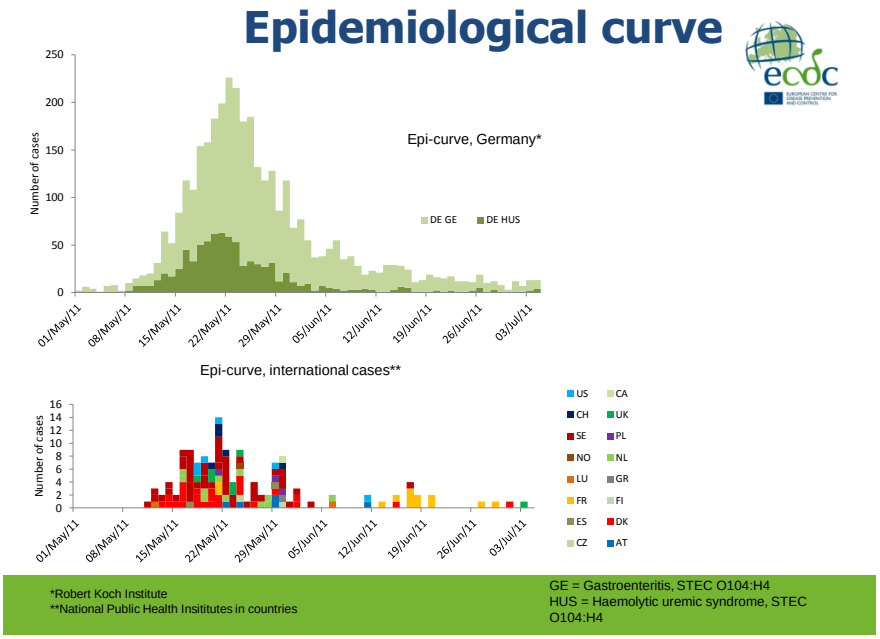


What was worrying with this alert was that it described 30 cases of "HUS", which stands for "haemolytic uremic syndrome".

This severe complication is caused by the Shiga toxin of *E.coli* and includes anaemia, low platelet count and acute kidney failure.

From direct contact with our colleagues in Berlin, and through epidemic intelligence in German media, we soon learned that there were hundreds of cases.

This is what the epidemiological curve of the outbreak looked like.



And what you see below on this slide, is the epi-curve showing the international cases in relation to the German cases.

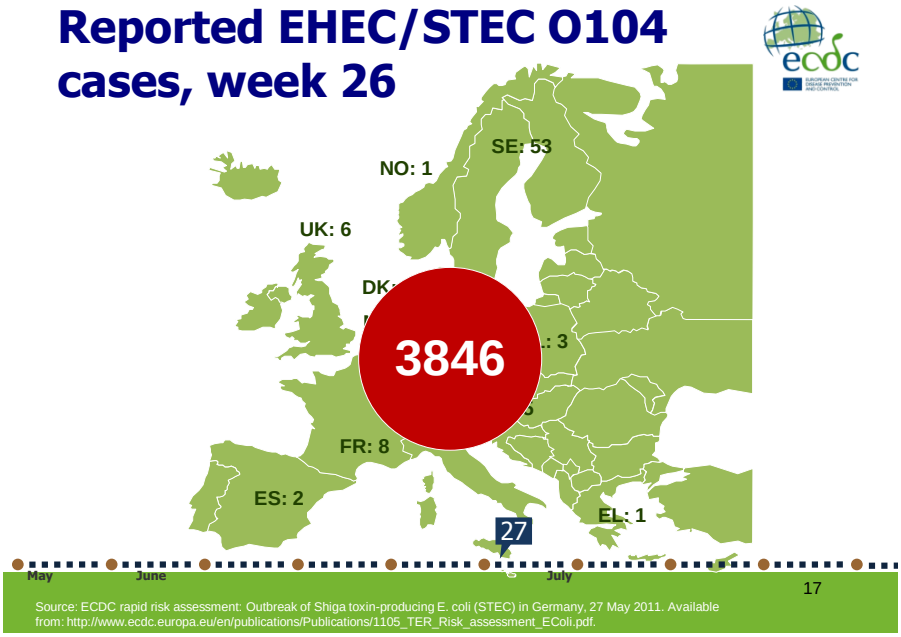
This is a sneaky preview from our food- and waterborne and zoonoses programme as the data has not been published yet (*with relatively high number of cases in Denmark and Sweden*).

What we do need to bear in mind, however, is that the real case numbers would be much higher in the initial phase due to a delay in reporting.

This applies in particular to a large scale biological attack, where many people are infected simultaneously.

As a result of the alert issued by Germany, national public health agencies in other Member States started looking for EHEC cases.

ECDC's role here was to monitor on a daily basis the number of cases in all European countries, and to produce risk assessments and regular epidemiological updates.

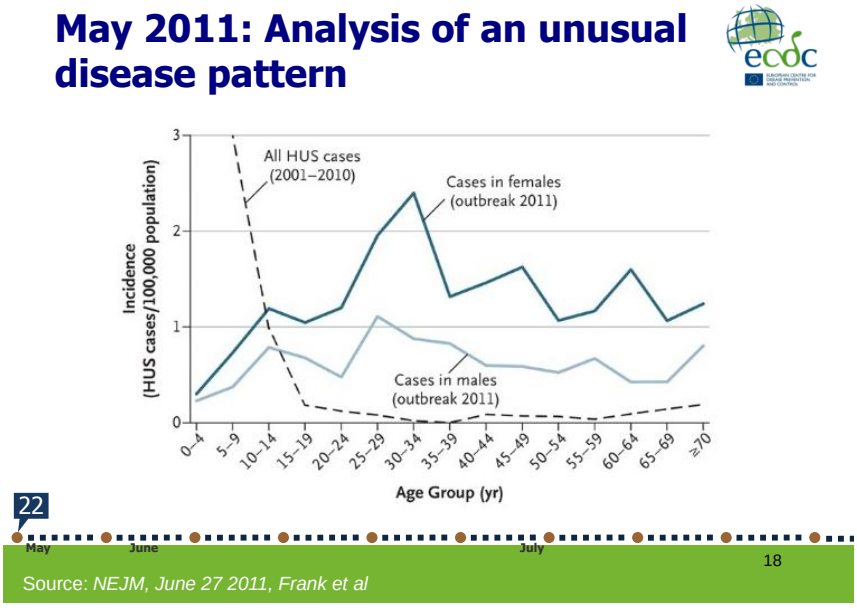


In some of the cases, such as in Sweden and in France, ECDC could contribute by detecting the travel associated linkage to the infection in Germany.

ECDC also developed detailed guidance for the public health laboratories in the Member States on how to test for this rare strain of EHEC, known as O104, which the Robert Koch Institute had identified.

What made us really concerned about this outbreak was the unusual severity of the illness. Hospitals in Germany were challenged by hundreds of cases of kidney failure. And most of these cases were in younger adults, in their twenties and thirties.

Usually it is just the very young or very old who get this sort of severe illness from EHEC. And in this outbreak, a lot more women than men became ill, which is also unusual.



So the first thing ECDC did, in this uncommon outbreak, was to rule out a potential deliberate threat.

By exchanging information with EUROPOL, we learned that there were no indications or findings that pointed towards illicit activity with coliform Bacteria. No claims of responsibility to the incident were made, and as threat analysts later pointed out: if a criminal group would have been able to genetically engineer the rather complex pathogen of STEC O104, they would most likely have preferred to develop a more "spectacular" agent.

So far we have been talking about previous health threats.

But how do we perceive future bio-threats, given that bioterrorism presents a large variety?

On the one hand, the latest achievements in bio-technology suggest that anybody with the right equipment is able to synthesise pathogens with custom tailored characteristics.

On the other hand, low-tech approaches based on easily accessible precursors do not require high level expertise or high-end equipment to do harm.

It is, therefore, not a coincidence that I have added some castor beans on this slide, as these can easily be used for the extraction of ricin – which is a most lethal toxin.

Bio-threats in transition

- Relicts of offensive bio-weapons programs
- Relicts of defensive bio-weapons programs
- Toxins
- Bio-tech revolution
- Low-tech approaches

So it is important to maintain awareness of all types of illicit biological activities.

Another topic that is getting more and more visibility is the potential dual use aspects of recent research.

Most of you will remember the huge controversy following the H5N1 transmissibility studies carried out at the Erasmus University Rotterdam and in Japan two years ago.

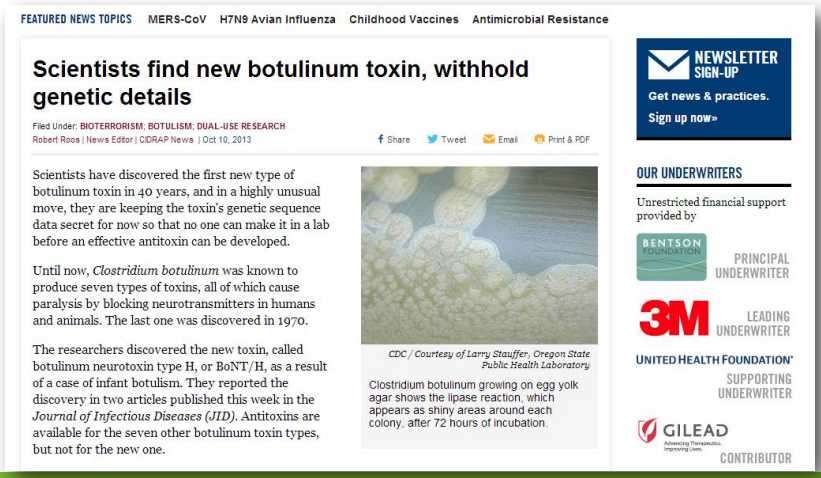
Concerns that the findings would provide potential terrorists with a kind of instruction booklet lead to a 1 year moratorium of the research work. This is also something ECDC issued a risk assessment on, in early 2012.

And just recently another discovery in the US has raised severe bio-security concerns. Here the concern is about a new type of Botulinum toxin for which none of the established antitoxins is effective. So the scientists decided to withhold the genetic details in order to prevent any risks of terrorists synthesising the toxin.

But it's also true, that a large-scale terrorist attack with any of the eight known Botulinum toxins would end in catastrophe.

This is because the quantity of antitoxin existing globally would simply be insufficient for the treatment of mass casualties.

Dual use awareness



And this leads me on to an example of the huge potential of the new legislation on cross border threats to health.

As we learned this morning from Germain Thinus' talk, one highlight lies in a joint procurement mechanism for medical countermeasures among EU countries. And this process is not limited to vaccines and antivirals for pandemic flu,it also enables a balanced and rational approach as well as highly specific countermeasures in the event of the spread of diseases from bioterrorism.

New legislation cross-border health threats

- Implementation of interoperable preparedness plans among Member States
- Establishing a common mechanism on joint procurement for medical countermeasures
- "All hazards approach" for detection, response and management of emerging health threats
- Strengthening cooperation with WHO on reporting and notification mechanisms and adherence to IHR
- Formalisation of the Health Security Committee

In this context I would like to mention Botulinum antitoxin, a new generation vaccines and antivirals for smallpox or a stockpile of antibiotics for a mass treatment of anthrax or tularaemia.

However, from what we have seen in these two days, there is little to worry about regarding bio-preparedness in Germany. And I would like to congratulate you for your capacity and capabilities, which includes running large scale exercises like this LUEKEX exercise.

But the new legislation actually tackles a very sensitive gap in specific preparedness in Europe as it enables countries with less resources to equally participate in the exchange, the harmonisation of preparedness plans and to gain access to specific and cost-intensive countermeasures.

So, to conclude, what are my take home messages from this exercise:

- That it is important to raise awareness;
- That cross-border threats are best approached by cross-border cooperation;
- The need to foster inter-sectoral exchange and partnerships, and;
- That coordinated risk communication is essential.

In all these areas ECDC aims to support and add value. And I would like to end by conveying the message that we are ready to address any requests on this issue that European countries may have.

Now is the right time to establish and strengthen both our formal and informal networks, and to build trust and partnerships .

There is no time to do this once an incidence happens.

Thank you for your attention.

Thank you!