Exploring opportunities for support in healthcare-associated infections – Romania

4–7 July 2017
ECDC MISSION REPORT
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# Abbreviations

<table>
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<tr>
<th>Abbreviation</th>
<th>Description</th>
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<tbody>
<tr>
<td>HAI</td>
<td>healthcare-associated infections</td>
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<tr>
<td>SSI</td>
<td>surgical site infection</td>
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<td>ICU</td>
<td>intensive care unit</td>
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<td>PPS</td>
<td>Point Prevalence Study</td>
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<td>HCAI</td>
<td>healthcare-associated infections</td>
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<td>PHC</td>
<td>Public Health Capacity and Communication Unit, ECDC</td>
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<tr>
<td>MRSA</td>
<td>methicillin-resistant <em>Staphylococcus aureus</em></td>
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<tr>
<td>ECDC</td>
<td>European Centre for Disease Prevention and Control</td>
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<tr>
<td>EU/EEA</td>
<td>European Union/European Economic Area</td>
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<tr>
<td>NIH</td>
<td>National Institute of Public Health</td>
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<tr>
<td>MoH</td>
<td>Ministry of Health</td>
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<tr>
<td>MDR</td>
<td>multi-drug-resistant</td>
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<tr>
<td>XDR</td>
<td>extensively drug-resistant</td>
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<tr>
<td>PDR</td>
<td>pan drug-resistant</td>
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<tr>
<td>ER</td>
<td>emergency room</td>
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Executive summary

On 27 May 2016, the Romanian Minister of Health sent a letter to the Director of ECDC requesting support with the containment of healthcare-associated infections (HAI) in Romania. The country is facing serious challenges in both ‘reporting hospital acquired infections and fighting their causes’. Following the request, a team of multidisciplinary experts in public health, infection control and epidemiology, from ECDC and Norway, conducted an exploratory visit during the period 4—7 July 2016. The team visited the Ministry of Health, hospitals in and around Bucharest, and national institutes where they met key national stakeholders. The purpose of the visit was not to perform an inspection, but rather to gain an understanding of the situation, engage in collegial discussions, and propose actions for consideration by the responsible authorities in Romania.

The team was composed of Prof Dr Karl Ekdahl, Head of Unit, Public Health Capacity and Communication Unit (PHC), European Centre for Disease Prevention and Control (ECDC) (team leader), Dominique L. Monnet, PhD, Head of Disease Programme Antimicrobial Resistance and Healthcare-Associated Infections, ECDC, Irina Ljungqvist (Dinca), MD, PhD, Senior Expert, Capacity-Building and Communication (ECDC) and Oliver Kacelnik, MD, PhD, Department of Antibiotic Resistance and Infection Prevention, Norwegian Institute of Public Health, Oslo, Norway.

Observations

The team observed some very good examples of high awareness and strong commitment for change, however there were also examples of lower awareness and systems that were not conducive to change. The country is facing a difficult situation: in some instances overcrowded hospitals with few isolation rooms, in others a lack of trained staff, particularly for vital infection control functions, and scarce funding. The team noted that the system had traditionally been based on inspection but that this was now gradually changing towards support and learning. The inspection culture had probably contributed to an underreporting of HAIs. For example, hospital managers could be penalised if HAI rates were above 2%. The reported rate of 2.8% of patients with at least one HAI on a given day (described in the 10 hospitals that participated in ECDC’s PPS survey, 2012) is most likely an underestimation as the average rate for EU is 5.7%. The tendency to underreport has been aggravated by the media, portraying hospitals attempting to improve their reporting systems as ‘dangerous’. In previous years, Romania had a low participation rate in the ECDC-led surveillance of HAIs — e.g. the point prevalence study (PPS), surgical site infections (SSI) and infections in intensive care units (ICUs). An important element of infection control, as regulated by law, was based on a large number of environmental samplings, where the cost and efforts seem disproportionate to the information received and actions taken. Hospital laboratory systems are often not set up to provide the necessary feedback to end-users to ensure that they take proper infection control action. Moreover, there does not appear to be an ‘action loop’ in place whereby reported data systematically trigger problem analyses, forming the basis for action and a subsequent effectiveness analysis of the measures taken.

Observations

In the previous PPS, the rate for use of hand disinfectants in Romania was one of the lowest in Europe. When visiting the hospitals, we noted that while hand disinfectants are readily available in ICUs (although not by the patient beds as generally recommended), this is often not the case in the general wards. Based on experience, convenience is a key determinant of good hand hygiene and proper use of hand disinfectants. As HAIs are very expensive for the hospitals, minor but smart investment in preventive action with a focus on hand hygiene will probably prove to be cost-efficient within a short period of time.

At the national level there is also a lack of a proper microbiology reference function, putting public health surveillance at risk. We are unaware of a similar situation in any other EU Member State.

At the same time, there is also a strong political will to improve the situation and an opportunity for change, with legislation currently being updated. These initiatives were appreciated by the team.

Conclusions and recommendations

Based on these observations, the ECDC team is proposing to the Ministry of Health that it could consider actions in the seven areas outline below.

Raising awareness

There is a need for general awareness-raising. Healthcare workers need to be aware of the importance of HAIs and the need for proper and consistent hand hygiene, paired with the broad availability of hand disinfectants in hospital wards. While there is a high level of awareness of the importance of diagnosing and properly isolating patients with Clostridium difficile infections, there is no similar awareness for other multidrug-resistant bacterial infections (e.g. Gram negative bacteria).
The patients, their relatives, the general population and the media need to have a better understanding of HAIs. Hospitals are per se a risk environment for vulnerable patients, and not all HAIs are preventable. Even good practice cannot prevent all healthcare-associated infections (HAI). Even in the best hospitals in the well-resourced countries, such infections still occur due to the nature of the hospital setting. This has always been and will continue to be the case. Very low reported rates should therefore raise the suspicion of underreporting. Similarly, high rates could either signal a problem or be the result of high awareness, dedication and a good reporting system. This needs to be universally understood and, unless accepted, underreporting will remain.

**Need for a ‘culture shift’**

Like some of the other European countries, Romania has a tradition of fighting HAIs based on negative incentives through inspection. This is accentuated by the media portraying ambitious hospitals working hard to improve the reporting of their true infection rate as overly ‘dangerous’ for the patients. The media has a big responsibility to change this situation. There is a need to establish a new culture based on transparency, support for improvement and learning. Reporting the true figures needs to be seen as ‘safe’ and high numbers seen as areas for improvement, triggering collegial discussion.

**Training**

Infection control in the hospital is based on an outdated system whereby hospital epidemiologists are responsible for statistics and data collection, including routine environmental sampling which is of limited value. In a new setting, the hospital infection control teams (epidemiologists, nurses, assistants) should be the cornerstone for modern infection control and for this they need to be properly trained. ECDC has defined core competencies for infection control/hospital hygiene professionals and developed training curricula that can be implemented in the Romanian institutions responsible for post-graduate training and continuous professional development, including the National Institute of Public Health.

**Surveillance as data for action**

Hospital microbiology systems are designed for providing clinicians with patient based laboratory results, but not for extracting key epidemiological information that could be fed back to the end users and used for actions. There is a need for a good integrated (epidemiology and microbiology) reporting systems that could provide data for direct and immediate actions and their evaluation at the hospital level and allow for national trends and international comparisons at the Ministry of Health level. A broader participation in the 2017 ECDC Point Prevalence Survey and dedicated systems for surveillance of health-care associated infections is encouraged.

**Microbiology**

Without the appropriate microbiology function it will be impossible to monitor the HAI problem accordingly. While there is a need for good standards and proper protocols at hospital level, it is also vital to have a proper national reference function responsible for reference diagnostics (e.g. identification of unusual strains and antibiotic susceptibility testing) and epidemiological typing of outbreak strains. The national reference function can also provide support, training and External Quality Assurance (EQA) services to local laboratories.

**Governance**

The necessary actions will need to be embedded in a proper governance structure, building on multidisciplinary and cross-sectoral participation. Multidisciplinary infection control committees need to be in place both at hospital and national level, and they should drive the necessary change. These committees should have executive powers and should be encouraged to try pilot interventions. They should also be responsible for proper follow-up and evaluation of the measures taken. One aspect of governance would be to ensure that proper funding is in place for infection control activities. Although these investments would require additional funding in the short term, they would probably result in long-term cost savings. These new investments would require proper follow up and evaluation.

**Upgraded infrastructure and more resources**

The above-mentioned actions could be implemented in the short and medium term. A longer-term sustainable situation will require an upgrade of the hospital infrastructure, with proper isolation facilities and trained staff in sufficient numbers.

ECDC would be available on request to continue to support specific activities, as agreed. ECDC would also be available to perform a similar peer-review focused on the prudent use of antimicrobial agents in the context of Council Recommendation 2002/77/EC.
1. Introduction

On 27 May 2016, the Romanian Minister of Health sent a letter to ECDC's Acting Director requesting support in the containment of healthcare-associated Infections (HAI) in Romania. The country is facing serious challenges in both reporting hospital acquired infections and fighting their causes:

2. Objectives of the visit

- Collect the information and data necessary to understand the situation regarding HAI prevention, early detection and control;
- Meet key stakeholders in the area of HAI in Romania to discuss the critical issues, strengths and vulnerabilities relating to HAI prevention, early detection and control;
- Analyse the information collected (e.g. reports, notes from meetings and interviews during the country mission) to identify good practices and lessons learned, evaluate vulnerabilities and gaps in HAI work and identify possible areas for joint future work;
- Draft a technical country assessment report.

3. Scope and approach

The peer review visit took place over a three-day period (4-7 July 2016) at the invitation of Mr Vlad Voiculescu, Minister of Health (MoH) of Romania. It focused both on the general structures of HAI prevention and on early detection and control, particularly in area of tertiary care.

The visiting team included three ECDC experts and one expert from Norway. The team was selected based on the specific areas to be covered (experience in hospital infection control, experience in national planning design, control of hospital-born outbreaks of antibiotic resistant bacteria, etc.)

The review was based on a terms of reference document that was shared and agreed with the national authorities prior to field work. The visit content focused on critical aspects of the public health system in the area of HAI and included meetings with relevant stakeholders in Romania. The main methods used during the visit were individual and/or group discussions and observation. The public health system capacities and capabilities in the area of HAI were explored through:

- Study of existing documents in the relevant area, including current/ongoing legislation and regulatory framework documentation;
- Site visits: observations, semi-structured interviews, group discussions;
- Semi-structured interviews and group discussions with key stakeholders (informants);
- End-of-visit briefings with Romanian Ministry of Health (MoH) representatives.

Media briefings were jointly published on the websites by both ECDC and the Romanian Ministry of Health both prior to and after the visit. Lines to take were drafted and agreed upon between the two institutions prior to the visit.

The visit outputs included:

- Visit report to the Minister of Health, including system description, strengths, potential or actual weaknesses, proposals for action to strengthen HAI prevention, detection and control;
- Identification of potential further support from ECDC and the European Commission.

4. 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).
- Dominique Monnet, Head of Disease Programme Antimicrobial Resistance and Healthcare-associated Infections
- Dr Irina Dinca, Senior Expert, Capacity Building and Communication, Country Preparedness Section, PHC, ECDC
- Dr Oliver Kacelnik, Antibiotic Resistance and Infection Prevention, Norwegian Institute of Public Health, Oslo, Norway.
5. Background

The reported level of HAI for Romania in the passive surveillance system was less than 1% in the last 20 years, and no more than 0.25% in the past 10 years (Figure 1). Given that the PPS performed in 10 Romanian hospitals in 2012 indicated a level of HAI ten times greater (at least 2.8%, but probably over 5%, as reported in the revalidated data for five hospitals), it appears that in reality HAI are largely underreported. In fact, after 2011 Romania reported a very high level of antimicrobial consumption (one of the top five in Europe) and antimicrobial resistance, as published by two ECDC-based networks, ESAC Bet and EARS Net, respectively. Moreover, the levels of *Pseudomonas aeruginosa*, *Acinetobacter baumannii*, and *Klebsiella pneumoniae* resistance to antibiotics clearly indicated the presence of HAI in the participating hospitals. These antimicrobial-resistant germs could be circulating in hospitals, from one patient to another, generating MDR germ colonisation and HAI. The problem is clinical, due to the difficulties of treating a germ-resistant infection, and epidemiological due to scarcity of interventions to limit multi-drug-resistant germ circulation. An improved knowledge of *Clostridium difficile* infection, especially the healthcare-associated cases, seems to be the primary factor behind the slow emergence of reported HAI after 2011.

In Romania, the involvement of multi-drug-resistant germs in HAI was obvious after a fire at a club in Bucharest, October 2015, when dozens of burn patients were rapidly colonised and developed infections with these germs. Extensively drug-resistant (XDR) and even pan-drug-resistant (PDR) strains of *Enterobacteriaceae* and *Acinetobacter baumannii* were reported, making the first choice of antibiotics very challenging, for syndromes where these germs were involved.

**Figure 1. Reported incidence of HAI in Romania, 1995–2014**

*Blue line indicates patients discharged with HAI of the total discharged patients (as a percentage)*
6. Main findings

Governance

Information provided to the team

To date, there is no established intersectoral coordinating mechanism or national policy/plan to prevent, detect and combat healthcare-associated infections in Romania. Steps are being taken towards this but they have not finalised as yet. The team was provided with drafts of national plans for prevention, limitation and control of nosocomial infections and the control of antimicrobial resistance (AMR), including short- and medium-term actions in the following areas: improving staff training and staff professional development; increasing the quality of HAI surveillance at national level, and improving communication with the general public – both at national and local/hospital levels. The second draft included infrastructure measures to improve hospital layout and covered a longer period up until 2030.

At the time of the visit, a proposal had also been presented to the Minister for approval on setting up a national coordinating mechanism.

Direct observations by the team

The team met key stakeholders in the area of HAI prevention and control, at national and hospital level, including experts serving on national specialty advisory committees to the Romanian Ministry of Health, representatives of the National Health Insurance House (NHIH), professional associations and civil society.

Recommendations by the team

- Consider the official approval of a national intersectoral coordinating mechanism, involving experts in the field, academia and civil society representatives;
- Draft a comprehensive intervention action plan, backed-up by adequate funding, and make this plan widely available so that it can be replicated and adapted at the hospital level.

Follow-up action by ECDC

- ECDC could look into supporting the drafting of the national plan once the coordinating mechanism is in place and functional.

Hospital/healthcare institutions

Information provided to the team

In Romania, the hospital structure is by and large quite old, with no advanced isolation units in the general hospitals. At the time of the visit, Romania had a total of 360 public and 100 private hospitals. Around 40 of these are subordinated to the Ministry of Health, the rest are under the local authorities. During late 2015, a survey was carried out in 112 hospitals, based on a questionnaire. The purpose of the study was to assess hospital activities in the areas of prevention and control of nosocomial infections; laboratory work and antibiotic use. The items were related to the distribution of physicians and nurses working in HAI; the frequency of disinfectant use; screening done for resistant bacteria; patient isolation; laboratory work and use of antibiotic prophylaxis. For example, in these 112 hospitals a total of 202 physicians (113 of them epidemiologists) and 296 nurses (213 of them hygiene nurses) work in the department for HAI control. The team was informed that supervisory visits were also carried out to hospitals to evaluate their activities in HAI and some of these visits resulted in coercive measures (e.g. fines).

Direct observations by the team

The team visited three hospitals, two in Bucharest and a paediatric hospital outside the city.

Visit to Pitesti Paediatic Hospital

The team, accompanied by Romanian colleagues from the Ministry of Health, met representatives of the Arges District Public Health Authority, visited the hospital wards and laboratory and had discussions with hospital management and staff involved in HAI prevention and control.

Pitesti is a public hospital, built in the 1970s, catering for all children in the Arges district (600 000 inhabitants) and includes an emergency room (ER), an ambulatory and intensive care unit (ICU). The hospital belongs to the local authorities (there is no funding from the Ministry of Health unless it is for national public health programmes) and it does not have an epidemiologist. The hospital serves around 12 000-15 000 patients per year, has a total of 350 beds and, at the time of the visit, the occupancy rate seemed low. The key antibiotic-resistant pathogens are MRSA and multidrug-resistant gram-negatives (e.g. *Kl. pneumoniae*).
During the visit the team observed that there was no disinfectant easily available to patients and medical staff. The only disinfectant found (following a request by the team) was in a cupboard in the nurses’ room. The reason given was that the medical staff were concerned that the disinfectant would be stolen if it was easily available.

**Visit to Elias Emergency University Hospital, Bucharest**
The team, accompanied by Romanian colleagues from the Ministry of Health and the National Institute of Public Health (NI PH), met the hospital management and visited several wards and the laboratory. The hospital was built a long time ago and has been in close collaboration with the Elias Foundation. As a university (under the Romanian Academy) and an emergency hospital, the Elias hospital receives funding from the Ministry of Health under the national public health programme. It is a multi-disciplinary hospital, with an ambulatory unit, serving a total of 35 000 patients plus an additional 10 000 day hospitalisations each year. It serves the area of Bucharest but also takes patients from other areas – usually it is the most complicated cases that are referred here. The hospital has one epidemiologist and a team of nurses involved in hospital infection control, which is perceived as a key challenge. The hospital’s outdated infrastructure makes it very difficult to clean and disinfect, isolate patients and/or close the whole ICU. The team performs weekly environmental testing which in turn triggers action, where required. However, this activity seems to be quite resource-intensive, and it might be more useful to undertake action elsewhere (e.g. training staff on hand hygiene).

During the visit the team noted that disinfectants were available in the corridors between rooms.

**Visit to the Bucharest Emergency University Hospital**
The team, accompanied by Romanian colleagues from the Ministry of Health, met the hospital management and visited several wards and the laboratory. This is a public emergency university hospital (similar to Elias) which has 1100 beds and serves around 62 000 patients per year. One of the hospital’s main problems is the high occupancy rate of around 120%.

The team working on hospital infection control consists of one epidemiologist, one infectious disease specialist (to join), one microbiologist, five hygiene nurses, two laboratory nurses and five support staff involved in disinfection.

The staff were of the opinion that isolation worked well in the ICU but not in the other wards. Indeed, during the team visit it was obvious that this hospital was overcrowded and disinfectants were not easy available, only in the nurses’ room. Major reconstruction work was taking place and spaces were significantly affected. It was not possible to isolate patients in this hospital, with the exception of those with *Clostridium difficile*. The staff felt that awareness of HAI could be improved as action was normally only taken if something unusual happened.

**Recommendations by the team**

- To be efficient in day-to-day preventive work against hospital-acquired infections, hand disinfectants need to be immediately available at patients’ bedsides, enabling them to be easily used when moving from one patient to another within the room. While there is a need for a substantial initial investment to have bedside availability of hand disinfectants in all hospitals across the country, this would probably pay off in a relatively short time in the form of reduced costs for hospital-acquired infections.

- Easy access to hand-disinfectants will, however, not be sufficient unless there is also a broad general understanding of the importance of its use. Awareness-raising activities and training in hospitals is therefore necessary, targeting all staff categories in direct contact with patients. To be effective these activities need to be repeated, and should aim to not only increase knowledge but also change attitudes and behaviour. It cannot be overestimated how important it is for senior doctors and nurses to set an example. Therefore the key to success is full acceptance and support of the initiatives by both management and caregivers.

- The impression from the three visits is that there seems to be a high level of awareness of the importance of diagnosing and properly isolating patients with *Clostridium difficile* infections, however there is no similar awareness in relation to other multidrug-resistant bacterial infections (e.g. Gram negative bacteria). While there might not be resources available to isolate all patients with multidrug-resistant bacteria, we believe that cohort care of such patients with increased hygienic precautions and/or a flagging system may help improve the situation. This requires specific routines for cohorting/flagging and timely communication between the laboratory and the wards.

- The infection control functions in the hospitals visited were based on an outdated system whereby hospital epidemiologists are responsible for statistics and data collection, including routine environmental sampling. We believe that there is too much focus on the environmental control and insufficient time and resources devoted to sampling and following up on infected patients. A more efficient use of existing resources would be to provide the hospital infection control teams (epidemiologists, nurses, assistants) with proper training, to ensure that they are the cornerstone of modern patient-centred infection control. Such a system needs to be supported by a well-functioning multi-disciplinary infection control committee, chaired by the medical director and equipped with executive powers. The infection control teams and committees would need to have timely and detailed information on the local resistance situation per ward and be encouraged to implement pilot interventions at ward and hospital level.
ECDC has defined core competencies for infection control/hospital hygiene professionals and developed curricula for training that could be implemented in the Romanian institutions responsible for post-graduate training and continuous professional development, including the National Institute of Public Health.

**Laboratories**

**Information provided to the team**

According to information from a hospital assessment survey in 2015, laboratories are integrated into the public health system at both national and local level.

**Direct observations by the team**

During the hospital tours, visits were made to the laboratories. As these visits were short, it was not possible to evaluate the performance of the laboratories or the reporting, but we saw no evidence of systems having been implemented to provide resistance data feedback to the wards in order to trigger immediate infection control measures.

In addition to the hospital laboratories the team also visited the National Institute ‘Ion Cantacuzino’ in Bucharest. This visit highlighted once again that the role of this organisation in national public health surveillance is not clear. At the time of the visit the institute was under the Ministry of Education and Research and thus unable to fulfil specific public health roles which meant that it had had to sign a contract with the National Institute of Public health in order to analyse strains. However, despite the contract, only six strains had been analysed during 2015. The situation changed in 2014 and until then the institute had been a national reference laboratory, in charge of molecular typing and external quality assessment (EQA) for laboratories in Romania.

At present, Romania does not have a recognised and sufficiently funded national reference function for microbiology. Without the appropriate microbiology function, it will be impossible to monitor the HAI problem accordingly. While there is a need for good standards and proper protocols at hospital level, it is also vital to have a proper national reference function responsible for reference diagnostics (e.g. identification of unusual strains and antibiotic susceptibility testing) and epidemiological typing of outbreak strains. The national reference function can also provide support, training and external quality assurance (EQA) services to local laboratories.

**Recommendations by the team**

- The hospital laboratories would need to focus not only on patient-centred diagnostics, but also play a key role in providing timely data for infection control actions. The present laboratory systems do not support that second role. The team therefore recommends looking at other complementary software for such purposes (e.g. the WHONET application).
- Reinstating a national microbiology reference function is important, not only for national infection control activities but also for the wider national public health emergency preparedness.

**Surveillance/health information**

**Information provided to the team**

ECDC has worked very closely with the experts in the National Institute for Public Health (NIPH) and at the Institute ‘Ion Cantacuzino’ (IIC) in the past.

**Direct observations by the team**

Both teams in the NIPH and IIC have been working with ECDC for a number of years, taking part in various HAI and AMR-related projects, including the point prevalence study from 2012 onwards. The NIPH is in charge of developing methodologies, training programmes and guidelines. The NIPH team is very aware of HAI issues in Romania and they have also proposed some solutions: set up a functional national committee, develop a national surveillance network.

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1[http://www.whonet.org/software.html](http://www.whonet.org/software.html) WHONET is a free software developed by the WHO Collaborating Centre for Surveillance of Antimicrobial Resistance for laboratory-based surveillance of infectious diseases and antimicrobial resistance. The principal goals of the software are to enhance local use of laboratory data; and to promote national and international collaboration through the exchange of data. WHONET can be used by individual laboratories or as part of a national and international surveillance network. At present, the software, available in 17 languages, is used in over 80 countries around the world managing data from over 1000 clinical, public health, veterinary, and food laboratories. WHONET analytical tools facilitate the understanding of the local epidemiology of microbial populations; the selection of antimicrobial agents; the identification of hospital and community outbreaks; and the recognition of quality assurance problems in laboratory testing.
strategy and an operational plan and align the current legislation with these changes. Key current issues include changing the existing culture whereby reporting an HAI will result in punishment for the hospital manager; addressing the lack of training, also including case definitions; dealing with the lack of appropriate, adequately trained personnel in microbiology at all levels and non-existence of hospital infection control committees in all hospitals.

**Recommendation by the team**

- Widespread use of laboratory systems capable of extracting data for infection control and public health purposes will enable national trends to be identified and international comparisons to be made at Ministry of Health level. A broader participation in the 2017 ECDC Point Prevalence Survey and dedicated systems for surveillance of healthcare-associated infections is encouraged.
- The system should encourage rather than discourage proper estimations of HAI s, as a basis for counter action.

**Public information and communication**

**Information provided to the team**

The media in Romania gives a lot of coverage to HAI. This is due to fact that some of the victims of a fire at a nightclub in Bucharest (2015) developed HAI during their treatment. A lot of media coverage focuses on the negative aspects of HAI, while there is little information on hand hygiene, the general context in relation to HAI and the fact that these infections exist in any healthcare setting.

**Recommendation by the team**

- Patients, their relatives, the general population and the media need to have a better understanding of HAIs. Hospitals are per se a risk environment with vulnerable patients, and not all HAIs are preventable. Even good practice cannot prevent all HCAIs. Even in the best hospitals in the well-resourced countries, hospital-associated infections still occur due to the nature of the hospital setting. This has always been and will continue to be the case. Very low rates being reported should therefore raise the suspicion of underreporting. Similarly, high rates could either signal a problem or result from high awareness, dedication and a good reporting system. This needs to be universally understood, and unless accepted, underreporting will remain.
- The dire situation is accentuated by the media portraying ambitious hospitals working hard to improve the reporting of their true infection rate as ‘dangerous’ for patients. The media has a huge responsibility for changing this situation. There is a need to establish a new culture based on transparency, support for improvement and learning. Reporting the true figures needs to be seen as acceptable practice and high numbers seen as a challenge to be improved upon. Experience from other countries has shown that it can also be very useful to provide training to respected medical journalists.

**Human and financial resources**

**Direct observations by the team**

Funding for appropriate work in HAI and provision of adequate human resources to tackle the issue are still major challenges for Romania to address, especially at older hospitals where the infrastructure can make it difficult to isolate patients and ensure appropriate disinfection. Overcrowding of hospitals and lack of specialty staff are also an issue.

**Recommendation by the team**

- While these are complex issues to address, some simple measures can be taken in the short term, such as spending less time on environmental sampling and more on the training of staff in relation to hand hygiene.
- It may be worth considering a system where earmarked funding could be provided to install bedside hand disinfectant dispensers in hospitals across the country. This should be seen as a one-off investment as part of a larger package of measures for improving hand hygiene.
- The abovementioned actions could be implemented in the short and medium term. A longer term sustainable situation will require an upgrade of the hospital infrastructure, with proper isolation facilities and trained staff in sufficient numbers.
7. Possible input by ECDC

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

- ECDC would be available on request to perform a similar peer-review focused on the prudent use of antimicrobial agents in the context of Council Recommendation 2002/77/EC.
- ECDC could look into supporting the drafting of the national plan to combat HAI once the coordinating mechanism is in place and functional.
- ECDC could facilitate further sharing of good practices between Romanian HAI experts and experts from other countries. A possible mechanism for this could be participation in the ECDC Senior Exchange programme.
- ECDC would be available on request to continue to support other specific activities as agreed.
Annex 1. List of experts met during the visit

**Ministry of Health**
- Mr Vlad Voiculescu, Minister
- Mr Laurențiu Colintineanu, Communications Advisor to the Minister of Health
- Dr Elena Copaciu, Honorary Advisor to the Minister of Health
- Prof Dr Gabriel Popescu, Honorary Advisor to the Minister of Health
- Dr Amalia Serban, Deputy Director, Public Health and Control, Public Health Department

**National Institute of Public Health**
- Dr Dan Mihai Marius, Director General
- Dr Adriana Pistol, Director at National Centre for Surveillance and Control of Communicable Diseases
- Dr Roxana Serban, Chief of Communicable Diseases, Regional Ward Bucharest, Technical Coordinator of the National HAI Programme
- Dr Andrea Niculcea, Resident in Public Health

**Institute ‘Ion Cantacuzino’**
- Adrian Ioniță, General Director
- Prof Dr Mircea Ioan Popa, Counsellor to the Director
- Cerasella Dragomirescu, Public Health Microbiology
- Brândusa Lixandru, AMR Laboratory
- Prof Dr Irina Codită, ECDC NFP AMR

**Arges District Public Health Authority**
- Sorina Hontaru, Director
- Dr Adrian Stoica, Deputy Director, Arges Public Health Authority
- Dr Maria Boată, Epidemiologist
- Dr Aura Copciag, Head of the Public Health Department
- Dr Daniela Miță, Inspector
- Luminita Titu, Public Relations

**Pitesti Paediatric hospital**
- Dr Vasile Stan, Manager
- Dr Corina Caba, Clinical Laboratory
- Dr Deniza Morar, Clinical Laboratory
- Ioana Vasile, Hygiene Nurse

**Elias University Emergency Hospital, Bucharest**
- Dr Doina Dimulescu, Manager
- Dr Daniela Safta, Medical Director
- Dr Mugur Ardelean, Head of Management and Quality Department
- Dr Dan Corneci, Head of ICU
- Dr George Anghelăuță, Head of the HAI Department
- Ana Bragarin, Hygiene Nurse
- Dr Marilena Filipoiu, Clinical Laboratory
- Dr Roxana Bunghez, Clinical Laboratory

**University Emergency Hospital, Bucharest**
- Dr Dragos Davițoiu, Medical Director
- Claudia Dobre, Chief Nurse
- Dr Kata Lambru, Epidemiologist
- Dr Flaviu Plata, Epidemiologist
- Dr Anda Băicuș, Clinical Laboratory
Meeting with stakeholders

- Prof Univ Dr Adrian Streinu-Cercel, Manager, National Institute ‘Matei Bals’ for Infectious Diseases
- Prof Dr Alexandru Rafila, President of the Microbiology Association
- Prof Dr Daniela Pitigoi, Vice-President of the Epidemiology Association
- Corneliu Popescu, Romanian College of Physicians, ‘Victor Babes’ Hospital for Infectious Diseases
- Carmen Mazilu
- Sorin Ungureanu, National Authority for Quality in Medicine
- Oana Mocanu, National Insurance House
- Dr Flavius Pavelescu, GP and representative of the Cancer Patient Organisation.
Exploring opportunities for support on healthcare-associated infections (HAI) – Romania, 4-7 July 2016

MISSION REPORT

Annex 2.

Background

The Romanian Minister of Health requested support from ECDC via a letter sent to the ECDC Acting Director on 27 May 2016. The topic of the requested support is containment of healthcare-associated infections (HAIs) in Romania. Romania is facing serious challenges in both ‘reporting hospital acquired infections and fighting their causes’. ECDC has put together a team of multidisciplinary experts with backgrounds in public health, microbiology and epidemiology and will conduct an exploratory visit during 5-7 July 2016.

Exploratory visit approach

The visiting team will be led by an ECDC Head of Unit, and will include two ECDC experts plus one or two expert/s from other Member States. The team selection will be based on specific areas to be covered (e.g. experience in hospital infection prevention and control, experience in national planning design, control of outbreaks of multidrug-resistant bacteria in hospitals and other healthcare settings, etc.)

The visit will focus on critical aspects of the public health system in the area of HAI surveillance, prevention and control and it will include meetings with stakeholders in this area in Romania. The main methods used during the visit are individual and/or group discussions and observations. The public health system capacities and capabilities in the area of HAIs will be explored through:

- Study of existing documents in the relevant area, including current legislation and regulatory framework documentation;
- Site visits: observations, semi-structured interviews, group discussions;
- Semi-structured interviews and group discussions with key stakeholders (informants);
- End-of-visit briefings with representatives of the Romanian Ministry of Health (MoH).

IMPORTANT: Should the visit include working with media and/or media exposure, advance notice needs to be given by the Romanian Ministry of Health and joint Lines To Take (LTT) would need to be developed and agreed upon prior to the visit. ECDC will ensure that appropriate clearance and support is given for this activity.
Visit outcomes
The following outcomes are envisaged:

- Joint report from the Romanian Ministry of Health and ECDC, including short system description, strengths, potential or actual weaknesses, proposals for action to strengthen HAI detection, surveillance, prevention and control;
- Identification of potential further support from ECDC.

Visit objectives

- To collect information and data necessary to understand the situation related to HAI prevention, early detection and control;
- To meet and discuss with key stakeholders in the area of HAIs in Romania;
- To analyse the information collected (e.g. reports, notes from meetings and interviews during the country mission) to identify good practices, lessons learned, evaluate vulnerabilities and gaps in HAI work and identify possible areas of joint future work;
- To draft a joint report on the country visit.

Working methods
Both ECDC and the Romanian Ministry of Health nominate liaison persons who will coordinate the visit planning. Regular teleconferences will ensure that both teams discuss in details and agree on the content of the visit, background documents of relevance and expected outcomes.

Confidentiality and data protection
Any personal data that may be collected, stored or otherwise processed in the context of the assessment will comply with the Regulation (EC) 45/2001 of the European Parliament and of the Council of 18 December 2000 on the protection of individuals with regard to processing of personal data by the Community institutions and bodies and on the free movement of such data.

Visit report structure
A preliminary oral report will be provided by the ECDC team to representatives of the Romanian Ministry of Health on the last day of the visit. No written document will be delivered at this stage.

A draft written report will be produced afterwards and will include the sections below:

- Acknowledgements, Contents, Abbreviations
- Executive summary
- Introduction: objectives of the visit, scope and approach, composition of team
- Background
- Main findings divided into: information provided during the visit; direct observations during the visit; strengths, vulnerabilities, areas for review for each of the public health system components (see Annex 1 for the public health system approach to HAI) and for the key components included in the Council Recommendation 2009/C 151/01 as follows:
  - Governance, including but not limited to:
    - a national body to oversee HAI-related activities;
    - multisectoral and multidisciplinary collaboration;
    - a national plan on HAI prevention and control that includes prevention, early detection and reporting, control activities, information and communication activities to the public and monitoring and evaluation indicators relating to progress and success;
  - Hospital/ healthcare institution; including but not limited to: management support, prevention and control of infection control, ICU, microbiology laboratory
  - Laboratory
  - Surveillance/health information
  - Information: public information and communication
  - Resources:
    - Workforce, including professional development/ education and training
    - Funding
  Exploration of opportunities for support on healthcare-associated infections (HAI's) and potential further support from ECDC.
Annex 3. Programme

Exploring opportunities for support on healthcare-associated infections (HAIs)
Annotated programme for country visit to Romania
5-7 July 2016

Monday 4 July
15:00          Arrival of ECDC team from Stockholm
15:00 (tbc)    Arrival from Norway
17:00          Briefing with the representatives of the Romanian Ministry of Health (MoH)
19:00          Dinner and team briefing

Tuesday 5 July

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<th>Comment(s)</th>
<th>Where</th>
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<tr>
<td>7.00 – 8.00</td>
<td>ECDC team meeting over breakfast</td>
<td></td>
<td>Hotel</td>
</tr>
<tr>
<td>8.00</td>
<td>Departure to NIPH</td>
<td>Car</td>
<td>From the hotel</td>
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<tr>
<td>8:15</td>
<td>National Institute of Public Health; meet:</td>
<td>Car</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Director</td>
<td></td>
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<tr>
<td></td>
<td>Director of the Romanian National Centre for Disease Prevention and Control</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Staff working in HAI surveillance</td>
<td></td>
<td></td>
</tr>
<tr>
<td>9.30</td>
<td>Departure to Arges District</td>
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11:00 – 13:00 | Visit to Children's Hospital Pitesti
                 | Meeting with General and Medical Managers
                 | Meeting with Infection Control Team or people in charge of infection control (separately)
                 | Visit to the ICU
                 | Short visit (walk through) other wards (TBD)
                 | Short visit of Clinical Microbiology Laboratory
### Wednesday 6 July

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<td>ECDC team meeting over breakfast</td>
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<td>hotel, Grand Continental</td>
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<td>8:00 - 8:15</td>
<td>Walk to the Ministry of Health</td>
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<tr>
<td>8:30 - 13:30</td>
<td>Visit 2 hospitals in Bucharest; Meeting with General and Medical Managers; Meeting with Infection Control Team or people in charge of infection control (separately); Visit of the ICU; Short visit (walk through) other wards (TBD); Short visit of Clinical Microbiology Laboratory</td>
<td>Car</td>
<td>8.30 Sp. Elias; 11.30 Sp. Universitar</td>
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<tr>
<td>13:30 - 15:00</td>
<td>Lunch</td>
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<tr>
<td>15:30-17:30</td>
<td>Meeting with key stakeholders in the area of HAI; professionals, NGO representatives, etc.</td>
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<td>MOH</td>
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<td>18:00 - 20:00</td>
<td>ECDC team meeting debriefing over dinner</td>
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<td>Meet in the hotel lobby</td>
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### Thursday 7 July

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<tr>
<td>8:45 - 9:00</td>
<td>Walk to the Ministry of Health</td>
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<td>9:00 - 10:00</td>
<td>Debriefing to representatives of the Romanian Ministry of Health</td>
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<td>MoH</td>
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<td>10:00 - 11:00</td>
<td>Meeting with key stakeholders to discuss ‘next steps’</td>
<td></td>
<td>MoH</td>
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<tr>
<td>12:00</td>
<td>Departure to the airport</td>
<td></td>
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<tr>
<td>15:00 flight to Sweden</td>
<td>TBD flight to Norway</td>
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European Centre for Disease Prevention and Control (ECDC)

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