MISSION REPORT

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This report of the European Centre for Disease Prevention and Control (ECDC) was coordinated by Prof Dr Karl Ekdahl, Head of Public Health Capacity and Communication Unit (PHC), European Centre for Disease Prevention and Control (ECDC).

Contributing authors: Dr Birgitta de Jong, Senior Expert and head of the EU Preparedness section, Surveillance and response Support (SRS) Unit, ECDC; Dr Irina Dinca, Senior Expert capacity building and communication, Country Preparedness section, PHC, ECDC; Mr Ben Duncan, Senior Policy Expert, Office of the Director, ECDC; Prof Dr Todor Kantardjiev, Director, National Centre for Parasitic and Infectious Diseases, Sofia, Bulgaria; Dr Karin Nygård, Senior Advisor, Department of Infectious Disease Epidemiology, Norwegian Institute of Public Health.

This report was sent for consultation to: Dr Raed Arafat, Secretary of State, Ministry of Internal Affairs; Dr Călin Alexandru, General Director, Ministry of Internal Affairs; Dr Alexandru Rafila, personal Adviser to the Minister of Health, Ministry of Health; Dr Amalia Șerban, Deputy General Director, Ministry of Health; Dr Adriana Pistol, Director of the Romanian Centre for Disease Prevention and Control, National Institute of Public Health; Dr Florin Popovici, Senior Expert, National Institute of Public Health; Dr Lavinia Zota, Expert, National Institute of Public Health; Dr Denisa Janta, Expert, National Institute of Public Health; Dr Victor Olsavszky, Coordinator, WHO Country Office.

Acknowledgements
ECDC is very grateful for the time the two experts from Norway and Bulgaria dedicated to this mission, as well as to the Romanian colleagues that facilitated the ECDC team's access to key areas and activities.

Suggested citation: European Centre for Disease Prevention and Control. Ebola preparedness peer review mission, Romania. Stockholm: ECDC; 2015.

Stockholm, October 2015

ISBN 978-92-9193-671-7

doi 10.2900/68920

Catalogue number TQ-02-15-716-EN-N

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Abbreviations

CBRN	Chemical, biological, radiological and nuclear
CUMCE	Centrul unic de management al cazurilor de Ebola
DPHA	District Public Health Authority
EU/EEA	European Union/European Economic Area
ICU	Intensive care unit
IHR	International Health Regulation
MDR/XDR	Multidrug-resistant and extensively drug-resistant
MERS-CoV	Middle Ease Respiratory System Coronavirus
NCES	National Committee for Emergency Situations
NIPH	National Institute of Public Health
PCR	Polymerase chain reaction
PPE	Personal protective equipment
OTP	'Henri Coandă' Otopeni airport
SARS	Severe acute respiratory syndrome
SMURD	Mobile Emergency Services for Resuscitation and Extrication
SOPs	Standard operating procedures
WHO	World Health Organization
US CDC	United States Centers for Disease Control and Prevention

Executive summary

On 19-21 March 2015 an ECDC led team of experts visited Romania at the invitation of Dr Raed Arafat, Secretary of State and Head of the Department for Emergency Situations, Ministry of Internal Affairs. The principal objectives of the visit were to support national public health leaders in reviewing their health emergency systems, to identify strengths and desired improvements, in the context of preparedness for rapid identification and safe management of imported Ebola cases. The visit reviewed five critical areas of the case management pathway for actual or suspect Ebola cases: point of entry; community, inland transportation, designated hospital treatment and medical evacuation. The peer review was conducted using an ECDC protocol that was shared with Romania ahead of the visit. The team included senior experts from Norway and Bulgaria with responsibility for aspects of Ebola preparedness in their countries. This led to a valuable exchanges of ideas and good practice between the countries.

In Romania, aside from the Ministry of Health, the Ministry of Internal Affairs plays a crucial role in serious emergency situations, including ones produced by communicable diseases. In October 2014, following the declaration by the World Health Organization (WHO) of Ebola as a Public Health Emergency of International Concern, Romania's National Committee for Emergency Situations established a dedicated cross-sectorial National Ebola Committee chaired by Dr Raed Arafat. The programme for the visit therefore included visits to facilities, and meetings with experts, under the responsibilities of both the Ministry of Internal Affairs and the Ministry of Health. Most visits and meetings took place in and around Bucharest. However the team also visited facilities in Giurgiu county, which is a region bordering Bulgaria. The background and context of the visit are detailed in Part 1 of the report, while information gathered and observations made in relation to the five critical areas of the Ebola case management pathway are set out in Part 2.

The key finding of the report is that Romania has taken the threat from Ebola seriously, and in a short time initiated and established a large range of measures. Romania is well on its way to being fully prepared to detect, transport and care for an imported Ebola case with adequate staff protection. However, more work needs to be done in order to be fully prepared. Areas identified for further improvement mainly concern procurement of personal protective equipment (PPE) for health workers and transportation equipment, training in proper use of PPE, developing and disseminating more detailed national guidelines, and performing regular simulation exercises. In order to fully capitalise on the investment made in Ebola preparedness, the report finds it would be important to keep, continue to develop and apply this preparedness to future, as yet unknown, health threats: these could be due to other serious infectious diseases, such as Middle Ease Respiratory System Coronavirus (MERS-CoV), severe acute respiratory syndrome (SARS), highly pathogenic influenza strains, and multidrug-resistant and extensively drug-resistant (MDR/XDR) tuberculosis. These findings are set out in more detail in Part 3 of the report along with an analysis of strengths, vulnerabilities and areas for review within Romania's system of preparedness. The report ends by identifying areas in which ECDC may be able to provide further input to Romania on Ebola and other infectious disease threats.

Introduction

The European Union and European Economic Area (EU/EEA) Member States have been faced with challenges to prepare and respond to the serious cross-border health threat caused by the epidemic of highly contagious viral haemorrhagic fever (Ebola) that started in West Africa in 2014. For several months, the Member States have been revising preparedness plans and responding to suspected or confirmed cases, and they have been strengthening their health systems to deal with public health crisis situations. Key stakeholders from other sectors (e.g. transport, international affairs, civil protection, etc.) have been engaged in the discussions and inter-sectorial collaboration that has been taking place. Moreover, a number of EU/EEA Member States have participated extensively in international efforts to contain the epidemic in Africa by providing expertise, logistical and financial support.

Some European countries may still be at risk of exposure to Ebola health threats due to the fact that there are now returning nationals from Africa, and in particular healthcare and aid workers who supported efforts to contain the epidemic; in addition workers from other sectors/industry as well as students are also travelling from West Africa to various European countries.

The EU Health Security Committee has been working on ensuring common understanding and information exchange between Member States on the situation and the preparedness measures put in place. The European Commission, Directorate-General for Health and Food Safety initiated a survey on preparedness capacities in the EU in October 2014. There is also a plan to organise a high-level meeting in October 2015 under the EU Luxembourg Presidency to discuss with the Member States lessons learned from the Ebola epidemic with a view to further strengthening their public health preparedness planning. This will include looking at aspects of inter-sectorial and cross border collaboration as well as public health capacities and capabilities.

Taking these developments into account, ECDC is offering support for the Member States to review and discuss their Ebola preparedness activities and lessons learned for planning and capacity strengthening. Upon agreement and invitation from the country, ECDC organised peer review visits to some EU Member States. As well as the willingness of the Member State to receive such a visit, the criteria for selecting countries to visit included: possible fragility of healthcare and public health emergency infrastructure; intensity of exposure to potentially infected individuals (predominantly returning healthcare and aid workers); being a hub for international flights to Africa.

Romania is one of the countries that was interested in having such a peer review visit. It was further prioritised as a Member State with a large population and a GDP per capita significantly below the EU average.

Objectives of the visit

1. Collect information and data necessary for a review of the country's lessons learned from the Ebola health threat and feedback these lessons into preparedness planning.
2. Meet and discuss with key stakeholders in the country the critical issues related to capacities, strengths and vulnerabilities in preparedness for Ebola.
3. Perform analysis of the collected information (e.g. reports, notes from meetings and interviews during the country mission) to identify lessons learned, good practices and list vulnerabilities and possible gaps in Romania's public health preparedness framework.
4. Provide an opportunity for peer exchange of information between EU/EEA Member States (adopted policies and practices in preparedness planning in connection to Ebola as a health threat) due to the presence of senior experts from Bulgaria and Norway in the ECDC team.
5. Discuss possibilities for further collaboration and support.

Scope and approach

The peer review visit took place from 19-21 March 2015, by invitation of Dr Raed Arafat, Secretary of State and Head of the Department for Emergency Situations, Ministry of Internal Affairs. It focused both on the general structures of Ebola preparedness and on five critical areas of an Ebola pathway: point of entry, community preparedness, inland transportation, designated treatment hospital and medical evacuation.

The review was based on a classification framework of the system elements and organisational competences needed to ensure the prompt recognition and safe management of a person suffering from a viral haemorrhagic fever (VHF) such as Ebola. This was developed by an ECDC expert group based on published evidence and existing national and international protocols for management of VHF cases. Critical points of emergency preparedness capacities and capabilities and lessons learned from Ebola as a health threat were explored through: semi-structured interviews based on a short questionnaire, site visits for observations, and discussions at meetings with the main stakeholders. ECDC's protocol was shared with the national authorities prior to the field work.

In addition, the Romanian team asked ECDC to also include a discussion on public procurement and the specificities of this during emergency health threat situations as declared by international organisations. In this case, WHO declared the Ebola outbreak in West Africa to be a Public Health Emergency of International Concern (PHEIC) on 8 August 2014.

Team composition

- Team leader: Prof Dr Karl Ekdahl, Head of Public Health Capacity and Communication Unit (PHC), European Centre for Disease Prevention and Control (ECDC).
- Dr Birgitta de Jong, Senior Expert and head of the EU Preparedness section, Surveillance and response Support (SRS) Unit, ECDC
- Dr Irina Dinca, Senior Expert capacity building and communication, Country Preparedness section, PHC, ECDC
- Mr Ben Duncan, Senior Policy Expert, Office of the Director, ECDC
- Prof Dr Todor Kantardjiev, Director, National Centre for Parasitic and Infectious Diseases, Sofia, Bulgaria.
- Dr Karin Nygård, Senior Advisor, Department of Infectious Disease Epidemiology, Norwegian Institute of Public Health

Part 1. Background

In Romania, both the Ministry of Health and the Ministry of Internal Affairs play a crucial role in serious emergency situations, including in ones produced by communicable diseases. Thus in 2014, a new Department for Emergency Situations was set up in the Ministry of Internal Affairs, with the aim of providing an integrated approach across all response systems in case of serious emergencies, including health threats. This department coordinates the civil protection and fire service, the rescue ambulances and emergency departments, the rescue aviation, and the mountain rescue services. The department also coordinates operationally the ambulance system under the Ministry of Health.

All emergency issues in Romania are coordinated by the National Committee for Emergency Situations (NCES). This is an inter-ministerial body with wide-ranging responsibilities created under Romania's civil protection legislation[i]. NCES is chaired by the Minister for Internal Affairs, who is also Vice Prime Minister, and its members are the ministers or State Secretaries from each of the ministries that may play a role in emergencies. Following the August 2014 declaration by WHO of Ebola as a Public Health Emergency of International Concern, NCES established a dedicated cross-sectorial National Ebola Committee in October 2014.

The role of the National Ebola Committee is to coordinate interventions and measures required to prevent and control infection with Ebola virus in Romania. It is chaired by the Head of the Department for Emergency Situations (Secretary of State of the Ministry of Internal Affairs) with the Secretary of State of the Ministry of Health as Vice Chair, and reports to the National Committee for Emergency Situations. The members of the National Ebola Committee represent the Ministry of Health, the Ministry of Internal Affairs (Department for Emergency Situations), the Ministry of Foreign Affairs, the Ministry of National Defence, the Ministry of Education and Research, the Ministry of Transportation, as well as key institutions subordinated to these ministries, including the National Institute of Public Health, the National Institute for Infectious Diseases 'Matei Balș' and the Central Military Emergency Hospital 'Carol Davila'. The committee can call in appropriate experts and specialists from the public administration, public authorities or institutions according to need.

The National Ebola Committee has worked intensively to develop a coordinated and comprehensive country-wide preparedness for the identification and safe management of possible Ebola cases and has consequently adopted seven Decisions in this area that cover various aspects related to early detection, triage, management and preventions of further spread of Ebola haemorrhagic fever virus, as well as creating a dedicated budget to support these activities.

[i] See the Civil Protection Act (481/2004) and Government Decision no. 1489 / 09.09.2004 on the organisation and functioning of the National Committee for Emergency Situations.

The work has included the agreement of procedures and guidance; decisions on procurement of equipment (e.g. specially equipped ambulances, personal protective equipment); and also operational management of suspected or confirmed cases. It also details procedures at points of entry (air or sea), including the questionnaire to be administered on signs, symptoms and one of location while in Romania (in English). Of particular importance among the procedures issued is the National Ebola Committee's Decision No. 4 of 10 November 2014. This establishes operational procedures for the management of suspected or confirmed cases of Ebola virus disease including transportation of these cases and protection of health staff. It includes case definitions (based on ECDC's case definition), and procedures for identifying, reporting and managing suspected Ebola cases based on different scenarios such as: a suspect case presenting at a hospital emergency room; a suspect case being identified by the 112 emergency team after he or she for assistance; and a suspect case who becomes ill on an aircraft heading for a Romanian airport or a Romanian harbour.

One of the Decisions also clarifies that only the Chair or, when he is not available, the Vice Chair can communicate publicly about these topics. The decisions also contain two algorithms: one on triage for early detection, information and triage of patients with risk of Ebola virus diease in the hospital emergency rooms; and the procedure of alert, intervention and transport of a suspected case. A detailed description of technical specifications for PPE and when which type of PPE should be used are also included.

The Romanian health system includes a total of 460 hospitals and 11 000 GPs nationwide. The Ministry of Health oversees the policy and regulatory framework in the area of public health and healthcare services, as well as providing the funding for the National Public Health Programmes (emergency medicine being one of them). The local public health work is carried out by 42 District Public Health Authorities (DPHA).

The National Institute of Public Health (NIPH), working under the Ministry of Health, has five branches (Centres for Public Health) in the main cities of Timișoara, Iași, Cluj-Napoca, Târgu-Mureș, and Sibiu.

The National Institute of Public Health (NIPH) has several roles in Ebola preparedness under the National Ebola Committee. The Institute monitors the epidemiological situations related to Ebola at the global level (together with other relevant institutions), it is involved in activities aimed at increasing awareness (the institute website is the most complete source of up to date information on this topic, for both specialists and public). Although not written in the National Ebola Committee Decisions, we understood that the NIPH role besides monitoring the epidemiological trends is also in the area of population education campaigns, maintaining a continuous communication with the District Public Health Authorities (DPHA) on epidemiological aspects, and others as relevant, and in the training of public health and other relevant personnel in using PPE.

Additionally, the NIPH and the Ministry of Health represent Romania in the EU Early Warning and Response System and the Health Security Committee, as well as being responsible vis-à-vis WHO for issues related to the International Health Regulation (IHR).

Part 2. Ebola pathways – systematic approach

Points of entry

Information provided to the team

There are no direct flights from Africa to Romania. Nonetheless, there are many Romanian workers in Africa, including the epidemic countries, and also peace-keeping forces in West Africa. There are also students from West Africa who study in Romania. When these groups travel to Romania they typically come via airports in other countries in the European region, most notably Istanbul. There is a well-established international system for notifying the final destination country of any passenger having started the journey in an Ebola epidemic country. In addition, West Africans travelling to Romania are also identified by the Romanian Consulates in the affected countries, when they request visas for Romania. These passengers will be picked up by the passport checkpoint and referred to the airport medical personnel for information and initiation of the 21 day follow-up. The follow-up is based on a questionnaire covering travel history, health status and residency in Romania.

So far the airport has received 20 passengers from Sierra Leone, one from Guinea, two from Liberia and 24 from Nigeria. There has been at least one passenger who 'escaped' the airport entry system by arriving by car from Hungary. After being informed of this by WHO, the person could be quickly identified by the District Public Health Authority and followed up as per the standard procedures. The Henri Coandă airport (also called Otopeni airport - OTP) is the single dedicated airport selected to receive suspected cases of Ebola from all air flights to Romania. If there is an aircraft with another destination in Romania, this aircraft would be redirected to OTP. In case of needing to refuel before reaching OTP, it would be allowed to do that in another Romanian airport, but no one would be allowed to disembark the aircraft. Moreover OTP is the legally designated Point of Entry with respect to IHR 2005.

At OTP there is a 24/7 medical service, staffed with one doctor, one nurse and one driver working in 12 hour shifts. In addition to the airport medical staff, the airport is also staffed by four nurses from the Public Health Authority of Bucharest (Border Sanitary Service).There are two ambulances stationed at OTP. PPE from the Avian Influenza outbreak (not splash proof) is available and there is also a small examination room.

Any aircraft with a suspected case on-board must report to the air traffic control centre, which will alert the Emergency Operational Centre via the 112 emergency number. The Border Police will be alerted to arrange for special control procedures regarding the debarkation of passengers and patient, and the medical and public health staff at the airport will be mobilised.

After landing at Otopeni airport, the aircraft will be directed to a remote designated area. The handling agent will provide the aircraft with two stairs. A specific Mobile Emergency Services for Resuscitation and Extrication (Serviciul Mobil de Urgenţă, Reanimare şi Descarcerare - SMURD)[i] (see below) vehicle will come to the aircraft and the SMURD personnel using PPE will enter the aircraft and examine the suspected case. The case will then be evacuated through the rear door and transported to the 'Matei Balș' Infectious Disease Hospital for diagnostics. (*note: in the current Operational Procedure the designated hospital for isolation and care of the Ebola patient (suspected/confirmed) is CUMCE (Centrul unic de management al cazurilor de Ebola).*

The Border Sanitary Service will enter the aircraft and start to interview the other passengers and crew. After the passengers have filled in a specific form they will be allowed to leave the aircraft through the front stairs. Outside the aircraft they will be asked to identify their luggage and passport control will be conducted. They will then be free to leave the airport without going through the terminal building. The information gathered from the passengers would be shared with the public health authorities and passengers would be monitored in the community by their local District Public Health Authority.

The cleaning of the airplane and waste disposal is contracted to a private company. However, it was not clear to us how the waste from an aircraft which had had a suspected Ebola case on it would be treated. If a suspected case is detected after debarkation (e.g. at the passport control), this person will be isolated in one of the handicap toilets pending further transportation. No Ebola exercise has been carried out at OTP.

[i] SMURD is an emergency rescue service, with bases covering much of the country, and still expanding. It deals with the worst emergency cases, all in a good collaboration with the regular Ambulance Service (Serviciul de Ambulanţă).

In Norway for example, extensive discussions took place on this topic. It was decided that the other passengers are best evacuated first into a separate hangar in the airport. A challenge for airports is that it may be difficult to have a dedicated room where all passengers can stay, and therefore the registration and information is best given while still seated in the plane since when they are out of the plane, they may be lost for follow up. The Ministry of Health in Romania informed us that according to the Decision no 4 of the ENC the procedure is the same.

Direct observations by the team

The team visited both the Otopeni airport and a sanitary station in Giurgiu, at the border with Bulgaria. At the Otopeni airport we were shown the medical examination room by the doctor on duty, and in Giurgiu we were shown around by three staff members from the Border Sanitary Service who were then on duty. At both places there was a high awareness of Ebola and the routines for handling patients and reporting were well known. In both places, we were shown simple PPE from the time of avian influenza, these would be adequate for a 'dry' patient with no florid symptoms, but not being splash proof, they would be less suitable for handling symptomatic 'wet' patients, e.g. with diarrhoea and/or vomiting. Poster instructions from the time of avian influenza on putting on ('donning') and taking off ('doffing') PPE was available in the medical examination room at the Otopeni airport, but not visible at the border station in Giurgiu. The airport doctor was not familiar with the concept of assisted 'doffing'. Our impression was that the staff at neither place had PPE training adequate for optimal protection in case of handling a 'wet' Ebola patient.

Recommendations by the team

- Consider training for the staff at point of entry in the proper usage of PPE.
- Consider the appropriateness of present routines of first evacuating from an aircraft a suspected case that has been isolated in the plane, while the other passengers are still on the aircraft. There are not at present any international recommendations on how best to evacuate a plane. However, some countries evacuate the other passengers first before evacuating the suspected case.
- Ensure that staff cleaning an airplane having carried a suspected 'wet' Ebola case has proper PPE and are adequately trained.
- Establish routines for handling passengers that might have been exposed to vomit or other body fluids from a suspected case.
- Carry out a national Ebola preparedness exercise that includes point of entry.

Follow-up action by ECDC

- Handling of toilet sewage from aircrafts is a big question that needs to be explored on an international level by ECDC.

Community preparedness

Information provided to the team

Within Romania, the first potential point of contact of a case with the healthcare system would probably be either an emergency department, a regular ambulance, a SMURD rescue ambulance (see below), or a family doctor/GP. Of these, presentation at an emergency department was considered the most likely scenario.

There is a well-established 112 emergency phone system, which is widely used and well known by the general public in the country. The 112 operators are well briefed on how to handle calls concerning suspected Ebola, and how to redirect any suspected case to the nearest emergency department or to a SMURD team as appropriate.

In the country, there are 67 large emergency departments and 63 small emergency departments in hospitals at various levels, and most are connected by telemedicine for advice when needed. The emergency departments are, by law since 2014, organisationally under the Department for Emergency Situations, Ministry of Internal Affairs, and are well integrated with the mobile emergency service (SMURD). They have regular videoconferences arranged by the Department for Emergency Situations.

Funds have been allocated nationally for PPE training, but due to lack of PPE there has not been a national training programme put in place yet. We were informed that funds had also been made available for designing, printing and distributing information on donning and doffing of PPE, though this work had not been undertaken at the time of the visit, possibly also due to lack of the actual PPE.

There have been a few suspected Ebola cases in Romania over the past months, some of these did not fulfill the epidemiological criteria in Romania's case definition (which is based on the ECDC case definition). The patients were mainly detected between triage and consultation in emergency departments. Although these incidents have not been systematically assessed, it was the impression that the first responders used the correct procedure for management and reporting, but did not always correctly use the case criteria for suspected case in terms of exposure, e.g. a feverish case from Equatorial Guinea (a non-epidemic country) was handled as a possible Ebola case.

In each local area the District Public Health Authority (DPHA) is responsible for contact tracing and supervision of infection control in community settings. We visited one DPHA on site (Giurgiu and met a representative from the Bucharest Public Health Authority at one of the multi-stakeholder meetings in Bucharest). In both instances the officials we met were clear about their role as described in Decision No. 4 of 10 November 2014 of the National Ebola Committee (see Background section above). More detailed national guidelines for contact identification and infection control in community settings were not mentioned (i.e. if the patient lives in an apartment block, what would be the procedures for decontamination, who would be defined as contacts etc.).

In case of diagnosis of an Ebola patient, the family members would, in principle, be put in quarantine and the house of the patient decontaminated by the District Public Health Department assisted by fire personnel with chemical, biological, radiological and nuclear (CBRN) training. The experts and officials we spoke to believed that, under Romanian law, it may not be possible to enforce compulsory quarantine if an exposed person – or even a case – does not wish to cooperate. Romanian law makers are examining proposals to introduce a compulsory quarantine regulation (*note: at the time when the report was drafted, the law is with the Presidency for final approval*).

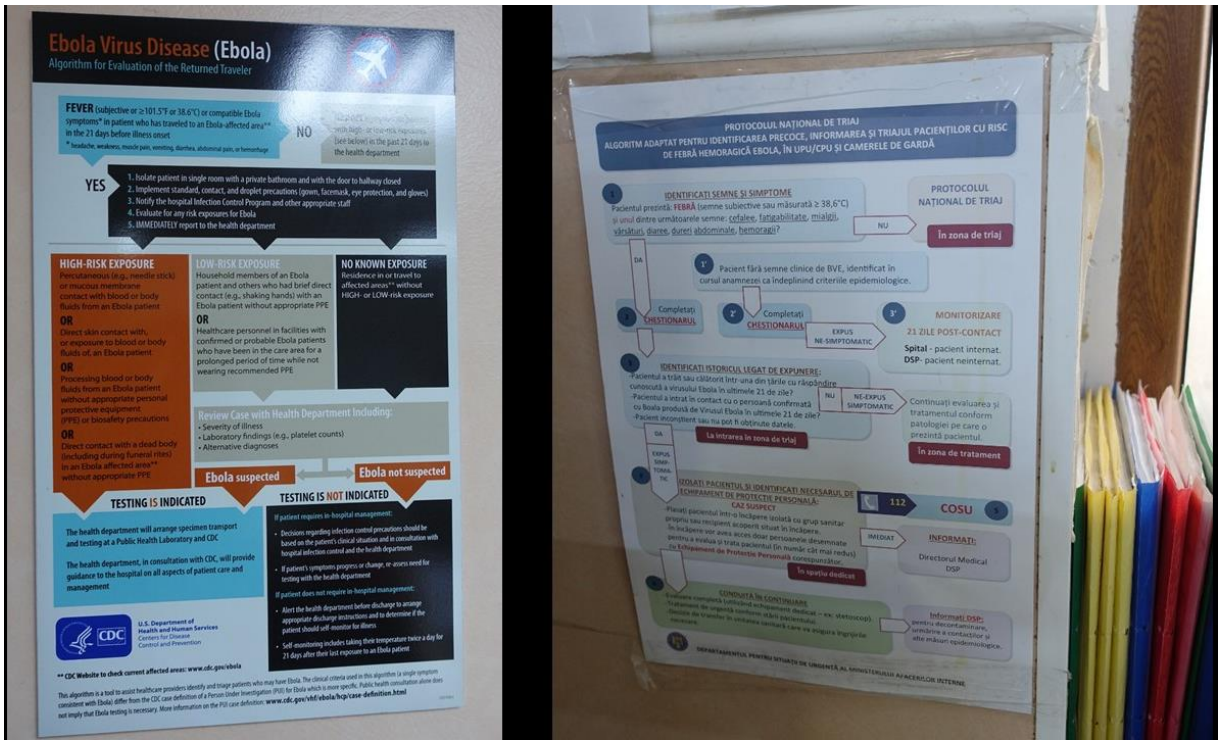
Direct observations by the team

We visited two emergency departments, one ambulance centre, one district inspectorate for emergency situations (Bucharest) and one GP office.

Decontamination and isolation room at triage point in emergency hospital in Bucharest

In the emergency departments, everyone was well aware of relevant decisions from the National Ebola Committee: in particular, the algorithm for case detection and management; when to isolate a person under investigation; when to call 112 to activate the procedure for a patient to be hospitalised; and the procedure for reporting of a suspected case to the District Public Health Authority (DPHA) responsible for contact tracing and infection control supervision. All places mentioned that they had read the decision, and signed that it was read. The dual reporting system via 112 and to the DPHA decreases the likelihood that a potential patient would not be picked up by the system.

The United States Centers for Disease Control and Prevention (CDC) algorithm for evaluation and handling of a returned traveller with suspected Ebola infection was posted on the wall of the emergency department in Bucharest, while the national triage protocol for early detection, information and triage of patients with risk for VHF was put on the wall on the emergency department in Giurgiu for easy referencing.



Triage flow charts from emergency department in Bucharest (left) and Giurgiu (right).

There was a clear understanding of the need for PPE, although detailed written instructions for donning and doffing was only observed in one place. There had been some training in the use of PPE in most of the visited places and most of them mentioned t the importance of including observers during the process. Where PPE was not available, distancing from the patient was mentioned as an alternative method for protection.

Recommendations by the team

- Agree on national detailed guidelines and algorithms for contact identification and infection control in community settings, including decontamination issues, to be used across the country for full consistency.
- Establish national guidelines/instructions/training material for proper use of PPE, taking into account available types and the added challenges of handling symptomatic Ebola patients (most available PPE are not 'splash proof').
- Consider training for selected staff in the emergency departments in proper usage of PPE.
- Carry out a national exercise for the whole patient management chain; suspected patient contacting first responders, reporting, transport, hospitalisation, contact tracing, infection control, decontamination in healthcare settings and the community, and waste management.
- Consider infection control in community settings; who will do this - are they qualified, how to do a risk-based approach to areas that need decontamination and what would be the procedure for furniture, fabrics, pets etc.
- Consider communication between central and local level – including both first responders and public health authorities. What are the challenges and needs at the local level in terms of guidance and advice when it comes to management of highly infectious patients? How well are they prepared for Ebola – and possibly other high-risk pathogens?

Inland transport via ambulances

Information provided to the team

In-country land transportation of any suspected Ebola case, to the 'Matei Balș' hospital for diagnosis or to the designated treatment centre for care, will be done by SMURD. Additionally, the helicopter emergency medical system (HEMS) has been implemented in six cities (Târgu Mureș, Bucharest, Iași, Arad, Craiova and Constanța), and covers virtually the entire national territory. Depending on the situation, police and army helicopters are also being used. The emergency system used by this service is based on the European 112 emergency phone number, used in Romania for all emergencies (police, firefighters, ambulance).

Land transportation of any suspected Ebola case will be done in one of five specifically equipped Class C SMURD ambulances equipped with state-of-the art equipment for medical emergency treatment of patients. For staff protection, these ambulances are presently equipped with small portable isolators. With the present equipment, Ebola patients with few or no symptoms could safely be transported. For patients with more florid symptoms, including vomiting, safe transport would be a severe problem. SMURD and the Department for Emergency Situations would therefore like to equip all five dedicated ambulances with special designed compartments with negative pressure for patients with highly contagious infections. Funding for these modifications of the dedicated ambulances is available, but due to procurement issues it is unclear when the isolation chambers could be in place and operational.

The ambulances will be manned by trained emergency medicine staff.

There has as yet not been any national exercise including inland transport with the SMURD ambulances, but the system was 'tested' when transporting a suspected Ebola patient from Constanța to Bucharest; as we were told there was no formal 'lessons learned' process after this event.

Direct observations by the team

The team visited the Inspectorate for Emergency Situations 'Dealul Spirii' in Bucharest. At the premises we were shown a sample of the various kinds of SMURD vehicles available, including a Class C ambulance with equipment for advanced emergency care, CBRN vehicles with decontamination equipment and a mobile decontamination tent, a mobile lab for field environmental sampling and analysis, and a mobile command centre. All equipment shown to us were state-of-the-art and the staff appeared to be well trained to use the equipment.

SMURD Class C ambulance.

Mobile ambulance isolator

The team was also shown the command centre and the 112 call centre where all the alerts and emergency calls in Bucharest are received and the response coordinated. Again we got the impression of a well-run and efficient organisation where all aspects of emergencies, including threats from infectious diseases, were well addressed in an integrated way.

The team visited the ambulance service from Bucharest that serves the city and surrounding areas and has a similar organisation to the Inspectorate for Emergency Situations related to the 112 system. There was a dedicated ambulance only for the transport of Ebola suspected cases and a system for waste management (which is externalised). The staff have been trained, mostly using locally produced hand-outs, using PowerPoint slides from the Institute 'Ion Cantacuzino' and the manufacturer's instructions of use.

Local ambulance in Giurgiu with paramedic wearing PPE from the time of avian influenza

Recommendations by the team

- Once proper PPE has been procured, ensure that staff is properly trained according to a standardised approach throughout the organisation

Designated treatment hospital

Information provided to the team

The hospital structure is generally very old with no advanced isolation units in the general hospitals. The professional competency for handling patients with haemorrhagic fever are mainly concentrated to the National Institute for Infectious Diseases 'Matei Balș' and the Central Military Emergency Hospital 'Carol Davila'. Both institutes are represented in the National Ebola Committee, and the infection disease ward of Central Military Emergency Hospital 'Carol Davila' is located in the courtyard of National Institute for Infectious Diseases 'Matei Balș', using the same standard operating procedures (SOPs) on patient management.

All Romanian Ebola tests will be performed at the 'Matei Balș' hospital using a commercial PCR kit. An answer could be given within three hours (compared with four hours for conventional PCR) and this diagnostic capacity is available 24/7. Confirmatory tests will be done in Germany.

The laboratory has modern PCR equipment with the possibility to also sequence the PCR amplicons. The DNA sequencing needs two purifications, 30 minutes each, sequencing PCR needs 2–3 hours and sequencing itself about 1 hour. It was unclear to us whether the laboratory is part of any external quality assurance scheme.

Within its intensive care department the 'Matei Balș' hospital has built up a specific unit for handling patients with highly infectious disease of severe consequences, including haemorrhagic fevers. Staff in this unit have been regularly trained and exercised in proper use of PPE, using an adapted version of the ECDC PPE training manual, as well as using intensive care equipment in the isolation tent. While the 'Matei Balș', Intensive Care Department is reasonably well staffed with infectious disease doctors and nurses, there is a clear lack of intensive care doctors, presently one full time and one part-time doctor – which would be insufficient for 24/7 intensive care patient management.

Waste management in 'Matei Balș', as well as in the other emergency hospitals, is handled by contracted private firms. It is unclear what would happen in a situation where the private firm refused to handle the waste from a diagnosed Ebola patient.

When designated hospital treatment was discussed in the National Ebola Committee, the main concern was to limit any possibility of spread to staff and other patients. It was therefore unanimously agreed by the Committee that any patient diagnosed with Ebola will be treated in a military field hospital. This is in a secluded, and easy to secure site.

The hospital will administratively function as an external ward of the 'Matei Balș' and Carol Davila hospitals, and draw its staff from these two hospitals complemented with intensive care specialists from other hospitals. There is a list of dedicated staff (names and contact details) from Carol Davila Military hospital, but as yet not from 'Matei Balș' hospital. The necessary intensive care physicians from other hospitals have also not been identified by name or institution. There is also a need to identify auxiliary staff including for managing the autoclave. The idea is to have the necessary medical and auxiliary staff staying on site for the duration of the Ebola patient's care. These staff would therefore have no contact with any other patients during this time. There will be the possibility to open up a campus hosting the staff of CUMCE over a period of several weeks. It was first considered to only man the hospital with infection and intensive care unit (ICU) doctors and nurses, but the present concept is to have a broader staff base also including auxiliary staff.

Direct observations by the team

'Matei Balș' Infectious Disease Hospital

During the visit at the 'Matei Balș' hospital, we were shown the facilities for initial triage of the patient, where an asymptomatic 'dry' suspected patient would be staying in a small quarantine room waiting for the results of the PCR test. The PCR lab has modern machines.

We were also shown the ICU isolation unit, which has been equipped to receive and treat an Ebola patient. The isolation unit has state-of-the-art equipment including an isolation chamber located in a negative pressure room, a small dedicated laboratory for emergency blood chemistry, and easy access to x-ray, mechanical ventilation, and haemodialysis.

The PCR lab has modern equipment, and the technician appeared to be well trained and comfortable with the testing procedures.

Existing procedures, easily available on the hospital intranet, include decontamination, isolation procedures, waste management, accidental exposure of staff, use of PPE, reporting of suspected cases, case management, PCR screening, and handling deceased bodies. All government decisions, reporting forms, etc. are also available on the intranet.

ICU negative pressure isolation chamber in 'Matei Balș' hospital

Centrul unic de management al cazurilor de Ebola (CUMCE)

The military field hospital to be used as the designated treatment centre for a confirmed Ebola case is a standard mobile NATO Brigade hospital (inflatable tents and containers). It is in place and manned with necessary military staff for its technical/logistic facilities, e.g. oxygen supply, heating, ventilation, etc. Some heavy medical equipment including x-rays machine and ventilators are in place but more equipment and medical consumables would need to be quickly mobilised in case of urgent patient management. As part of the hospital there is an incinerator with capacity to handle any infective waste from the hospital. The incinerator as well as the other equipment is operated by military personnel.

The main areas of the hospital have been dedicated for specific purposes, e.g. patient management, areas for donning/doffing of PPE, hygiene, rest, eating etc., but our impression was that more work needs to be done to finalise the logistic details, including workflows. Patient management will take place in container parts of the hospital with room heights of 195 cm. As the standard isolation negative pressure units are 245 cm high, specially fitted units are under procurement.

There has as yet been no mobilisation exercise, and no exercise on patient management under secure conditions. Given that the intended treatment team will draw its members from three (or more) hospitals, proper joint on-site training and exercises would be vital.

Recommendation by the team

- Organise exercises on mobilisation of staff and equipment as well as on all aspects of simulated patient care and running the hospital under 'wet' conditions (i.e. management of a symptomatic VHF patient).
- Participate in the External Quality Assurance Proficiency panel for Ebola PCR diagnostic organised by the European Network of Imported Viral Diseases/Collaborative laboratory response network under ECDC.

Medical evacuation and in-country air transportation

Information provided to the team

Based on a risk analysis of potential difficulties in arranging medical evacuation (MedEvac) through external partners (private companies and/or third countries), a Government decision has been made to set up a Romanian system for medical evacuation based entirely on national resources. Another key factor behind this decision was the potential need for in-country transportation of an Ebola case to the designated treatment centre in Bucharest from remote parts of the country.

The basis for Romanian MedEvac is existing aircraft capacity within the Romanian Air Force, using either C27G Spartan aeroplanes for short and medium long transportation as well as for transportation within the country, and C130 Hercules airplanes for longer evacuations. In all, seven military aeroplanes are available for such transports.

For shorter in-country air transportation of potential Ebola patients, there is also an immediate availability of four Puma 330 helicopters, presently distributed across the country as part of the SMURD system.

Presently, air transportation of cases relies on the use of simple isolators (same as in the designated SMURD ambulances), for which there is availability of one isolator in each of the 43 districts, pending procurement of negative pressure isolation units to be fitted for the aeroplanes. Two potential solutions are being considered. The first option would be a 10 meter long metal container with capacity for one patient and three staff members, fitted with three negative pressure compartments for treatment, decontamination and resting, respectively. The container solution would allow for transportation from the airfield to the treatment centre on a truck, without evacuating the patient. The second option would be a 'soft shell' exoskeleton solution, similar to the ones used by the commercial MedEvac provider Phoenix.

Air transportation personnel that have gone through specific CBRN training will be supplied by the Romanian Air Force, while doctors and nurses managing the patients (in all 10–12 staff) will need to be mobilised from one or more hospitals. The intention is that the supplier of the isolation unit will train the medical staff in the unit during transportation as per the contract.

Funding for the isolation units is available, but the procurement is for the time being within the procurement department of the Ministry of Health (for ambulances) and of the General Inspectorate for Emergency Situations, a structure which is legally under the Department for Emergency Situations of the Ministry of Internal Affairs. At the time of the visit it was unclear when the isolation units could be in place and operational.

Another yet unsolved issue, would be possibilities for refuelling in a third country during long-distance flights.

As soon as the negative pressure compartments are in place, Romania will be willing and able to offer MedEvac services also to other Member States.

Procurement issues

Information provided to the team

Funding for appropriate PPE for Ebola protection, including 60 positive pressure type A PPE, as well as isolation units/chambers for designated SMURD ambulances and MedEvac airplanes is available from the General Inspectorate of Emergency Situations in the Ministry of Internal Affairs. It is foreseen to have a large central stockpile and a smaller number of PPE distributed across the country.

Procurement needs to be done by the procurement department of the General Inspectorate for Emergency Situations, under the Department for Emergency Situations of the Ministry of Internal Affairs and the Ministry of Health. So far procurement has been delayed due to different interpretations as to whether the declaration by WHO in August 2014 of a Public Health Emergency of International Concern (PHEIC) under the IHR constitutes an 'emergency' justifying use of the emergency procurement procedure under Romania's national legislation on public procurement. The prevailing view among the procurement experts has been that the PHEIC does not by itself constitute an 'emergency' for this purpose, even in the situation where Romania's National Committee for Emergency Situations has declared an emergency and established a sub-committee (the National Ebola Committee) to take emergency measures.

These procurement experts have advised that emergency procurement of equipment would only be legally justified in a situation where Romania has a confirmed Ebola case. As an EU Member State, Romania's legislation is based on the EU Procurement Directive (Directive 2014/24/EU)[i]. This is therefore an issue of relevance of other EU/EEA Member States, all of which base their public procurement legislation on EU Directives and all of which are also parties to the IHR. This issue has not yet been resolved.

Presently, most of the available PPE in the country are from the times of avian influenza. They are fit for that purpose, but as they are not 'splash proof', and they are inadequate for optimal protection against an Ebola patient with florid symptoms.

The ECDC peer review team supports from a technical perspective that, for optimal protection of public health, PPE and other protective equipment need to be in place before the appearance of an Ebola patient. From a health protection perspective, starting the procurement only once the patient has been identified would be too late. However, as there was no procurement/ legal expertise in the team, ECDC is seeking information on how other countries have approached the issue, and will also request the view of the European Commission. The team member from Bulgaria has indicated that his country also encountered challenges in procuring PPE suitable for the treatment of Ebola in sufficient quantity. National procurement procedures took a long time, and the procedure to purchase Ebola suitable PPE was still not complete at the time of writing this report. Information provided by the team member from Norway indicates that Norway may already have had a framework contract for purchasing PPE in place at the start of the Ebola epidemic. In Norway the responsibility for purchasing PPE lies with regional and local health authorities.

ECDC can advise on the PPE specification based on its technical work to support the EU joint procurement, as Romania would be interested to be part of this mechanism. However, as the EU level framework contract will only be in place towards the end of 2015, this does not provide an immediate solution.

Staff availability

Information provided to the team

The overall Romanian national Ebola preparedness is being hampered by a lack of trained medical staff. Since Romania's accession to the European Union in 2007, 16 000 doctors out of a total workforce of 45 000 doctors have left to work in other Member States. This has resulted in a lack of doctors in the public health system and in intensive care units. Presently, only one full time and one part time intensive care physician is working at the 'Matei Balș' Infectious Disease Hospital. Dedicating the staff to the exclusive 24 hour care of an Ebola case may put a strain on the hospital system.

Ebola as part of generic infectious disease preparedness planning

Information provided to the team

There is presently no generic preparedness plan for infectious diseases in Romania. However, it would be relatively easy to establish such a plan based on the pandemic influenza preparedness plan used during the 2009–2010 pandemic, and the present Ebola preparedness documents. As most infectious diseases covered under such a plan would not require the same emergency measures as Ebola (level 3 emergency), the Ministry of Health and the National Public Health Institute would need to be more prominent actors in such a plan than has been the case during the Ebola emergency.

We learned during the visit that RO-RISK, an EU-funded project, is under way and aimed at ranking risks for emergencies. Once this has been completed, the next phase of the project will be to design a generic preparedness plan for Romania. Communicable diseases feature among the risks examined in this exercise. Due to the limited scope of the Ebola preparedness peer review visit, we had no possibility to follow up or verify this information, but if correct this is an important issue that would need to be properly addressed.

[i] Directive 2014/24/EU of the European Parliament and of the Council of 26 February 2014 on public procurement and repealing Directive 2004/18/EC

An important aspect to consider in a new national preparedness plan for infectious diseases is the national reference and public health laboratory functions which are both of vital importance for national preparedness for infectious disease threat, as well as for the obligatory reporting to the European Union via ECDC of diseases under EU-level surveillance. We learned during the visit that some of these functions, carried out by the National Institute of Research and Development for Microbiology and Immunology 'Ion Cantacuzino' are threatened due to economic problems of the institute. In 2014 the institute moved from being under the Ministry of Health to the Ministry of Education, Research, Youth and Sports. The uncertainty surrounding the funding of this key part of the public health system appears to be a significant vulnerability.

We understand that for highly pathogenic diseases, a military BSL4 laboratory outside Bucharest, able to serve both the military and the civilian sector needs, is close to completion. In addition, we have also been informed of plans to construct a BSL4 laboratory linked to the 'Matei Balș' infectious disease hospital. However, it is not clear to the team how these initiatives are linked to each other and coordinated across the sectors.

Part 3. Main findings

The present Ebola epidemic in West Africa is the largest ever seen, both in terms of the number of cases and geographical spread. As of early May 2015, well over 25 000 cases have been reported, including more than 800 healthcare workers. Epidemic incidence is presently declining in the three principally affected countries and the risk of importation of cases to EU Member States must also be considered to be going down. However, the risk of importing cases is still there and will remain for some time due to the substantial number of European healthcare workers and aid workers in the affected countries. It is therefore important for Member States not to lower their guard, but to continue in their national Ebola preparedness, and to consolidate lessons learned during the crisis to improve their preparedness against future health threats.

We have seen that Romania has taken the threat from Ebola seriously, and in a short time initiated and established a large range of measures. Based on a review of documents provided to us, information given to us and our own observations during field visits, we are of the view that Romania is well on its way to being fully prepared to detect, transport and care for an imported Ebola case with adequate staff protection. However, more work needs to be done in order to be fully prepared. Areas identified for further improvement mainly concern procurement of PPE and transportation equipment, training in proper use of PPE, developing and disseminating more detailed national guidelines, and performing simulation exercises.

In order to fully capitalise on the investment made, it would further be important to keep, continue to develop and apply this preparedness to future, as yet unknown, health threats: these could be due to other serious infectious diseases, such as MERS-CoV, SARS, highly pathogenic influenza strains, and MDR/XDR tuberculosis.

In the sections below we have listed a number of strengths and vulnerabilities. It should be noted that these are based on information given to us, and complemented with a few short field visits during a three-day visit. These observations should therefore not be regarded as a comprehensive national preparedness assessment: they are points for discussion and further consideration following the peer review visit.

System strengths

During our visit we have identified a number of strengths in Romanian Ebola preparedness:

1. There is a strong National Ebola Committee in place since October 2014, having a cross-sectorial approach and involving all relevant actors at a high level.
2. Romania has a well-established and functional national public health system (national–regional–district–GP), with efficient flows of information from central to local level and in the opposite direction.
3. Necessary governmental decisions covering the main features of Ebola preparedness are efficiently distributed and well known.
4. There is a high technical and scientific competency in the National Institute for Public Health and in the 'Matei Balș' Infectious Disease Hospital, available as a national resource for giving advice and for adaptation of international scientific reports and guidelines to a Romanian context.
5. A designated treatment facility in a field military hospital has been identified as a single treatment unit for an Ebola case. This hospital is located with nearby premises suitable to host and cater for assigned staff within a secluded compound.
6. There is experienced and knowledgeable staff in the 'Matei Balș' infectious disease hospital, which has developed SOPs and is trained on the use of advanced isolation equipment, including negative pressure chamber.
7. There is a parallel reporting system in place to detect a potential Ebola case both through regular surveillance reporting within the public health system and reporting through the emergency number 112.

8. The laboratory in the 'Matei Balș' infectious disease hospital has 24/7 capacity for PCR diagnosis of Ebola within 2–3 hours using commercial kits. There are agreements in place with a German laboratory for confirmation testing.
9. There is a highly proficient rescue service in place with five dedicated SMURD ambulances with isolators. There is also availability of helicopters and airplanes for patient transport inside and outside the country.
10. There is an efficient emergency medicine system integrated with the rescue services in place all over the country, including patient management, infection control and staff protection.
11. The staff in the visited emergency rooms are well aware of Ebola and have efficient routines in place for triage and isolation, pending patient transportation to a dedicated treatment centre.
12. There is a good expert support to most local emergency rooms through a telemedicine initiative (in daily use).
13. The border control is well integrated with the district public health system and cooperates well with the police/customs/rescue services.
14. There is an efficient re-use of avian flu PPE in a situation where new PPE are lacking.
15. It seems that GPs are aware of Ebola symptoms, reporting routines and personal protection with 'light PPE' and distancing but this is based on limited access to information due to lack of time.

System vulnerabilities

Despite the obvious strengths in the system we have also been informed of, or ourselves observed, a number of vulnerabilities that should be further considered, discussed and if possible addressed. Ebola preparedness should not be seen in isolation: it is relevant also to consider preparedness for future threats beyond the current Ebola epidemic. We have therefore included some observations related to more generic infectious disease preparedness.

Capacity issues

1. Romania is suffering from a significant staff shortage, notably trained ICU doctors. Romania has lost 14 000 doctors in all to other countries since joining the EU.
2. There is a shortage of clearly identified ICU doctors trained in emerging virus disease patient care, which in practice would mean difficulties in handling an Ebola patient at short notice. Mobilising the staff needed to care for an Ebola patient for a sustained period would put considerable pressure on the provision of services elsewhere in the health system.
3. Some important issues remain to be solved in order to have the military hospital fully operational. These comprise of legal issues (official assignment of the hospital as an external ward of the 'Matei Balș' hospital), administrative issues (notably establishing lists of assigned staff that could be immediately mobilised), and technical issues (identifying in detail the exact equipment, consumables to be brought in as well as their placement and co-training of the assigned staff). The mobilisation of hospital staff has also not been tested through exercises.
4. Although it seems that all the actors are aware of their own roles, there has been no national Ebola exercise, testing the full sequence of events and the interactions between the various involved institutions and authorities.

Staff protection issues

1. The capacity for safe transportation of 'wet' Ebola patients is not yet in place due to the lack of dedicated ambulances for patients with highly contagious diseases, and a lack of special containers for domestic air ambulances used for in country transport of patients with highly contagious diseases
2. There does not seem to be broad availability of Ebola-appropriate PPE due to issues related to procurement. Most of the available PPE we saw derived from the time of avian influenza. They are not 'splash proof' and would therefore not properly protect in 'wet' situations with vomiting, etc.
3. There are no national guidelines in place for putting on ('donning') and removing ('doffing') PPE. Local procedures follow either package instructions or old guidelines for PPE related to avian influenza. The concept of supervised donning and doffing is not widely known.
4. Other than in the emergency hospitals, local staff do not appear to be properly trained on safe use of PPE. To our understanding there is no general awareness of national or international training materials related to PPE use for Ebola, including from ECDC.
5. There is across the field a dependency on private firms for waste management and disinfection. It is not clear whether these firms have routines and capacities for safely handling an Ebola situation. It also unclear what would happen in case one of these firms would refuse to engage in such a situation.

Broader preparedness issues

1. It seems that also beyond PPE and safety issues, there is a lack of detailed national guidelines throughout the organisations (public health, healthcare and emergency services).
2. The IHR core capacities are not yet fully implemented in the country.
3. There is a pandemic influenza preparedness plan used in 2009–2010 and a general national disaster preparedness plan, but no national generic preparedness plan for infectious diseases.
4. The financial difficulties of the 'Ion Cantacuzino' Institute raise major concerns for the sustainability of vital national reference laboratory functions, presently hosted by the institute.

Areas for review

Short term

1. A national Ebola exercise, testing the full sequence of events and the interactions between the various involved institutions and authorities, should be undertaken to identify remaining gaps and serve as a basis for further improvement of preparedness.
2. Romania could capitalise on the experiences from avian flu, the H1N1 pandemic and Ebola through a comprehensive 'lessons-learned' exercise, including critical incident reviews of the handling of suspect cases.
3. In order to increase preparedness for safe handling of an Ebola patient, further attention could be made to provide training on the proper use of PPE among all staff involved, including auxiliary staff, taking into account their different likely exposures.
4. Based on practices from other countries, the procurement system, including interpretation of the EU procurement directive, should be reviewed to examine the scope for more timely procedures for urgent needs in emergency situations. It would be prudent to have at least a small stock[i] of Ebola appropriate PPE in place as soon as possible.
5. Specific aspects of the Romanian system and experience, e.g. in having integrated rescue services and emergency departments, could most usefully be shared with other countries, e.g. in the upcoming October conference on lessons learned from Ebola under the Luxembourg EU Presidency.

Medium/long term

1. The long-term sustainability of the military hospital solution once the immediate Ebola threat is over should be considered. The pros and cons of a dedicated Ebola hospital versus an integrated approach using existing facilities in the 'Matei Balș' hospital should be weighed against each other, based also on the experiences from other countries.
2. The experience gained from Ebola preparedness should be used for development of a generic integrated, cross-sectorial infectious disease preparedness plan, with clear division of responsibilities between actors depending on the threat level. Preparedness against Ebola and other serious infections of high consequences could be integrated into such a plan (e.g. as detailed annexes).
3. In the long-term, resources needed for maintaining Romania's Ebola preparedness should be weighed against the needs for other essential public health functions.
4. The extensive use of the 112 emergency number, the emergency departments and emergency response system could be considered for national epidemic intelligence purposes in a collaboration between the National Institute for Public Health and the Department for Emergency Situations in the Ministry of Internal Affairs.
5. The national needs for two separate P4 labs should be weighed against the resources needed to maintain and run such facilities.
6. Romania should consider further collaboration with neighbouring countries on preparedness for cross-border health threats including simulation exercises.
7. Romania should consider making its MedEvac and P4 facilities available to other Member States.

[i] The US CDC's interim guidance for US hospital preparedness recommends having sufficient Ebola appropriate PPE in stock to care for a symptomatic patient for 4 to 5 days, and arrangements to rapidly procure PPE to care for a patient for 4 weeks if needed.

Possible input by ECDC

During the discussions a number of issues were raised, where ECDC could provide further support to Romania.

1. ECDC could by invitation facilitate the development of a cross-sectorial generic preparedness plan for Romania – such input would need to be planned and have clear terms of reference.
2. ECDC could by invitation provide technical input during the planning stage and then participate as an observer in Romania's national preparedness exercises.
3. ECDC could compile and share some examples of national practices on procurement, waste management and staffing needs for caring for Ebola patient.
4. ECDC could facilitate useful contacts between Romania and other national and international actors.
5. ECDC could support Romania with training material on proper PPE use, including an instructional video in Romanian language

European Centre for Disease Prevention and Control (ECDC)

Postal address:
Granits väg 8, SE-171 65 Solna, Sweden

Visiting address:
Tomtebodavägen 11A, SE-171 65 Solna, Sweden

Tel. +46 858601000
Fax +46 858601001
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