



Influenza Surveillance in a Pandemic Paper from ECDC Working Group

August 2007



1. Summary

Tailored surveillance during phase 6 can provide the virological and epidemiological information needed to inform and determine some crucial actions that may save lives and providing these information (for action) should be the priority for this work. This needs careful planning of activities which can and should be undertaken by each country, while other data can be collected by a few countries for the benefit of all. However, excessive expectations may exist from policy makers and politicians of data that cannot even be delivered during ordinary seasonal influenza and this should be also considered.

2. Background

This paper has been developed by ECDC with specialists bringing experience in microbiology, epidemiology and public health from EU Member States, EEA countries, EISS, EMEA and WHO (see Annex 1 for members). It follows two meetings of the working group and one influenza workshop (Uppsala, May 2006), and the experience gained by member states in planning preparedness and practice (exercises) and from the national self-assessments of pandemic preparedness undertaken with ECDC.

The **Scenario** which the paper principally addresses is WHO Phase 6 (from when a pandemic has been declared by WHO). It covers all EU Alert Levels 1 to 4 (from transmission with the pandemic strain not yet taking place being in the EU to full transmission within the EU). Although it assumes that some information will have been gained about the virus from Phases 4 & 5 and from early Phase 6 in other countries, it notes that because of the changing nature of pandemic strains of influenza even if such information is available it will need to be gathered again and verified when the pandemic affects Europe.

3. Objectives

The **objectives of this technical paper** are:

- To serve as a resource for EU countries to identify surveillance activities that should be done in preparation for and during a pandemic
- To guide the planning of ECDC and other interested parties in designing surveillance in a pandemic that needs to take place at an EU level while recognising that most actual activity will be undertaken at MS level.
- To seek agreement on some technical developments and prior agreements on data and specimen sharing and distribution before a pandemic

The summary objectives of **surveillance of pandemic influenza during Phase 6** (Tables 1 & 2) are like most other surveillance informing action, in this case making key operational decisions in a pandemic:

1. Early detection of pandemic activity in Europe countries so as to trigger operational plans
2. Prediction of likely spread across Europe (based on knowledge of existing transmission and previous pandemics)
3. Gathering of key information and data concerning the pandemic strain (and other relevant information) for diagnostic purposes, risk of transmission, possible resistance to antivirals, judging severity, indicating where prevention should be directed as well as identifying the virus for vaccine production and vaccine updates.
4. Supporting national and local estimated numbers of infections, severe cases, deaths etc.
5. Evaluating interventions (pharmaceutical, including safety and public health)

4. Essential Considerations

4.1 An Especially Difficult Task

Preparing for conducting surveillance in a pandemic when it affects the EU represents an uniquely difficult set of challenges to those responsible for surveillance and the health of the public. The form and severity of the pandemic is unclear, the last relevant experience is 40 years past (90 years for a severe pandemic). Also epidemiological and microbiological surveillance tools have developed considerably as have the actions and countermeasures their outcomes could direct (especially antivirals, vaccines) but these have never been tested in a pandemic.

4.2. Excessive Expectations at a Time of Stress

Experience of pandemic exercises and planning and what actually happens during complex emergencies (SARS, post 9/11) is instructive. Those experiences strongly suggest that the requirements and expectations of influenza surveillance in the run up to and during the experience of a pandemic in EU countries will be an order of magnitude greater than during a normal influenza season.

Unless there is preparation and exercises expectations will run ahead of what can be delivered. Those responsible for surveillance may be expected to deliver reports on data that have not been previously collected; reports may be expected to be far more timely and precise; and to deliver parameters that are outside the scope of classical surveillance. There will particularly be increased requests for information and status reports from politicians / decision makers and the media. At the same time the technical capacity to deliver even routine influenza surveillance data may be prejudiced by overload of work and staff illness among traditional data providers (primary care and laboratories), and data gatherers and analysts. This is true at the member states

level and even more so at the EU level. Without preparation and agreement the sharing of data and outputs with EU bodies, WHO and other MS will probably be a secondary consideration for countries. Even then it will be important to be realistic and not expect too much.

4.3. Some Ordinary Surveillance May be Compromised

Many routine influenza surveillance systems could be compromised as Europe moves towards and into Phase 6 and Alert Level 4 (widespread transmission of the pandemic strain in Europe). There will probably be two forms of saturation; firstly, inability to capture relevant data where this is not done automatically (e.g. by automatic electronic extraction and transfer) and secondly an inability of the primary and secondary care facilities to deal with all those who might seek care, a so-called '*ceiling effects*'. Also some countries are considering alternative primary care systems, especially for distributing antivirals which may distort outputs from the current surveillance systems which rely on primary care. In this context the experience of SARS in the Far East (Hong Kong, Beijing, Singapore) and Toronto is sobering. With few cases routine surveillance almost stopped for a while and provided hardly any of the information required for control. That information mostly came from focused studies initially based on informal impressions and then carried out formally by research groups. Service public health staff was generally too busy managing the situation, doing contact tracing, and providing situation reports to undertake surveillance. Also some research teams held onto data rather than forwarding them centrally (WHO's global SARS data-base was never adequately populated). It is therefore essential to have separate teams delivering priority surveillance and situation reports. On the more supportive side the new International Health Regulations will be operating in addition to Decision 2119 and therefore countries should be more amenable to forward data and biological specimens than in 2003 though only if there is pre-planning and agreement as to what data should be gathered, what specimens will be shared what will happen to them and clarity on commercial and intellectual property rights.

4.4. Information for Action - Objective Driven Surveillance with Rationales

Given the stresses on the surveillance systems and the prejudiced capacity it will be even more crucial than usual to focus on gathering and analysing information of public health value. That is *information for action* to allow decisions to be made that will save lives and trigger essential actions. It will be important to reinforce key systems ahead of time, to determine which systems are likely to break down due to work overload and to have mechanisms for systems to indicate that they are experiencing ceiling effects and to pre-plan special studies that can replace conventional systems and capture key data. I.e. as usual all surveillance work must be driven by considerations as to what actions they will inform. Negotiations ahead of a pandemic to agree on the objectives and priorities to establish what might be reasonable to expect are crucial. So also are exercises and practice especially during the flu season to see what is possible. This is a vital protection for those engaged in surveillance against the potentially massive demands of monitoring for more data and decision makers for situation reports. People who are requesting data from surveillance staff need to critically consider what action the data are going to determine.

4.5. Distinguishing Surveillance from Service Monitoring

It is crucial to separate surveillance from service monitoring. Surveillance is a public health activity gathering and analysing health related information so as to undertake and guide public health action. Service monitoring is an essential management tool measuring service parameters so as resources can be best deployed e.g. determining if hospital activities are reaching critical levels and managing antiviral stocks. In a pandemic it will extend well beyond health care to include schools, supply of essential services etc. The distinction is not complete since some surveillance data will contribute to monitoring and trigger management plans e.g. levels of consultation in primary health care. Equally some data used for monitoring will produce information that will contribute to surveillance (e.g. hospitalisation data)

Service monitoring will be needed everywhere in a pandemic while surveillance can afford to be more focused. For example it will be important to establish the viral genotype and the drug resistance pattern, which are the groups experiencing transmission, what is the case fatality rate and the effectiveness of antivirals. This may be done best by teams using an outbreak investigation approach where transmission is high rather than routine surveillance. That will only need to be done in a few places in Europe, as long as it can be established, done in a standardised manner to be comparable and the results shared.

4.6. Providing Short Term Data, Combining Real Time Modelling & Surveillance Data

The requests by data-receivers for indications of what is happening now and will happen shortly in the future (how many infected? how many needing secondary care? how many dead? etc) are to be expected and are reasonable albeit extremely difficult to fulfil. One way round of providing answers data for decision makers and the public is to use pre-planned real time models of what might happen in a pandemic given reasonable assumptions so called *Now-Casting*. The working group has had reported one such system and some countries are known to considering this approach in what is essentially *the interface between surveillance and real time modelling*.

These models can be run daily and would have two data requirements from surveillance systems.

- Data on the assumptions – changing the basic assumptions (case fatality rate - CFR, the reproductive number - R_0 , serial interval, pre-existing immunity etc) – these could come from other countries
- Data on what is happening in country – all manner of primary care data, hospital, laboratory data especially indicating local occurrences so that the outputs of the models can be adjusted to more closely reflect reality especially given the inevitable local variations seen with influenza.

4.7. A Need for Information and Data for Europe from Europe

To compound the problems it should not be assumed that everything that the EU will want to know about the virus (Table 1) will be supplied through WHO (though it is hoped that early indications will come as they did for SARS). Also the experience of influenza and pandemics is that the virus evolves and changes its behaviour. Hence even if other countries provided much the EU would like to know through the WHO and under the International Health Regulation it would

still be necessary to repeat measurements when the virus affects Europe, and to repeat measurements over time.

4.8. A Special Need to Establish the Severity of the Pandemic

Pandemics are not standard. The three pandemics of the 20th Century varied in their severity, and amongst whom they transmitted. A number of public health measures have been suggested to limit transmissions. Some of these will be disruptive in themselves and there could be a fine balance between the effects of the measures that are proposed and the damage of the pandemic. Hence early grading of the pandemic will be crucial, probably based on Case Fatality Rate.*

4.9. Minimum Standards, Sharing Protocols – Sharing Outputs

It will be important to determine what surveillance activities and outputs will be needed by all EU and EEA countries (e.g. identification of transmission with the pandemic strain) versus what more efficiently can be done by a few countries or at an EU level or even globally (e.g. genetic analysis) and to establish agreements that if at all possible these systems will deliver and their outputs will be shared. Fortunately there is a good working model for this principle (the virological experience with SARS) and there is now some underpinning with liberal interpretation of the [2005 International Health Regulations](#)

5. Work done so far

To discuss **surveillance needs during an influenza pandemic**, a group of experts from EU Member States, ECDC, EISS, EMEA, and other countries, working on the surveillance component of the national preparedness plans was established by ECDC in early 2006. In addition during the [self-assessments of pandemic preparedness](#) ECDC and national team members always ask about preparation for surveillance in a pandemic. The working group had a first meeting in 15-17 January 2006, and some members met again during the [3rd European Pandemic Preparedness](#) Workshop in May 2006 and a third meeting took place in early May 2007. Outcomes of these meetings can be summarised as follows:

A first draft set of summary surveillance objectives and more detailed needs during an influenza pandemic was established. Objectives were proposed for the different WHO pandemic phases and EU alert levels (*see minutes of the Influenza Surveillance in a Pandemic Working Group Meeting ECDC Stockholm, 15-17February 2006*).

After a revision of the needs, rationale and objectives (Table 2), and which surveillance systems can cover each objective, areas for improvement or further development were identified for the following systems and functions:

- Virological and other microbiological surveillance
- Primary care surveillance

* No international grading system has been agreed as yet though the United States has a national 5-point [‘Hurricane’ Scale](#)

- Hospital based surveillance
- Mortality surveillance
- Combining real time modelling with surveillance data
- Outbreak investigations and focused studies
- Effectiveness of countermeasures
 - Public health measures
 - Therapeutics (antivirals and antibiotics) including antimicrobial
 - Vaccines (human avian influenza and specific pandemic vaccine)
- Safety of countermeasures
 - Therapeutics
 - Vaccines

The Group has focused on what would be done in Phase 6 as that is the scenario where will eventually occur and affect the EU (Phases 4 & 5 remain somewhat theoretical, may occur quickly and might affect the EU little). Also ECDC has observed in the self-assessments that while a number of countries have made preparations for phases 4 & 5, (often based on experience with SARS and human avian influenza) there are far fewer preparations for the much more difficult Phase 6.

Based on the above considerations the group has made recommendations for what should be undertaken as a **minimum in every Member State (Table 2)**

What doesn't need to be done in every Member State but has an EU added value and should be agreed as being done at EU level (in some but not all countries) and the results should feed back all the Member States (Table 2)

Following from this there is an agreed list of **priority activities** in Table 3 to be done and: where should they be done, what the involvement of Member States; ECDC and others (EISS, WHO, the Commission, etc) should be; what specific tools should be developed to carry on the activities (e.g. ECDC to publish a call for tender, working group of EU experts appointed to develop a protocol, etc).

Table 1 - Objectives of surveillance of pandemic influenza during Phase 6

With special emphasis on making of key operational decisions during the pandemic (see Table 2)

1. Early detection of pandemic influenza virus activity in European countries so as to trigger operational plans.
2. Collection of virus isolates for:
 - development/refinement of diagnostics
 - genotypic characterisation and assessment of evolution
 - vaccine development
 - susceptibility to antivirals
3. Collation of key clinical and epidemiological data on the impact of the pandemic virus in order to:
 - Assess clinical severity, case fatality and health care needs
 - Assess epidemiological parameters of transmission including R_0 and age distribution
 - Assess occurrence of complications including bacterial superinfection and antibiotic resistance
4. Provision of data for forecasting future levels of activity using real time modelling.
5. Evaluation of effectiveness and safety of interventions including:
 - antivirals
 - vaccines (pre-pandemic and pandemic specific)
 - public health and social distancing measures

Table 2 – Surveillance in a pandemic of influenza in EU: summary of surveillance objectives, items already existing or to be developed

Objective(s)	Rationale (for directing actions)	Tools: pre-existing <i>to be developed continuous or intermittent</i>	Identified stakeholders and contributors	Potential Work to be done pre-existing <i>to be developed</i>	European involvement (all/some countries/EU level)
1. Early detection of pandemic activity in Europe	<p>Prediction of likely spread across Europe</p> <p>Triggering of national operational plans</p>	<p>Sentinel clinical reporting of ILI and/or ARI from week 40 to week 20, in EU countries combined with rapid expert viral testing by National Influenza Centres(NICs)/National Reference Laboratories (NRLs) able to detect the pandemic strain.</p> <p>System of alerts on suspect cases (from clinicians) triggering specialised outbreak investigation teams</p> <p><i>System for quick activation of the sentinel reporting system during weeks 21-39, or year-round surveillance</i></p>	<p>- EISS</p> <p>-CNRL (Community Network of Reference Laboratories for Human Influenza in Europe)</p> <p>- surveillance institutes in Member States (MS)</p> <p>- Outbreak control teams (OCTs)</p> <p>- ECDC (Influenza team, SCU, PRU)</p>	<p>EISS + MS: <i>Provide data on feasibility of sentinel surveillance outside the surveillance period (weeks 21-39)</i> <i>Identify countries that can more easily maintain reporting to EISS during a pandemic (e.g. countries with flexible computerised reporting systems, etc)</i></p> <p>ECDC-EISS <i>Obtain a list of countries who are considering reporting of individual data at the start of the pandemic</i></p> <p>ECDC-EISS-MS <i>Identify countries that undertake surveillance of outbreaks of influenza and countries who investigate outbreaks of influenza CNRL</i> <i>Ensure that in all countries there are laboratories with capacity to characterise the virus HA subtype. When WHO declares phase 6, enhance swabbing and testing of ILI/ARI or other clinical syndromes (from sentinel doctor, paediatricians, hospitals)</i></p>	All countries
2. Identify and monitor changing genotypic characteristics of the pandemic strain in Europe. Provide timely and representative virological input data to WHO	<p>Deployment of human avian influenza vaccine (if H5). Determine antiviral resistance pattern to direct initial decision on antiviral recommendations</p>	<p>Network of reference laboratories in Europe</p> <p><i>Develop terms of reference for sample sharing between EU countries (in collaboration with WHO in order to avoid conflicting mechanisms)</i></p> <p><i>Rapid standardised communication tools and information flow between reference laboratories, WHO reference centre, ECDC, centres with expertise in antiviral resistance</i></p>	<p>CNRL</p> <p>WHO reference laboratory (London)</p> <p>WHO Collaborating Centres and Reference Laboratories involved in annual influenza vaccine composition recommendations</p> <p>OCTs (responsible for collection of specimens during the first outbreaks, whose location could be not covered by the sentinel system)</p>	<p>EISS-CNRL</p> <p>Have an inventory of all reference laboratories in Europe and for each of its influenza detection capacity</p> <p>ECDC-MS <i>Check National Preparedness Plans for existence of: a) laboratory preparedness plans; b) procedures for rapid collection and testing of specimens and whether geographical representativeness issues are considered; c) Identification of health providers that can maintain and/or supplement virological surveillance if the sentinel system is saturated; set of essential variables that should be reported in conjunction with the viral strain</i></p>	<p>Samples need to come from all countries. Genotyping/susceptibility monitoring in Reference Laboratories (countries with stockpiles/only some?)</p>

Objective(s)	Rationale (for directing actions)	Tools: pre-existing <i>to be developed continuous or intermittent</i>	Identified stakeholders and contributors	Potential Work to be done pre-existing <i>to be developed</i>	European involvement (all/some countries/EU level)
3. Give estimates of incidence by age-group	Target interventions. Meet the requests of information from the public, media, governments, etc	Sentinel clinical reporting of ILI and/or ARI (EISS) <i>Capacity to switch on sentinel surveillance out of the winter season</i> <i>Year round surveillance, for countries with electronic reporting</i> <i>Identification of other non-sentinel surveillance sources to complement information</i> <i>System for estimating total number of cases and deaths</i>	EISS and MS	ECDC-EISS <i>agreed protocol for rapid activation or year round surveillance of ILI/ARI through the sentinel system</i> ECDC-PRU <i>Revision of national preparedness plans to search for current systems in place to maintain surveillance during the pandemic</i> ECDC-MS-EISS <i>Explore feasibility of using a modeling approach plus monitoring proxies (e.g. antiviral usage, primary care use etc) for determining the total number of cases and deaths</i>	All countries
4. Define characteristics of transmission and patterns of disease severity including case fatality rate & hospitalisation rates	Confirm or refine groups for: 1) targeted interventions 2) recommended deployment of human avian influenza vaccine Confirm or refine the influenza case definition and determine the symptoms that should trigger initial testing and offering antivirals Guide the implementation of public health intervention according to the severity of the pandemic [A high (0.3%) or very high (over 1%) CFR will justify potentially disruptive measures]	Investigation of the first few hundred cases and share findings with other countries (UK approach) Outbreak investigation approach in areas where there is transmission <i>Repeat investigations over time and measure separately case fatality rates with and without pharmaceutical interventions</i> <i>Guidelines for the composition and roles of outbreak control teams to investigate outbreaks of:</i> <i>- First cases of infection with pandemic influenza</i> <i>- Pandemic situation</i> <i>Outbreak Investigation protocols for the following situations</i> <i>- First outbreaks of pandemic influenza in EU</i> <i>- to answer specific scientific questions during the pandemic</i>	MS OCTs ECDC- PRU tool kit	ECDC: <i>provide support through a consultant working with countries or by a call for tender.</i> <i>Support to other countries outside EU to be considered (sharing protocols)</i>	Only some countries will do, but protocols and outputs available to all

Objective(s)	Rationale (for directing actions)	Tools: pre-existing to be developed continuous or intermittent	Identified stakeholders and contributors	Potential Work to be done pre-existing to be developed	European involvement (all/some countries/EU level)
5. Monitor mortality over time	Help more precise estimation of the impact of the disease which will be useful for planning in future pandemics.	<p><i>European mortality network to become operational</i></p> <p><i>Definition of guidelines on how to conduct surveillance of mortality in EU during an influenza pandemic</i></p>	<p>Network on mortality monitoring in Europe (see Euro Surveill 2007;12(1):E070104.1. Available from: http://www.eurosurveillance.org/w/2007/070104.asp#1MS (or similar networks if available)</p>	<p>ECDC-MS Collaboration with European networks for studying mortality</p> <p>Identify the support from that is needed for the European working group on mortality to develop the work: <i>a) Make an inventory of systems for surveillance of mortality in the EU</i> <i>b) Evaluate current systems for surveillance of mortality</i> <i>c) Develop guidelines on how to conduct surveillance of mortality in EU during an influenza pandemic</i> <i>d) Assess feasibility of measuring excess mortality in Europe during the pandemic (availability of historical data, etc)</i></p>	All countries should attempt to do
6. Estimate Antiviral effectiveness	Decide on recommended use of antivirals for treatment Estimate the impact at population level (effect on transmissibility) and refine use for prophylaxis and early treatment	<i>Study protocols to be shared</i>	OCTs or other research teams	<p>ECDC Support call for tender to develop protocols, after checking there is no planned work. A variety of methodologies could be envisaged.</p>	Some countries should do

Objective(s)	Rationale (for directing actions)	Tools: pre-existing to be developed continuous or intermittent	Identified stakeholders and contributors	Potential Work to be done pre-existing to be developed	European involvement (all/some countries/EU level)
7. Monitor/Study Antiviral safety	To decide on recommendations on antivirals use.	Automatic reporting of drug adverse events <i>Epidemiological investigation to establish risk factors and causality</i>	Public health institutes in MS OCTs or other research teams	ECDC-MS-EMEA <i>Inventory of existing monitoring systems (ECDC)</i> <i>Identification of expertise in Europe to conduct the epidemiological studies (ECDC)</i> <i>Collection of existing protocols</i> <i>Call for tender:</i> <i>a) Develop a protocol for surveillance of antiviral side effects and toxicity (to be conducted on a larger scale)</i> <i>b) Evaluation protocol to assess flexibility of detection systems to work in 'war-time'</i> <i>c) Protocol for investigation of risk factors for toxicity and causality (to be conducted in selected settings and smaller sample size)</i> <i>Public health institute to support regulatory agencies and pharmacovigilance institutes</i>	All countries will be involved but some will be better placed to detect and investigate potential adverse effects
8. Estimate Vaccine effectiveness	To decide on recommendations for use of vaccine. To trigger further investigations on pandemic vaccine (improve composition, adjuvants, boosters)	<i>Study protocol to be first piloted, then routinely performed, during next seasonal influenza epidemics</i>	ECDC Working group on H5N1 vaccine Consortia of countries	<i>ECDC</i> <i>Call for tender for a consortia to undertake effectiveness study for the seasonal vaccination routinely in a number of countries</i> ECDC Public health use of the expert advice from working groups on H5N1 vaccines	Shared Protocols but only certain Countries will do
9. Monitor/Study Vaccine safety	To decide on recommendations for use of vaccine To properly deal with possible safety concerns and avoid that these affect the immunisation campaign	Automatic reporting of vaccine adverse events <i>Protocols for investigation of causality</i> <i>Communication tools</i>	EMEA Public health institutes in MS ECDC OCTs or other research teams	EMEA (leading institution) <i>Inventory of existing monitoring systems</i> <i>Identification of expertise in Europe to conduct the epidemiological studies</i> <i>Collection of existing protocols and identification of the ones to use as reference</i> <i>Develop study protocol to investigate risk factors and causality of adverse events reported through the surveillance</i> <i>ECDC-EMEA:</i> <i>Develop communication tools</i>	All countries will be involved but some will be better placed to detect and investigate potential adverse effects

Objective(s)	Rationale (for directing actions)	Tools: pre-existing to be developed continuous or intermittent	Identified stakeholders and contributors	Potential Work to be done pre-existing to be developed	European involvement (all/some countries/EU level)
10. Predictive value of case definition	To determine when laboratories can reduce the amount of confirmatory testing of cases	<i>Routine calculation and monitoring of PPV of specimens sent to be tested</i>	EISS ECDC	ECDC-EISS <i>Start measuring weekly proportion of positive results out of the total swabs collected by SPs/hospitals for seasonal influenza to assess feasibility.</i>	All countries
11. Assessment of public health impact of interventions (use of antivirals and vaccine, non-pharmaceutical measures such as social distance)	Confirm or refine recommendations Provide information for future pandemic planning	<i>Development of indicators</i>	MS	ECDC-MS Define a protocol with main indicators Explore available data sources Involve local public health authorities and health care centres	11. Assessment of public health impact of interventions (use of antivirals and vaccine, non-pharmaceutical measures such as social distance)
12. Monitoring of bacterial superinfection – bacterial type and resistance	Limit the emergence of antimicrobial resistance Refine antibiotic recommendations	<i>National protocols for sample collection and analysis.</i>	MS –hospitals and laboratories	MS with ECDC support if needed	12. Monitoring of bacterial superinfection – bacterial type and resistance

Table 3. Recommended Developments (Work plan of Group and ECDC 2008)

1. Group to continue to meet to share its outputs with all member states and to promote exchange of good practice and experience
2. Concerted work on core information and data items to be gathered from first cases by outbreak or central mechanism and then repeated later – Consultant or call for tender
3. Principle of shared protocols and agreement to share outputs through ECDC
4. Protocols for determining and monitoring antiviral effectiveness – ECDC to develop call for tender
5. Mechanism for monitoring vaccine effectiveness – ECDC to develop a call for tender
6. Special project on the interface between real time modelling and surveillance
7. List of minimum requirements for laboratory and clinical surveillance for all MS (the former would draw from the WHO terms of reference for NICs and further work undertaken by the laboratory component of EISS)

Annex 1. Members of the Group

Member States Experts:

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