MEETING OF THE STATES PARTIES TO THE CONVENTION ON THE PROHIBITION OF THE DEVELOPMENT, PRODUCTION AND STOCKPILING OF BACTERIOLOGICAL (BIOLOGICAL) AND TOXIN WEAPONS AND ON THEIR DESTRUCTION

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Existing mechanisms for the surveillance, detection and diagnosis of infectious human diseases in Italy

Submitted by Italy

Surveillance of human infectious diseases within the Italian territory

Legislative framework

1. Since 1934, the Italian "Health Act" ("Testo Unico delle Leggi Sanitarie") has established a nation-wide mechanism for the surveillance of infectious diseases. Any medical doctor is therefore obliged to report to the competent "Local Health Agencies" (ASL) - units of the Ministry of Health at the level of each municipality - all cases of infectious diseases dangerous for public health detected in his ordinary activity.

2. With the aim of strengthening epidemiological controls and the national health information system, on 15.12.1990 a decree of the Ministry of Health updated the list of infectious diseases whose detection activates specific public health measures, and determines the related notification procedures.

Operational frameworks

Routine notification system

3. According to the 15.12.1990 decree of the Ministry of Health, relevant infectious diseases are now divided in five classes, with the following ad hoc notification procedures:

4. **Class I** (diseases requiring immediate notification, due to provisions of the International Health Regulation or because of their particular interest)

Diseases

Cholera
Yellow fever
Relapsing epidemic fever
Viral hemorrhagic fevers (Lassa, Marburg, Ebola)
Plague
Poliomyelitis
Exhanthematic typhus
Botulism
Diphtheria
Flu with viral isolation
Rabies
Tetanus
Trichinosis

Notification procedures

(i) Any doctor detecting an alleged case must report it to the competent ASL within 12 hours;

(ii) The ASL must immediately notify the alleged case to the regional administrative authority;

(iii) The regional administrative authorities must immediately notify the alleged case to the Ministry of Health and to the national High Institute for Health (ISS), indicating the suspected disease, name and address of the patient, place of hospitalisation, basic diagnosis, name and address of the notifying doctor;

(iv) Eventually, the ASL must immediately notify to the regional administrative authority (and the latter must do the same with the Ministry of Health and to the ISS) the results - either positive or negative - of further analysis of the alleged case;

(v) The Ministry of Health must immediately notify the confirmed case to WHO;

(vi) Through the above-mentioned notification chain (ASL, regional administrative authority, Ministry of Health), a format related to the case is sent to the National Institute of Statistics (ISTAT).

5. **Class II** (relevant diseases due to their high frequency and/or subject to control activities)

Diseases

Blennorrhoea
Brucellosis
Infectious diarrhoea (non typhus)
Viral hepatitis A, B, NANB
Non specific viral hepatitis
Typhoid fever
Legionellosis
Skin and visceral leishmaniosis
Rubella
Scarlet fever
Tularemia
Leptospirosis
Listeriosis
Acute viral meningitis and encephalitis
Meningococcal meningitis
Measles
Parotitis
Whooping-cough
Rickettsiosis different from exhanthematic typhus
Non typhoid salmonellosis
Syphilis
Chickenpox

Notification procedures

(i) Any medical doctor detecting an alleged case must report it to the competent ASL within 2 days;

(ii) The ASL must send the above-mentioned notification format to the regional administrative authority, and the latter must forward it to the Ministry of Health and ISTAT;

(iii) Through the same notification chain (ASL, regional administrative authority, Ministry of Health and ISS, ISTAT), monthly aggregated data are circulated and filed.

6. **Class III** (diseases requiring specific documentation)

Diseases

AIDS
Leprosy
Non tubercolar mycobacteriosis
Tubercolosis

Notification procedures

(i) Specific and differentiated notification procedures are foreseen;

(ii) Through the same notification chain (ASL, regional administrative authority, Ministry of Health and ISS, ISTAT), monthly aggregated data are circulated and filed.

7. **Class IV** (diseases for which notification of single cases must be followed ASL notification only for epidemic outbreaks)

Diseases

Dermatofitosis
Infections of food origin
Pediculosis
Scabies

Notification procedures

(i) Any medical doctor detecting an alleged case must report it to the competent ASL within 24 hours;

(ii) The ASL must send the notification format to the regional administrative authority, and the latter must forward it to the Ministry of Health and ISTAT.

8. **Class V** (infectious diseases notified to ASL and different from those listed in classes I to IV, zoonosis indicated in the regulation of veterinary policy)

Notification procedures

(i) ASLs must notify on an annual basis the aggregated data to the regional administrative authority, and the latter must forward it to the Ministry of Health;

(ii) In case of epidemic outbreaks, notification procedures indicated for class IV will apply.

9. On a biannual basis, the Ministry of Health publishes through its web site the National Epidemiological Bulletin, containing all information on cases of infectious diseases registered in Italy.

The "Infectious Disease Electronic System" (SIMI)

10. In 1994, the High Institute for Health (ISS), in co-operation with the Ministry of Health, established an electronic system (SIMI) to receive and file notifications of infectious diseases of classes II, III (only tubercolosis and non-tubercolar mycobacteriosis) and IV illustrated in paragraphs 3 to 27, until then circulated by paper formats. The project aimed at creating updated and standardised archives, both at the local and central level. To this end, an ad hoc software was developed and distributed to ASLs.

11. The medium term goals of the initiative were:

(i) Improving data reliability;

(ii) Allowing prompt evaluation of diseases' notifications;

(iii) Enhance effectiveness of the notifications' system, facilitating feed-backs with notifying doctors;

(iv) Improving infectious diseases surveillance.

12. The long-term goal of the initiative is to reach full nation-wide coverage of all infectious diseases notifications.

13. In 1998, SIMI and its database on infectious diseases' notifications became accessible on Internet.

14. In order to make SIMI operational, intensive training courses were organised at the local and regional level for personnel tasked to receive relevant notifications of infectious diseases and to transmit them to competent central authorities. In the meantime, at the central level, electronic procedures were developed with the aim of checking and evaluating the consistency and correctness of collected data.

15. An accessible web site for online requests, containing aggregated data of infectious diseases of class II, was eventually established.

"Special Surveillance"

16. Whenever it appears necessary to acquire additional information with the aim of furthering the knowledge of a specific pathology and/or developing targeted response strategies, the routine notification system in paragraphs 3 to 8 can be integrated by "systems of special surveillance".

17. The latter usually have a determined duration and can collect data from alternative sources (for instance laboratories for microbiologic analysis). Information can be either received by doctors in the field or gathered from direct observation of actual cases.

18. Some of those systems provide important information to the European network for infectious diseases surveillance, established by the decision of the European Parliament and Council n. 2119/98/EC of 24.9.1998.

19. The "High Institute for Health" (ISS) is generally the co-ordinating body for special surveillance projects.

20. Over the last years, Italy introduced special surveillance for the following diseases:

(i) Antibiotic-resistance;

(ii) Heamophilus influenza;

(iii) Legionellosis;

(iv) Creutzfeldt-Jakob disease and related syndromes;

(v) Sexually transmissible diseases;

(vi) Bacterial meningitis;

(vii) Haemolytic-uraemic syndrome;

(viii) Integrated epidemiological system for acute viral hepatitis.

"Italian Surveillance Influenza Network" (INFLUNET)

21. On 28.9.2000, the Italian Ministry of Health and the regional administrative authorities ("Regioni") - recognising that influenza represented an important problem for public health and that its accurate epidemiological and virological control was needed - agreed to establish an ad hoc surveillance system (INFLUNET) aimed at:

(i) Creating a net of "sentinel" doctors and paediatricians able to monitor influenza trends throughout the Italian territory;

(ii) Indicating the cases of influenza observed by a sample group of doctors;

(iii) Evaluating the impact of influenza over the time;

(iv) Studying, in periods between influenza pandemics, the circulation of different relevant virus through laboratory testing, identifying its beginning and peak circulation;

(v) Providing relevant International Organisation (i.e. WHO) with useful data for vaccines development;

(vi) Using the net of "sentinel" doctors to effectively respond to pandemic influenza emergencies by promptly identifying and curtailing the first centres of infection.

22. INFLUNET is based on both epidemiological and virological surveillance activities.

23. To this end, *at the local level* each administrative regional authority has established its net of "sentinel" doctors and collects relevant data.

24. Actual surveillance should involve 1.5% of the Italian population, with a homogeneous distribution according age (0-14, 15-64, over 64 year-old) and territory. Data are collected starting from week 42 of the year till the last week of April of the following year.

25. On a weekly basis, such information is sent to ISS.

26. Regional administrative authorities also develop influenza virology investigations, according to operational procedures agreed with ISS Laboratory of Virology, whose results are forwarded to ISS.

27. *At the central level*, the Ministry of Health co-ordinates - through ISS - surveillance related activities. At the Ministry of Health Prevention Department have been instituted:

(i) The final point of the surveillance network;

(ii) The collecting centre for information on influenza trends, to be eventually made available to operators, users and European and international surveillance systems (WHO, EUROGROG).

Recent developments - The "National Centre for Prevention and Control of Diseases" (CCM)

28. With the aim of countering public health emergencies caused by infectious diseases and bio-terrorism, Law n. 138 of 26.5.2004 established at the Ministry of Health the "National Centre for Prevention and Control of Diseases" (CCM), that will co-operate, inter alia, with the regional administrative authorities, the ISS, the "High Institute for Prevention and Safety at Work" (ISPESL) and the military health system.

29. The CCM tasks are, inter alia:

(i) Assessment of risks for public health;

(ii) Co-ordination of surveillance and active prevention planning;

(iii) Co-ordination, with regional administrative authorities, of national alert and early response systems, also related to bio-terrorism.

30. The CCM operates through:

(i) A "Strategic Committee" (chaired by the Minister of Health) that, inter alia, identifies priorities and plans of actions and assess their implementation and effectiveness. The Strategic Committee is supported by an operative centre, established at the Ministry of Health, linked with relevant regional, national and international bodies and organisations;

(ii) A "Permanent Scientific Committee", a consultative body that provides views and evaluations on planning and programmes related to risk and crisis management;

(iii) A "Technical Committee", that ensures co-ordination with competent regional authorities;

(iv) An "Operative Directorate", that implements priorities and plans decided by the Strategic Committee, activates early investigation systems on issues related to public health and ensures the circulation of information on infectious diseases' epidemiology and bio-terrorism.

Surveillance of human infectious diseases outside the Italian territory

31. "Force Health Protection" (FHP) represents the conceptual framework of activities aimed at enhancing the protection of Italian Armed Forces engaged in operative missions abroad and faced to risks for their health and safety. An effective and reliable system of health surveillance is essential to this end.

32. The Ministry of Defence has recently approved a technical directive, developed by the Joint Military Health Directorate (DIFESAN), establishing a flow of medical information on the staff deployed in operational areas. Such a directive, consistent with NATO guidelines, is focused on monitoring:

(i) Pathologies/traumas originating generic or specialist medical exams and causing the evacuation of patients from operational theatres;

(ii) Acute pathologies linked to infectious and contagious scenarios and notified for the first time, either on syndromic (i.e. according to detected symptoms) or etiological (i.e. with certain or presumed identification of the involved biological agent) basis.

33. The information flow also aims at testing the effectiveness of infectious diseases' detection, also studied by NATO as a pillar of the common system of health surveillance aimed at enhancing NATO's NBC defence capabilities.

34. The goal is to verify the feasibility of a surveillance system relying not only on diagnosis made by doctors on the spot, but also on a mechanism able to directly collect and send all relevant data from different operative theatres to a central technical structure of evaluation and monitoring. By analysing data received, such a structure could detect possible anomalies in a determined area and give early warning, thus reducing the timeframe for effective response.

35. Given the knowledge of the yearly/seasonal epidemiological baseline of a determined community in a specific area, the new mechanism could therefore promptly identify unusual "clustering" of cases related either to the natural presence of biological agents or to their deliberate release.

36. The monitoring system is based on the collection of the following data:

(i) Weekly basic information on diseases affecting the local staff, clustered according pre-determined classifications;

(ii) Monthly basic information on all local staff requiring medical assistance;

(iii) Detailed individual notification of each alleged or verified case of infectious disease, as well as of syndromic events of infectious nature specifically identified.

37. The above-mentioned technical directive requires that relevant information be collected according to three formats by military units in the field that shall directly forward to DIFESAN and to the Italian Joint Operational Command (COI).

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