

EuroNHID project

European Network for Highly Infectious Diseases

Manual for the safe and appropriate management of Highly Infectious Diseases patients in isolation facilities

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Executive Summary

Introduction

The European Network for Highly Infectious Disease (EuroNHID) is an EC-funded network (EU contract N° 2006205) of experts in the management of Highly Infectious Diseases (HIDs). EuroNHID involves 15 countries (Austria, Bulgaria, Denmark, Finland, France, Germany, Greece, Italy, Ireland, Luxembourg, Malta, Poland, Slovenia, Spain, United Kingdom). The main aims are to enhance and maintain co-operation, and exchange of information on HIDs among infectious disease clinicians, epidemiologists and public health experts, and to promote exchange of good practices, in order to enhance preparedness and response within Europe to health threats from HIDs.

Specific objective of the EuroNHID project

The specific objective of the project is to conduct an on-the-field assessment of current capabilities in isolation, infection control and HCWs safety in the hospitals designed, in participating countries, to give care to HID patients, in order to identify critical points and to implement the sharing of good practices among isolation facilities. The current document presents the results of the EuroNHID surveys and produce recommendations for the safe and appropriate management of patients with HIDs in isolation facilities.

Methods

During the first year of project activities, three specific checklists have been developed as shared and standardized tools for the assessment of hospital capabilities in dealing with HIDs. In particular, the items explored in the checklists are:

• Hospital resources: isolation capacity, maintenance and control, availability of skilled personnel, availability of medical equipment and laboratory diagnostic capabilities, resource and structures for isolation in the Emergency Department.

• Hospital policies: administrative aspects, use of PPE, hand hygiene, prevention of needlestick injuries, patient's transport, routine hygiene and disinfection, waste management, post-mortem procedures, bio-security issues.

• HCWs safety: management of healthcare personnel, safety and surveillance of HCWs working in HLIU/referral unit, surge capacity of staff, education and training.

Only the isolation facilities identified by National Health Authorities for the referral and management of HIDs should have been surveyed through the checklists. In order to identify these centres we asked to partners to contact national authorities in order to acquire and collected documents (including national preparedness plans) in which the hospitals to be surveyed are clearly indicated. Totally, 47 facilities have been selected.

All surveys were performed during the period March-November 2009. All surveys were performed on-the-field, and included both a visit of isolation facility and the fulfillment of checklists. In 3 cases only, for logistic reasons, on-site surveys were not performed, and fulfilled checklists only are available.

During the third and last year of project activities a specific feedback has been developed and sent to each surveyed facilities, in order to identify strengths and weaknesses of each one, to disseminate good practices, and to suggest affordable solutions for the improvement of the facility.

Moreover, this Manual on the good management of infection control and HCWs safety in case of HIDs has been produced, starting from partners' experiences and expertise and from data emerged during the surveys.

Main results

Data are available from 47 isolation facilities in 15 European countries.

Isolation capabilities. The overall isolation capabilities are: 289 rooms and 408 beds for adults, 166 rooms and 239 beds for children; overall isolation capabilities by country range from 0,05 to 17,9 beds for millions of inhabitants.

Logistic and other general characteristics. The vast majority of the surveyed facilities is located within, or in close proximity to a general hospital. The majority of them are fully operating and able to admit a patient within 5 hours of notification. As isolation method for HCWs, PPE are used in 45 facilities, while plastic isolator beds are in use in 2 facilities. 30 facilities are able to isolate both adults and children, beds for adults only are available in 14, isolation beds for children only in the remaining 3. 21 facilities report to have real-life experiences with both confirmed and suspected cases of HIDs, 18 with suspected cases only, and 8 report to have no real-life experiences with HIDs.

Technical features. In 42 facilities negative pressure room(s) are available, while anteroom, HEPA filtration, material adequate for decontamination and sealed doors and windows are available in 42, 40, 43, 31 facilities, respectively.

Medical issues. Intensive care capabilities are available in 44 facilities: in 32 cases, in the isolation room, in 12 cases in another area. The vast majority of them have access to dedicated or pre-identifies medical instruments and devices.

Personnel. Availability of Infectious Diseases specialists trained for the management of HIDs ranges from 0,15 to 7,97 for millions of inhabitants, while availability of Intensive Care specialists with the same skills ranges from 0 to 13,9. Specifically developed shift plan for the management of HIDs has been developed in 12 facilities only.

Diagnostic. 10 facilities report to have a direct access to a BSL4 lab, while specific procedures for the safe transport of specimens are available in 30. No specific plans are in place in 7 facilities. 38 and 9 facilities, respectively, report to have direct access to BSL3 lab or specific procedures for the safe handling of specimens. Other tests are performed safely (inside isolation room, in a BSL3 lab or in general lab after inactivation) in 15 facilities.

Emergency Departments (EDs). Data are available from 40 EDs. Isolation room(s) are available in 33 of them, but in only 6 they have adequate logistic and technical features. Procedures for the management of HIDs are available in 45 EDs, while triage personnel specifically trained for the early recognition of HIDs are available in 24 facilities.

Transport of HID patients. 29 facilities report to have procedures for the external and internal safe transport of patients. About vehicles, in 12 facilities specifically designed ambulances are available, while in other 9 facilities normal ambulances specifically reserved for HID patients are present.

Infection control. Procedures for the selection, donning and removal of Personal Protective Equipments are in place in 43 facilities, while adequate protocols for their correct use and adequate supply are available in 19 and 17, respectively. All facilities but one report to have protocols for hand-hygiene, but adequate technical features are available in 28 only. Most frequently reported methods for hand-hygiene are liquid soap, alcohol-based solution and gel (in 45, 36 and 24 facilities, respectively). 45 facilities state to have procedures for the prevention of needle-stick injuries, and 44 report to use an adequate number of engineered medical devices, also. In 39 facilities there are procedures for the routine hygiene and/or the final disinfection of the isolation room, while similar procedures for other areas are in place in 34. Personnel specifically trained for the performing of hygiene and disinfection during the care to a HID patient is available in 23 facilities only. In 13 facilities the solid clinical waste are disinfected within the isolation area, while in other 31 special procedures for their disposal are available, but not include decontamination in the facility. The most used method is autoclaving or transport to incineration in special containers. Procedures for the disinfection of liquid waste before disposal are in place in 32 facilities, and frequently used methods include autoclaving after jellification and pre-treatment with chemical or physical process. Procedures for the safe management of human remains are in place in 38, procedures for the safe performing of autopsies are available in 18, while technically equipped autopsy room is available in 7 facilities only. Adequate procedures for bio-security are reported in 27 facilities.

HCWs safety – administrative, psychological and medical issues. Services for the HCWs' safety are available in 45 facilities, but on 24-hour-basis in 34 only. All facilities but one report to have protocols in place for the management of more common accidents involving HCWs. A psychological support is available for the staff in 21 facilities. Health status of HCWs before working into isolation area or during the employment is evaluated in 36 facilities. Protocols for HCWs vaccination, chemoprophylaxis and post exposure management are in place in 28, 39 and 45 facilities, respectively.

HCWs training. Specific training to be completed before working into isolation facility is required in 27 facilities, while in 37 a continuous educational program is in place. 34 facilities report to have participated into table-top exercises, and 33 report to have participated into practical exercises.

Conclusion

The general level of preparedness strongly differs among countries and within the country. In general, the overall isolation capability in Europe is adequate, such as, in general, infection control procedures. Main critical points are emerged. In particular the surveys have evidenced the general lack of specific expertise in the management of pediatric patients; the limited availability of adequate features and location for Intensive Care, especially in some countries; the not adequate management of diagnostic specimens in some facilities; and the general level of preparedness in Emergency Departments, not completely adequate. Among infection control procedures, some inadequacies have emerged in the technical features for hand-hygiene, in the management of solid

waste and in the procedures for the safe management of human remains and autopsies. In general, a lack of attention in HCWs' psychological aspects is emerged, also, such as the presence of not adequate training procedures in some facilities.

Introduction

The general context

In the last 10 years, many newly-appeared events have increasingly focused the attention of scientists and policymakers on threats to health security.

At the beginning of this century, breaking events such as terroristic attacks on September 11, and the circulation of anthrax letters in USA in 2001, have increased concerns about possible terrorist attacks using biological agents. In the meanwhile, other events, such as the increasing of international movements of people, animals and goods, climate change, and an increase in intensive animal farming especially in Asian emerging countries, are currently favoring the appearance and spread of emerging and re-emerging diseases. The SARS outbreak, the increasing number of Viral Haemorrhagic Fever cases, also including autochthonous cases of Crimea-Congo Haemorrhagic Fever in the European region, the introduction of West Nile Virus in USA and recently in Europe, the outbreaks of Monkeypox in USA and Chikungunya in Italy, the global re-emergence of Dengue, are just some of the examples of breaking events threatening public health.

Moreover, the number of laboratories managing bio-safety level (BSL) 3-4 pathogens is increasing, with a consequent increase of possible lab-workers' exposure due to needle-stick or other accidents

Finally, the appearance of H1N1 pandemic, despite its impact having been weaker than initially predicted, highlighted once more that a newly appeared transmissible disease may have a strong impact not only on global health, but also on economy and social security.

The threat of Highly Infectious Diseases (HIDs)

Among emerging and re-emerging diseases, a particular concern is posed by some diseases, prone to cause large outbreaks both in health-care and community settings. During the EUNID project (European Network for Infectious Diseases, a 2004-2007 co-funded European network involving expert clinicians and epidemiologists from 16 European countries) the panel of experts defined these **Highly Infectious Diseases (HIDs) as those:**

- being easily transmissible from person-to-person,
- causing life-threatening illness,
- presenting a serious hazard in health-care settings and in the community, requiring specific control measures.

The same panel of experts included among HIDs the following:

- Viral haemorrhagic fevers (VHF) (marburgvirus, ebolavirus, Crimean Congo haemorrhagic fever virus, Lassa virus, the recently-recognised Lujo virus, and South American haemorrhagic fever viruses Junin, Machupo, Sabia, and Guanarito).
- SARS Co-V
- Multi Drug- and Extensively Drug- resistant M. tuberculosis (MDR- and XDR-TB, known or suspected infection)
- Newly emerging highly pathogenic strains of influenza virus
- Smallpox and other orthopox infections (eg monkeypox, camel pox, but excluding vaccinia virus)
- Other emerging highly pathogenic agents, including agents of deliberate release (eg pneumonic plague), some of which could also be extensively antibiotic-resistant.

HIDs in Europe

Several cases of these diseases have been reported in Europe since 2000: 32 cases of SARS were imported in eight countries, and approximately 15 imported confirmed or suspected cases of VHFs have been reported, mainly Lassa fever [1-4]. Recently, two isolated cases of Lassa fever have been diagnosed in London in travellers who returned to the UK from Nigeria and Mali [5,6], and several cases of autochthonous Crimean-Congo haemorrhagic fevers have been reported in the European region (in Turkey and in some states in the Balkans) and in some countries within the EU (Bulgaria and Greece) [7,8]. Moreover, a fatal case of Marburg haemorrhagic fever has been imported in the Netherlands from Uganda [9], and a laboratory worker in Hamburg has been treated with an experimental vaccine after high-risk exposure to Ebola virus (and did not develop symptoms) [10]. No human cases of highly pathogenic Influenza A (H5N1) virus have occurred in Europe, but two suspected cases were managed in the Netherlands and Belgium, public health authorities in Greece faced a pseudo-outbreak, and 13 lab employees working with ferrets in the Czech Republic were treated with oseltamivir after they handled flu vaccine that had been contaminated with the H5N1 avian influenza virus [11-14]. Moreover, several recent cases of cowpox infections have been reported recently in Europe: 18 confirmed cases in Germany, one suspected case in the Netherlands, five confirmed and seven suspected cases in France. Although human cowpoxvirus infections are not classified as HID, these cases are worth mentioning here as an example of how an unexpected agent can disseminate rapidly. Some of the cases described above were proven to be caused by the same virus, indicating exposure to a common source of infection related to an international trade in pet rats by a Czech rat breeder [15]. Two cases of human infection with an orthopoxvirus, similar to but distinct from cowpox, have been identified in northeastern Italy in two veterinary doctors who had been exposed to infected cats [16]. This finding, and the fact that the two infections occurred independently of one another, underscore the need to enhance awareness of zoonotic poxvirus transmission (possibly endemic) also in regions where this problem has not been addressed so far.

Almost all of the cases requiring isolation were first admitted to a general hospital without adequate isolation capabilities, and later transferred to a high-level isolation unit. Despite the fact that no outbreaks occurred in Europe, these experiences exposed weaknesses in terms of recognition, public health response, diagnostic and clinical management. Indeed, despite the wide availability of national and international plans and guidelines, their application in 'real-life' scenarios remains poor. Not surprisingly, public health, policies and diagnostic and clinical approaches to HIDs differ widely among European countries, and a common platform that would enable scientists to respond in a quick and powerful manner is still lacking.

Special needs in health-care settings

The global spread of emerging infectious diseases has further highlighted the importance of hospital planning for HIDs. Indeed, the health-care setting (HCS) may play a dual role.

On one hand, the HCS represents an "hot-point" for the spreading of contagious diseases, for several reasons:

- the presence of infectious patients and many susceptible individuals in the same limited space;
- the lack of isolation of infectious patients because of mis-diagnosis or unavailability of adequate facilities;
- the frequent and close contacts among patients and health care workers (HCWs) often not protected by Personal Protective Equipment (PPE).

The impact of these events is particularly high in the HCS, as was clearly demonstrated by the SARS epidemic. Initially, hospitals represented the most important sites of SARS disease transmission: about 60% of new infections were hospital-acquired [17], and the disease struck heavily among HCWs who mainly became infected after unprotected, close contacts with infectious patients or through performing aerosol-generating procedures. HCWs represented about 21% of all SARS cases [17].

On the other hand, infection control measures, when adequately applied, greatly reduce the risk of transmission of contagious diseases in hospital settings. Indeed, safe hospital procedures such as early isolation of infectious patients, medical surveillance of contacts, and use of appropriate PPE are essential for the prevention and control of an outbreak.

The need of special bio-containment facilities and infection control procedures

As a consequence of emerging threats posed by HIDs, the need for an adequate hospital biopreparedness is currently increasing. In particular, the existence of highly specialized centres for referral of HIDs is very important, since HIDs, for the protection of HCWs, other patients, and the whole community, require levels of infection control and clinical expertise that cannot easily be provided in common HCS. In order to face these challenges, pre-identified facilities for the isolation and management of HIDs are present in most developed countries. The technical level of these facilities varies widely, ranging from standard hospital rooms to High Level Isolation Units (HLIUs), that are health-care facilities specifically designed to provide safe, secure, high-quality, and appropriate care with optimal infection containment, and infection prevention and control procedures, for a single patient or a small number of patients who have, or who may have, an HID.

The EuroNHID (European Network for Highly Infectious Diseases) project

Since 2001, The European Commission has funded several activities intended to improve health security, build capacity, and strengthen preparedness for response to infectious disease emergencies. These ventures include the EuroNHID (European Network for Highly Infectious Diseases) project, a 36-months project (then extended to 42 months, June 2007-December 2010) bringing together European infectious disease clinicians with experience in the management of HIDs and/or HLIUs. EuroNHID consists of 16 partners and 47 participating centres from 15 states (Austria, Bulgaria, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Luxembourg, Malta, Poland, Slovenia, Spain, and United Kingdom).

EuroNHID is led by Dr G. Ippolito, and managed by the Coordination Team, based at the National Institute for Infectious Diseases (Istituto Nazionale per le Malattie Infettive, INMI), IRCCS, "Lazzaro Spallanzani", Rome, Italy. A Steering Committee, including project partners from four countries (France, Germany, Greece and UK) and the Coordination Team, manages, with the support of all other project partners, all medical and scientific aspects of the project.

The general aims of EuroNHID are to enhance and maintain co-operation, communication, and exchange of information and experiences on HIDs among infectious disease clinicians, and to enhance preparedness and response within Europe to health threats from these diseases, whether naturally occurring, newly emergent, or deliberately released. In particular, the mission of EuroNHID is to promote and exchange good practices in the fields of isolation, infection control and HCWs safety, in the case of emergencies deriving from naturally emerging or deliberately released agents of HIDs, as well as in the care of sporadic or imported cases. EuroNHID continues and reinforces the work done during European Network of Infectious Diseases physicians (EUNID) project, a previous project co-funded by EC focussed on management of HIDs. The EUNID project, lasting 2004-2007, brought together many European experts in HID/HLIU management, and reached some valuable results: (i) an agreed definition of HIDs; (ii) an archive of existing international and national guidelines on isolation and management of HID patients; (iii) an inventory of isolation facilities in participating countries; (iv) a list of clinicians with specific expertise in these fields, to be contacted in case of need; (v) an exchange of good practice, with special focus on PPE selection and management; (vi) a consensus management guidelines including some medical procedures and criteria for patient's admission in case of suspected/confirmed HIDs; (vii) a consensus document on the definition of requirements for isolation facilities/HLIU in Europe; (viii) a core curriculum and training modules for HCWs who are involved in the care of patients affected by HIDs. Most of these results have been published on peer-reviewed international

journals and bulletins [18-21], while all of them are available, after registration, on the web-site <u>www.eunid.ue</u>.

Specific objectives of the EuroNHID project

The mission of EuroNHID is to prepare and support isolation facilities to provide appropriate infection control measures and strategies for HCWs safety during a coordinated and effective care to patients in the case of emergencies deriving from naturally emerging or deliberately released agents of HIDs, as well as in the care of sporadic or imported cases, improving patient management and reducing the risk of hospital acquired infections. The vision of EuroNHID is to provide effective healthcare through adequate environment and a well trained and equipped workforce, enhancing safety in the isolation units/referral centres treating HID patients.

These objectives have been reached through the following steps:

- development of specific checklists for the standardized collection of data;
- identification of target isolation facilities;
- on-the-field surveys of selected isolation facilities conducted by the same investigator, supported, when feasible, by a project member/collaborator;
- setting up of specific "Evaluation Forms", including identification of strengths, weaknesses and critical points of each surveyed facilities. These forms have been sent to and discussed with all surveyed isolation facilities.

Moreover, the analysis of collected data allows the identification of recurrent critical gaps, as well as the identification of good and affordable practices to be shared among isolation facilities. The collated data allow a general evaluation of preparedness level of centres identified for HID isolation and management in EuroNHID participating countries, and provide a format which can be used for the evaluation and re-evaluation of individual units..

In this document, the EuroNHID project team presents and discusses the collected data from 47 isolation facilities in 15 European countries. Moreover, EuroNHID also aims to propose a practical manual for the appropriate and safe handling of suspected or confirmed HIDs in isolation facilities. The recommendations included in this manual will take into account the available scientific evidence, as well as international guidelines and regulations on this topic, the data emerged from the surveys, and the personal opinions/experiences of the project members and participants.

Methodology

At the beginning of the project, national public-health authorities in all European countries were contacted by the Coordination Team, with the help of the EC, and their interest to take part of the project was explored. If interested, they were asked to suggest (although not formally to endorse) physicians with expertise in HID/HLIU management as national representatives. Most of these partners also contributed to the previous EUNID project, while new partners from Bulgaria, Malta, Poland and Slovenia were included. Most of them are clinicians working in HLIUs or centres designated for referral of patients with HIDs, who, together, have backgrounds in infectious diseases, intensive care, infection control, pulmonary medicine, occupational health, and public health. A project Steering Committee, including partners from France, Germany, Greece, UK, and the Coordination Team, was constituted at the beginning of the project. Partners to be included in the Steering Committee were selected on the basis of their personal expertise, their familiarity with HIDs/HLIU, and their availability to take part more actively into the project activities. The role of the Steering Committee is to actively contribute to all scientific aspects of the project.

Development of checklists

A networking strategy was adopted in order to develop the checklists. During a preliminary meeting (Rome, October 2007) with the Steering Committee, topics and items to be explored in the checklists were selected, starting from partners' experiences, available literature, preparedness plans, as well as guidelines of international authorities for the management of HIDs. The list of selected topics and items was sent to, discussed with and finally approved by all national partners. Each main topic was then assigned to a Steering Committee member with specific expertise, who drafted a preliminary checklist. Advanced checklist versions were developed in order to incorporate comments, suggestions and additional evidence from all partners. Final agreement was reached during a general meeting (Rome, April 2008). The checklists were developed as standard and shared survey tools and are not intended to set forth mandatory requirements or establish a national standard for legal preparedness.

Finally, three different checklists have been developed, including 44 items and 148 specific questions. The main areas explored were:

- Checklist 1, hospital resources: infrastructure (including location, capacity and infrastructures), technical aspects (including technical infrastructures, control and maintenance issues, availability of medical equipment, diagnostic capability), personnel availability, and an optional section on infection control in the Emergency Department/Medical Admission Department.
- Checklist 2, hospital procedures: administrative aspects, management of personal protective equipment (PPE) (including selection, donning and removal procedures, and supplying), hand hygiene (including specific procedures and existence of adequate

technical features), prevention of needle-stick injuries (including existence of adequate devices), transportation of patients (including logistic and technical aspects), routine hygiene and disinfection, waste management (including logistic and technical features), post-mortem procedures, surge capacity procedures.

• Checklist 3, HCW safety: organizational and administrative aspects of HCW safety (including services available, procedures of assessment of safety culture and climate), medical aspects of HCW safety (including pre- and post-exposure management), education and training of HCWs.

In order to check the applicability of these checklists, the Coordination Team and the Steering Committee decided to perform a pilot phase of the survey, applying the checklists in their own HLIU. Moreover, we also contacted the staff of another HLIU in Sweden, which is not included in the project, and asked them to apply the checklists, as an external control. After this pilot study that included 5 facilities [22], checklists have been applied in other 43 isolation facilities. During their extensive application, some further limits of their applicability emerged, so after the collection of data the checklists were again slightly modified. Indeed, the intent of checklists is not only the standardized collection of data during EuroNHID project, but they are also intended as a standard, affordable tool for self-assessment of other isolation facilities not surveyed during the project. The final version of the checklists in attached at this document as **Annex 1**.

Identification of isolation facilities to be surveyed

Only the HLIUs and/or other isolation facilities identified by National Health Authorities for the referral and management of HIDs should have been surveyed through the checklists. In order to identify these centres we asked to partners to contact national authorities in order to acquire and send to Coordination Team official documents (including national preparedness plans) in which the hospitals to be surveyed are clearly indicated. Moreover, the list of National Focal Points for each country has been furnished to all partners. In the meanwhile, 2 letters were sent by the European Commission to members of Health Security Committee, asking them to support the EuroNHID Coordination Team in the collection of official documents. When there was uncertainty about the nature of the information required, we suggested asking the National health authorities the following simple question: "If tomorrow a suspected Ebola hemorrhagic fever case is detected/imported in your country/region, where do you plan to manage it?"

These processes led to the successful collection of official documents in 14 countries (Austria, Bulgaria, Denmark, Finland, France, Germany, Greece, Italy, Ireland, Luxembourg, Malta, Poland, Slovenia and UK). Limited data were available from Spain (only the Catalonia region is included), despite strong efforts to contact National authorities in order to have data from other regions, too. According to our current knowledge, the total number of HLIUs and/or referral centres identified by National Health Authorities for the management of HIDs in participating countries is 47.

Find attached in table 1 the list of isolation facilities selected and surveyed.

Table 1 – Isolation facilities selected and surveyed during the EuroNHID project, in the periodMarch-November 2009

Country		Hospital name, city	Modality of survey
Austria	1	"Otto-Wagner" hospital, Vienna	Site visit (Project Coordinator and project partner)*
	2	"Prof. Ivan Kiroff" hospital, Sofia	Site visit (Project Coordinator and a collaborator of the project partner)
Bulgaria	3	"Saint Marina" hospital, Varna	Site visit (Project Coordinator and a collaborator of the project partner)
Denmark	4	"Hvidovre" hospital, Hvidovre, Copenhagen	Site visit (Project Coordinator)
Finland	5	"Aurora" hospital, Helsinki	Site visit (Project Coordinator and project partner)*
rimanu	6	University hospital, Turku	Site visit (Project Coordinator and project partner)
	7	"Pitié-Salpêtrière" hospital, Paris	Site visit (Project Coordinator and project partner)
	8	"Bichat-Claude Bernard" hospital, Paris	Site visit (Project Coordinator and project partner)
	9	"Raymond Poincaré" hospital, Paris	Site visit (Project Coordinator and project partner)*
France	10	University Hospital Centre, Bordeaux	Site visit (Project Coordinator and project partner)
	11	"Oscar Lambret" Regional University Hospital Centre, Lille	Site visit (Project Coordinator and project partner)
	12	University Hospital Centre, Rennes	Site visit (Project Coordinator and project partner)
	13	Civil hospital, Lyon	Site visit (Project Coordinator and

			project partner)
	14	North hospital, Marseille	Site visit (Project Coordinator and project partner)*
	15	Brabois hospital, Nancy	Site visit (Project Coordinator and project partner)
	16	"Charles Nicolle" hospital, Rouen	Site visit (Project Coordinator and project partner)
	17	New Civil hospital, Strasbourg	Site visit (Project Coordinator and project partner)
	18	"Gustave Dron" hospital, Tourcoing	Site visit (Project Coordinator and project partner)
	19	"Charité" hospital, Berlin	Site visit (Project Coordinator and project partner)
	20	Goethe University Hospital, Frankfurt	Site visit (Project Coordinator and project partner)*
	21	University Hospital, Hamburg	Site visit (Project Coordinator and project partner)
Germany	22	"St. Georg" Hospital, Leipzig	Site visit (Project Coordinator and project partner)
Germany	23	Städt. Klinikum München GmbH Klinikum Schwabing, München	Site visit (Project Coordinator and project partner)
	24	Klinikum Saarbrücken gGmbH, Saarbrucken	Site visit (Project Coordinator and project partner)
	25	"Robert Bosch" Hospital, Stuttgart	Site visit (Project Coordinator and project partner)
	26	Medical Missionary Hospital, Würzburg	Site visit (Project Coordinator and project partner)
Greece	27	"Evangelismos" hospital, Athens	Site visit (Project Coordinator and project partner)

28 Attica, Athens project part 29 "G. Gennimatas" hospital, Athens Site visit (P project part	iner)
29 "G. Gennimatas" hospital, Athens	
	Project Coordinator and ner)
30"Aghia Sophia" children's hospital, AthensSite visit (P project part	Project Coordinator and mer)
31University General hospital, CreteSite visit (P	Project Coordinator)
32 "AHEPA" University hospital, Site visit (P Thessalonica	Project Coordinator)
33 "Mater Misericordiae" hospital, Site visit (P Dublin project part	Project Coordinator and mer)*
34"Our Lady's" Children's hospital, DublinSite visit (P	Project Coordinator)
35"L. Spallanzani" hospital, RomeSite visit (PItaly	Project Coordinator)§
36"L. Sacco" hospital, MilanSite visit (P	Project Coordinator)
Luxembourg37Hospital Centre, LuxembourgSite visit (P project part	Project Coordinator and (ner)*
Malta38"Mater Dei" hospital, MaltaSite visit (P project part	Project Coordinator and mer)*
Poland39HospitalofInfectiousDiseases,Site visit (PWarsawWarsawProject part	Project Coordinator and mer)*
40 "Clinic" hospital, Barcelona Site visit (P project part	Project Coordinator and mer)*
	Project Coordinator)
Spain 42 "Sant Pau" hospital, Barcelona Site visit (P	Project Coordinator)
43 "Del Mar" hospital, Barcelona Site visit (P	Project Coordinator)
44"Val d'Hebron" hospital, BarcelonaSite visit (P	Project Coordinator)

United	45	"Royal Free" hospital, London	Fulfilled checklists only*	
Kingdom	46	General hospital, Newcastle	Fulfilled checklists only	
Slovenia	47	University Medical Centre, Ljubljana	Fulfilled checklists only*	
* the project partner is part of the staff of the surveyed facility; § the project Coordination Team is part of				
the staff of the surveyed facility.				

On-the-field surveys of selected isolation facilities

During the project meetings many partners expressed concerns about the modalities of surveys in isolation facilities. Indeed, these structures may be very different, and the applicability of checklists may sometimes be difficult. In order to assure homogeneity in the data collection, and flexibility in the application of checklists, it was agreed that the same investigator performed all the surveys. Thus, the project coordinator, who has an adequate background for this task and actively participated into the writing of the checklists, was identified as the investigator.

All surveys were performed during the period March-November 2009. When feasible, the surveys were conducted by the project coordinator helped by the project partner of the explored country. This has not been always possible, because, in some cases, surveys have been performed in the same facilities where project partners work and the coordinator did not need to visit. In other cases, the partner could not be available and the coordinator worked alone. All surveys were performed on-the-field, and included both a visit of isolation facility and the fulfillment of checklists. In 3 cases only, for logistic reasons, surveys were not performed on-the-field, and fulfilled checklists only are available. In table 1, the modality of surveys is included, too.

This process assured, in our opinion, adequate harmonization in the application of checklists and homogeneity of the survey outcomes.

Setting up of specific "Evaluation Forms" to be sent to surveyed isolation facilities

A standard Evaluation Form was developed initially by the Coordination Team, then discussed and drafted with Steering Committee, finally sent to, discussed with and approved by all partners. The Evaluation Form is attached in this manual as **Annex 2**.

In the Evaluation Form, all data collected from checklists has been summarized in 18 items, each one including one or more topics, with totally 53 topics. Each topic is represented by a statement describing the "optimal" condition, and depends by one or more questions included in the checklists. Topics are ranked with 2 different scores:

• the strength score, ranking the "importance" of the topic (A-Indispensable; B-Very Important; C-Important; D-Advisable), that means that the condition described in the

topic may be from indispensable for an adequate and safe management of HID patients to advisable only;

• the evaluation score, ranking the level of appropriateness of the observed, real, situation compared with the "optimal" condition (A-Fully/mostly achieved; B-Partially achieved; C-Not achieved; NA-Not applicable). The different conditions being fully/mostly achieved, partially achieved and not achieved are clearly described in the Form.

Moreover, at the end of each item, a large part is dedicated to comments, where all topics previously schematically scored are developed and explained in details. The identified weaknesses are clearly identified, and affordable solutions, if possible, suggested.

As an example, in the general item "Medical Assistance", the first topic is dedicated to availability of intensive care. The statement describing "optimal" condition is "The isolation facility is able to provide Intensive Care in place". The strength score – the importance of the topic – is ranked A, it means that this topic is considered as indispensable. The evaluation score, that derives from the answers to 3 different questions in the checklist 1, is: A: Intensive Care capabilities available in the isolation facility; B: Intensive Care capabilities available in another area (i.e. isolation room in ICU); C: Intensive Care capabilities not available at all. If the surveyed facility has Intensive Care capabilities available in the isolation score A), otherwise it may be B or C. All explanations/observations/suggestions related to that item are finally included in the comments. This system, although elaborate, allows a standard and complete assessment of each observed condition.

The Coordination Team also tried to develop a "summary score", based on numerical values, but this was not finally developed, in order to avoid the misleading perception from the surveyed facilities that this was a formal ranking, with "good" facilities at the top. The intent of the EuroNHID surveys is to support surveyed facilities, through the identification of potential weaknesses and suggestions for possible solutions; it is not the identification and classification of "good" and "bad" facilities.

These Evaluation Forms were sent to all surveyed facilities, asking for a feedback in a reasonable time. Most of surveyed facilities sent a feedback, that were very useful to better clarify some points. In some cases, these discussions led to a modification of the original Evaluation Form. Moreover, some facilities sent us an update of their procedures and capabilities, after the emergence of the H1N1 2009 pandemic. Indeed, the emergence of this pandemic influenza strain caused, at least in the initial phases of pandemic, an increased use of isolation facilities, in order to isolate the first patients and to delay as much as possible the early spread of the pandemic within the country. This effort permitted the re-evaluation of some procedures, from which necessary modifications were, promptly communicated to other EuroNHID partners also. Thus, the feedback process acted as an open and effective channel for communication and exchange of experiences and good practices.

Development of the Manual

The present document has been developed during 2010, taking into account the data derived from the surveys, the available scientific evidence, the European legislation framework around the key identified issues, and personal experiences and opinions of the project participants.

This Manual as been divided in general subject headings, based upon and including all data collected with checklists. Each subject has been endorsed to a Steering Committee member with a special expertise on it. The chapters have been drafted and discussed among the coordination Team and Steering Committee members, and an advanced draft has been sent to all partners for comments, amendments, and suggestions. The final version incorporates all contributions of the project partners, and has been approved by all of them.

General Structure of the Manual

The Manual is divided in chapters, each one including one or more items, as divided into the Evaluation Form.

In particular, the Manual includes:

- An introduction;
- A methodology section;
- A presentation of the Manual;
- Chapter 1: logistic, technical and infrastructure issues of isolation facilities;
- Chapter 2: medical issues;
- Chapter 3: personnel requirements in isolation facilities;
- Chapter 4: diagnostic capabilities;
- Chapter 5: logistic and technical features, and infection control procedures in Emergency Departments connected with isolation facilities;
- Chapter 6: transport issues for patients with HIDs;
- Chapter 7: Infection control procedures PPE management;
- Chapter 8: Infection control procedures Hand hygiene;
- Chapter 9: Infection control procedures Prevention of needle-stick injuries;
- Chapter 10: Infection control procedures Routine hygiene ad disinfection;
- Chapter 11: Infection control procedures Waste management;
- Chapter 12: Infection control procedures Post-mortem procedures;
- Chapter 13: Bio-security issues in isolation facilities;
- Chapter 14: Healthcare Workers safety: administrative, psychological and medical issues;
- Chapter 15: Healthcare Workers education and training.

Structure of each chapter

For each item, after a brief introduction, data from checklists are presented. All topics are separately presented, with a clear indication of Strength Score and of checklist questions from which Evaluation Score is derived. For each topic, distribution of Evaluation Scores are presented and briefly discussed. Moreover, more interesting punctual data are presented and discussed, also. Finally, in each chapter is included a large comment paragraph, that gives general recommendations on the discussed item and affordable suggestions, if any, for the achievement of minimal requirements.

Chapter 1 – Infrastructure issues

Main author: S. Schilling

1.1 Introduction

Required levels of infection control for HIDs cannot easily be provided in a routine care facility. Indeed, special logistic, infrastructure and technical features are recommended for effective infection control. In particular, appropriate design and construction of isolation facilities are crucial points for the safe management of HIDs.

The current situation about logistic, infrastructure and technical issues in the surveyed isolation facilities are described, and recommendations about these points are addressed in this chapter.

Design and construction of clinical care facilities for HIDs is a major limitation for the efficacy of infection control as well as HCW's and patient's safety. Detailed recommendations for any newly planned isolation facility can be drawn from previously published recommendations of the European Network for Infectious Diseases (EUNID) [20]. However, many EU member-states already have existing structures whose compliance with recommendations mentioned were the focus of the study described. In order to gain most effective infection control regimen a need to modify and upgrade existing structures was often necessary. Thus, they were limited by architecture and the possibility to modify infrastructure-related technical equipment. Give the lack of EU regulations for the construction and design of such facilities, individual solutions had to be achieved in close co-operation with regional and national public health authorities in the past.

In general, any clinical care facility responsible for HIDs must ensure the functional separation of isolation rooms from other common areas either by architecture or functional barriers (e.g. controlled gates). In addition, enough space to ensure containment within and limited access to the isolation area should be provided (e.g. rooms for the team in charge and space for the storage of clinical waste). Infrastructure-related technical equipments such as HEPA (High Efficiency Particulate Air) filtration, negative pressure rooms, the existence of an anteroom and an autoclave are considered indispensable for any clinical care facility responsible for HIDs. Any material used within the isolation facility should be chosen with respect to decontamination procedures and centres should provide protocols for the maintenance of any technical feature in use. Additional

functional independence from other hospital resources and facilities may be achieved by ensuring the availability of standard technical equipment which is described and discussed in Chapter 2.

Facilities not providing those features should be carefully prepared and trained to deal with infection control issues on other ways. If those aims cannot be achieved due to the given building structure, non-permanent solutions (e.g. inflatable isolation tents) can provide a desirable solution and can be well positioned in a national or regional response-system for HID management.

1.2 Data from the surveys (aggregate and punctual data)

General item: 1. Logistic

Topic 1.a) Location of isolation Unit

The isolation facility is located as part of, or in strict connection with, a general hospital. (Deriving from: Checklist I, Questions A.1.e, A.3.a)

Strength score: B

Evaluation score:

- A: The facility is part of, or in strict connection with, a general/university hospital.
- B: The facility is a mono-specific centre/hospital connected to a general/university hospital.
- C: The facility is a mono-specific centre not connected to a general/university Hospital.

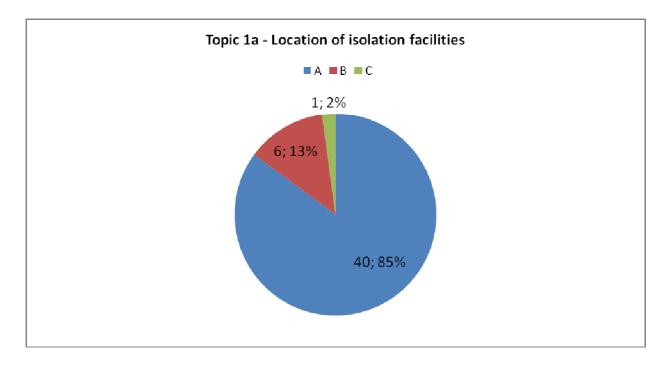


Figure 1.1 – Topic 1a. Location of isolation facilities (valid answers: 47)

The majority of surveyed centres (85%) are part of a general/university hospital. It is considered by EuroNHID the optimal solution (Evaluation score A), because a broad range of consultants in other specialties may be easily available. Seven facilities are located in a mono-specific centre (mainly Infectious Diseases or Paediatric hospitals only), but 6 out of those are located within or very close to a general/university hospital, where additional specialists and consultants are considered accessible. In only one case, the isolation facility is located in a mono-specific infectious diseases centre not connected with a general/university hospital: This location is considered not adequate, also if some solutions (written agreement with another hospital for the rapid supply of consultants, extensive use of tele-medicine) may be developed.

Topic 1.b) Adequate access to isolation facilities

The isolation facility is accessible for HID patients without contamination of common area (i.e. separate entrance, dedicated elevator if needed, dedicated pathway). (Deriving from: Checklist I, questions A.3.a, A.4.c, D.1.c; Checklist II, questions E.1.a, E.2.d, E.2.e)

Strength score: A

Evaluation score:

A: Presence of completely dedicated entrance/pathway.

- B: Presence of separate entrance/pathway with partial use of common areas OR completely dedicated pathway/entrance but not completely appropriate (i.e. presence of stairs) OR not separate entrance/pathway, but specific procedures (i.e. evacuation of common areas) in place.
- C: Not separate entrance/pathway or procedures in place.

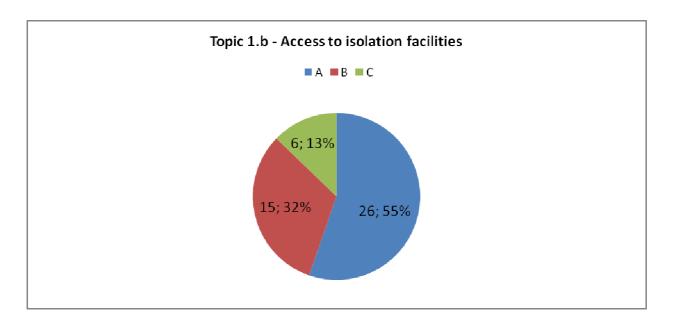


Figure 1.2 – Topic 1.b. Access to isolation facilities (valid answers: 47)

Among 47 surveyed facilities, 26 (55%) are able to admit HID patients using completely dedicated entrances and pathways. Such exclusive entrances and pathways are considered very important (Evaluation Score A) in order to avoid any potential contamination of other common areas, and to reduce the time needed for the admittance of the patient (because no additional time is needed for warning, evacuation and a consecutive disinfection of those areas). In 15 facilities (32%) entrances/pathways are not considered optimal for reasons such as the partial use of common areas, presence of stairs or not-dedicated elevators. Such conditions are acceptable only if procedures to be used are detailed, functional, well-known by HCWs, and periodically exercised. Finally, a complete lack of dedicated entrances/pathways, and lack of specific procedures for in-house patient transport, makes 6 facilities not adequate.

Topic 1.c) Possibility of manage HID patients without use of common areas

The isolation facility is a self-functioning unit able to operate in a functionally separated manner (i.e. there is a place for donning and removal of PPE, enough spaces functioning as nurse stations/meeting rooms, an area for the decontamination of the material). (Deriving from: Checklist I, questions A.1.d, A.2.a, A.3.a, A.4.c, B.3.a-k, B.4.a-c, D.1.c; Checklist II, questions E.1.a, E.2.d, E.2.e)

Strength score: B

Evaluation score:

- A: The unit is functionally independent.
- B: The unit is partially functionally independent (some areas are in common with the normal ward).
- C: The unit cannot operate in a functionally independent manner by other areas.

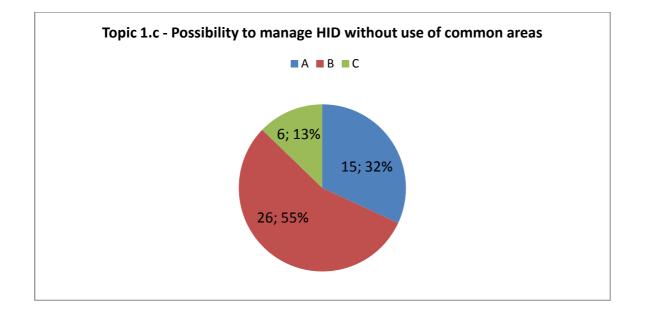


Figure 1.3 – Topic 1.c. Possibility to manage HID without use of common areas (valid answers: 47)

Overall, 15 facilities provide sufficient space/rooms within the isolation facility to be functionally independent in the management of HID patients. This is considered very important, because it helps preventing the risk of contamination of other hospital areas. In the remaining centres, (32,68%) isolation facilities can not operate completely independently, or are fully integrated in common areas of the surveyed hospital. Thus specific infection control procedures should be developed and carefully applied on the basis of a risk assessment process, and may range from the creation of non-permanent dedicated pathways/separated areas, to the complete evacuation of common areas.

Topic 1.d) Time needed for facility activation

The isolation facility is fully operating within 5 hours. (Deriving from: checklist I, question C.1.a)

Strength score: B

Evaluation score:

- A: The isolation facility is fully operating within 5 hours for both ICU and not ICU cases.
- B: The isolation facility is fully operating within 5 hours for ICU or not ICU cases.
- C: The isolation facility is not fully operating within 5 hours.

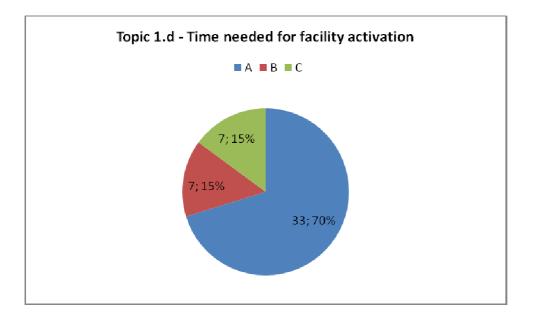


Figure 1.4 – Topic 1.d. Time needed for facility activation (valid answers: 47)

The majority of facilities evaluated are fully operating and able to admit a patient within 5 hours of notification (33, 71.74%). In 7 facilities classified as "B" most often more time is needed for admitting HID patients requiring Intensive Care. Finally, in the remaining 7 facilities, more than 5 hours are needed independently from the need of Intensive Care.

Topic 1.e) Geographic location of isolation facilities

The centre is located in a place where HID cases can easily be referred to (i.e. in a city with a large international airport) or where HID cases are more likely to occur (in connection with a BSL-4 laboratory). (Deriving from: Checklist 1, question B.4.b, no specific question about airport)

Strength score: B

- A: The facility is located in the same city as a BSL-4 lab OR in the same city of the main airport in the country.
- B: The facility is not located in the same city as a BSL-4 lab but in the same city of an international airport.
- C: The facility is neither located in the same city as a BSL-4 lab, nor in the same city of an international airport.

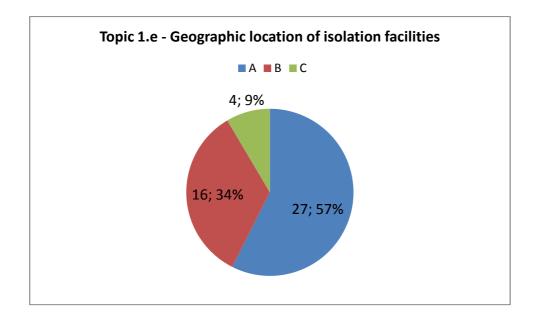


Figure 1.5 – Topic 1.e. Geographic location of isolation facilities (valid answers: 47)

More than half of all centres evaluated (n=27; 57%) are located in a place where HID cases can easily be referred to or where HID cases are more likely to occur. Indeed, these isolation facilities are co-located with BSL-4 laboratories (where there is a possibility of an occupational exposure involving BSL-4 agents), or with main international airports (where there is a large number of international travellers). Other 16 facilities (34%), despite not in the same city, are located in the proximity of an international airport. Finally, for 6 facilities the location is considered less optimal, because HIDs are less likely to occur where neither an international airport nor a BSL-4 lab is present. Despite that, given that most VHFs imported in Europe were initially admitted to small hospitals, the location of such centres may be considered adequate if domestic re-location of patients is not feasible.

General item: 2.Infrastructure-related technical equipment

Topic 2.a) Fundamental technical requirements for infection control

The isolation facility has adequate technical requirements for infection control (anteroom, negative pressure, HEPA filtration of exhausted air, door and windows sealed, material used in the room easy to be decontaminated). (Deriving from: Checklist I, questions B.1.a-d)

Strength score: A

- A: The facility has 4-5 technical explored technical requirements.
- B: The facility is equipped with negative pressure but 2 among other explored technical requirements are not present.
- C: The facility is equipped with negative pressure but more than 2 among other explored requirements are not present OR the facility is not equipped with negative pressure.

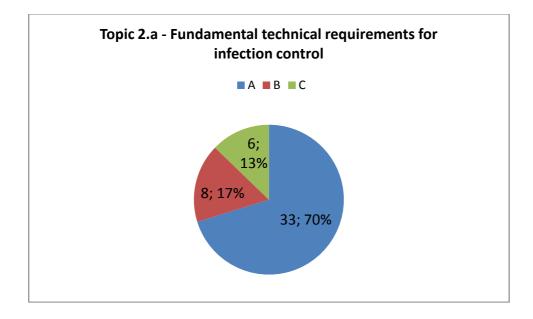


Figure 1.6 – Topic 2.a. Fundamental technical requirements for infection control (valid answers: 47)

Negative pressure, presence of an anteroom, HEPA filtration of exhausting air, sealing of doors and windows, and use of material easy to decontaminate inside the room, have been considered as the fundamental technical requirements for effective infection control. Negative pressure is essential for the isolation of patients confirmed or suspected to carry diseases with obligate, preferential or opportunistic airborne transmission (e.g. XDR-TB, SARS, human-adapted highly pathogenic strains of influenza virus, smallpox). The presence of an anteroom increases the efficiency of the system, such as the sealing of doors and windows, providing an obstacle against pressure loss and reducing the risk of movement of contaminated air into common areas; moreover

the anteroom provides a controlled environment in which donning and removal of PPE and other infection control procedures can be done safely. HEPA filtration of exhausted air is a fundamental measure for the safety of the environment around the isolation facility. Finally, it is important that porous material (tissues, wood, paint) is not used within the room and all material used withstands chemical disinfection.

Adequate infrastructure-related technical equipment (\geq 4 explored issues) to ensure infection control is found in the majority of centres evaluated (33, 70.2%). Among centres with 4 explored issues, the most lacking is adequate sealing of doors and windows. The remaining 14 isolation facilities (29.7%) have only 3 or less among explored technical issues, and among them 5 (10.6%) are not equipped with negative pressure.

Topic 2.b) presence of additional technical features

The isolation facility is equipped with other technical features that increase infection control and bio-security (internal communication systems – from HCW to HCW and from HCW to patient -, negative pressure indicators, self-closing doors, and separate evacuation pathway). (Deriving from: Checklist I, questions A.4.a, A.4.b, A.4.d, A.4.g)

Strength score: A

Evaluation score:

- A: The facility is equipped with 3-4 explored technical features.
- B: The facility is equipped with 1-2 among explored technical features.
- C: The facility is not equipped with explored technical features.

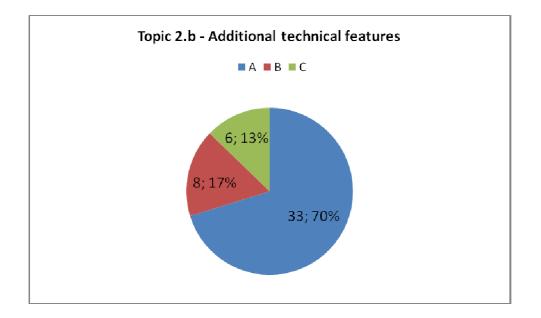


Figure 1.7 – Topic 2.b. Additional technical features (valid answers: 47)

More than half of all centres evaluated (27, 57,4%) are equipped with 3-4 of additional technical features mentioned providing a technical support of infection control regimen. On the contrary, a significant number (20 facilities, 42,6%) are equipped with 2 or less of explored issues whilst 6 facilities among those have none of them. Internal communication systems are considered effective if allowing patient-clinician and clinician-clinician communication without entering the isolation area, thus reducing the number of exposed HCWs. Visual and/ or audible negative

pressure indicators represent an additional measure of safety, as possible leakage or a general system failure may be easily/ immediately noticed. Self-closing doors contribute to the efficiency of the negative pressure system as well as infection control procedures. Separate or exclusively used evacuation pathways (e.g. in case of fire) may as well increase the safety of HCWs and other patients/visitors and are thus considered very important.

Topic 2.c) Maintenance and control of technical devices

The isolation facility has protocols/personnel for the maintenance of technical devices. (Deriving from: checklist I, questions B.2.a-c, C.2.a)

Strength score: B

- A: All explored items (presence of protocols, personnel and certification process) are in place.
- B: 1-2 explored items are in place.
- C: Explored items are not in place.

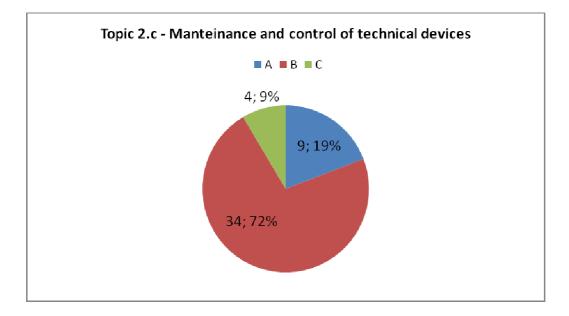
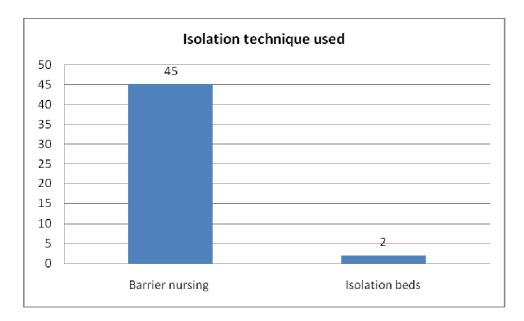


Figure 1.8 – Topic 2.c. Maintenance and control of technical devices (valid answers: 47)

In order to allow good function of the isolation facility the existence of protocols for the adequate maintenance of technical requirements is considered very important., including properly trained, supervised and equipped technical personnel available on 24-hours basis. Such requirements for the maintenance of technical devices are fully achieved in less than one quarter of all centres evaluated (n=9/46; 19.56%). The majority of surveyed facilities (34, 72.3%) have only 1-2 among explored items, with an official certification process largely lacking, confirming the lack of specific regulations about isolation facilities at national and regional level.



Data from the checklists: specific evaluation aspects and outcomes.

Figure 1.9 – Isolation technique used in centres evaluated. (Deriving from: checklist 1, question A.1.b, valid answers: 47)

Barrier nursing technique with HCWs working in high-level PPE is the most common isolation technique used throughout all centres evaluated. Only two centres in Great Britain use special plastic Isolation beds, with protective suites integrated into plastic draping.

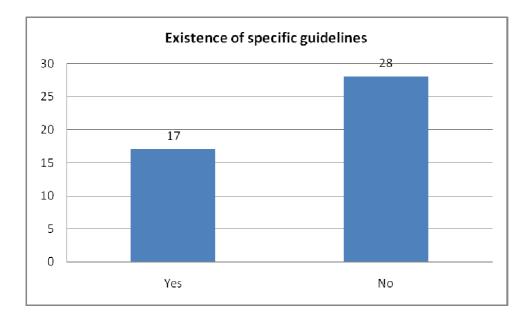


Figure 1.10 – Existence of specific guidelines for the construction of isolation facilities (deriving from: checklist I, question A.1.c, valid answers 45)

When centres were built or re-constructed, only 38.6% (n=17/44) had guidelines at hand to be followed. Available guidelines included a broad range of both national and international protocols not specifically drafted for the construction of isolation facilities (e.g. national guidelines for the construction of BSL3/4 laboratories; the British Health & Safety Executive Regulations; or CDC/US guidelines).

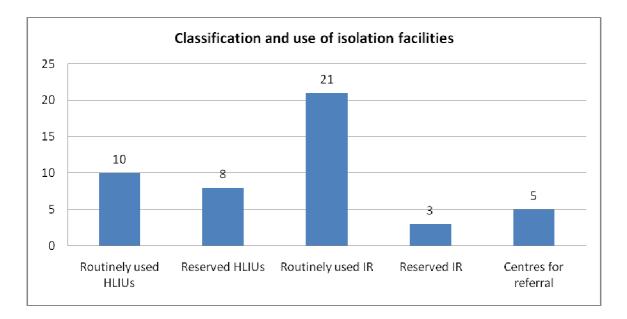


Figure 1.11 - Assessment of centres enrolled (deriving from: checklist I, question A.1.d, valid answers 47)

Although all surveyed isolation facilities are identified by National Health Authorities to isolate and give care to HID patients they do present a very broad assortment of solutions, ranging from units with very high technological level to hospital wards without any special technical and logistic features. In order to better understand the general level of isolation facilities surveyed, an operational classification was included into the checklists. This classification does not imply an assessment of quality of isolation unit. During the site visits, the project coordinator, in agreement with the staff of the surveyed unit, decided to which category the isolation facility belongs. In the 3 cases in which site visits were not performed, the decision has been taken on the basis of the checklist results analysis, and always arranged with facility staff.

The classification used is the following:

- High Level Isolation Units (HLIUs): A health-care facility specifically designed to provide safe, secure, high-quality, and appropriate care, with optimal infection containment and infection prevention and control procedures, for a single patient or a small number of patients who have, or who may have, an HID. In particular, HLIUs are equipped with special technical and logistic features for an effective isolation (i.e. negative pressure, HEPA filtration, anteroom), and are able to operate as an independent unit, without the need to share areas with other settings not dedicated to isolation of HID patients;
- **Isolation Rooms (IR)**: Rooms that are equipped with special technical and logistic features for an effective isolation (i.e. negative pressure, HEPA filtration, anteroom), but not able to operate functionally independent from other areas. For example, one or more isolation rooms may be integrated into an infectious diseases ward, with ward corridor, nurse station, or other areas not dedicated to isolation of HID patients;
- Centres for referral (CR): Isolation facilities not equipped with special technical and logistic features for an effective isolation, but identified by National Health Authorities as centres for referral of HIDs because of their expertise or their main role in the country/region in the management of Infectious Diseases.

As mentioned before, this operational classification does not imply an assessment of quality of the isolation unit evaluated but refers to just of their technical and logistic features, only.

According to this classification, among the 47 isolation facilities, 18 (38%) are HLIUs (6 in Germany, 5 in France, 2 in Italy and United Kingdom, and 1 in Finland, Greece and Ireland); in 24 (51%) isolation rooms are operating (5 in France, Greece and Spain, 2 in Germany and

1 in Denmark, Finland, Ireland, Luxembourg, Malta, Poland and Slovenia), and finally 5 (11%) are centres for referral (2 in Bulgaria and France, 1 in Austria).

Moreover, in the checklists the routine vs. reserved use of isolation facilities have been explored. Among HLIUs, 10 routinely use their isolation area, among the facilities with isolation rooms 21 use these rooms routinely, as all centre for referral. Generally speaking, isolation areas are used on daily base in 36 facilities (77%), while their use is reserved for HID patients only in 11 facilities (23%).

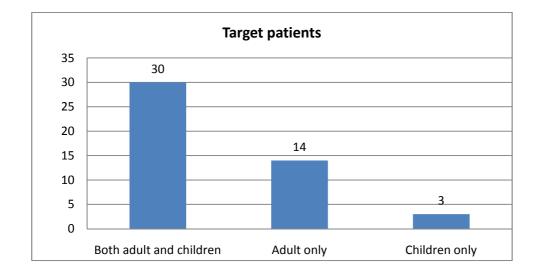


Figure 1.12 - Target patients care is provided for (deriving from: checklist I, question A.1.f, valid answers 47)

The majority of centres evaluated (64%) are able to provide care for both adult and paediatric patients. Three centres (6%) in Ireland, Greece and Slovenia) are exclusively equipped and designed for paediatric HID cases.

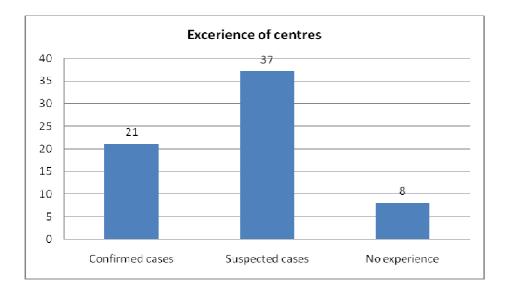


Figure 1.13 – Previous experience with suspected or proven HID cases. (Deriving from: checklist I, question A.1.g, valid answers 47, multiple answers possible)

Only eight (17%) of all centres evaluated did not have any experience in the management of suspected or proven HID cases. Within the confirmed cases, SARS (n=13 centres) and VHFs (Lassa, Ebola, CCHF; n=9 centres) were most common.

Table 2 – Isolation capacity for adults and children in the 47 surveyed facilities						
	Total number	Maximum	Minimum	Medium	Median	
Isolation rooms for adults	289	40	1	6,5	4	
Isolation beds for adults	408	56	1	9,3	4	
Isolation rooms for children	166	20	1	5	3	
Isolation beds for children	239	56	1	7,2	4	

Table 3 – Overall isolation capacity by country					
Country	Centre/s surveyed	Overall isolation rooms	Overall isolation beds	N° of beds/ million of population*	

Austria	1	11	24	2,9
Bulgaria	2	34	64	8,5
Denmark	1	20	56	10,1
Finland	2	48	54	10,1
France	12	91	112	1,7
Germany	8	30	47	0,6
Greece	6	14	20	1,8
Ireland	2	4	4	0,9
Italy	2	10	19	0,3
Luxembourg	1	9	9	17,9
Malta	1	1	3	7,3
Poland	1	2	2	0,05
Slovenia	1	1	2	0,1
Spain	5	44	46	1,0§
United Kingdom	2	3	3	0,05
*Total population c	calculated on	the basis of most recei	nt estimates from E	urostat web-site (access

on December 6, 2010)

§Accurate calculation not possible because the surveys cover Catalonia region only

Tables 2 and 3 - Overall isolation capacity for adults and children of centres evaluated(deriving from: checklist I, question A.2.a 2, valid answers 47)

The overall isolation capacity for adults and children in the 47 surveyed isolation facilities is showed in the table 2. The overall isolation capacity, including both adults and children, in each country is showed in the table 3.

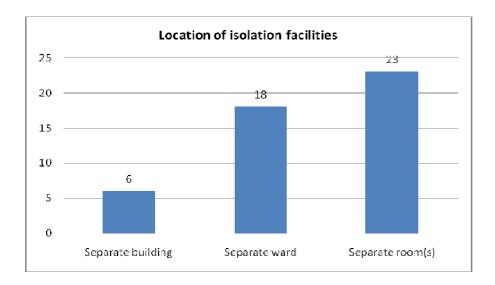


Figure 1.14 - Specific location of isolation facilities on hospital compounds (deriving from: checklist I, question A.3.a, valid answers 47 answers)

All centres evaluated are located on a hospital compound. The majority of facilities provide rooms and wards within other hospital structures, only 13% (n=6/46) are located within a separate building.

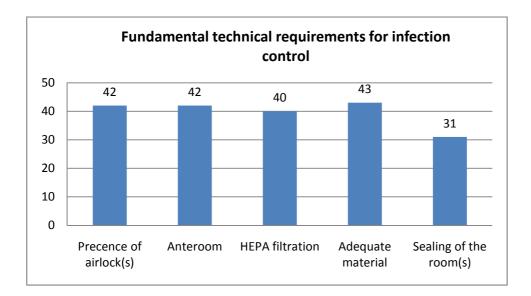


Figure 1.15 - Existence of technical equipment promoting infection control (deriving from: checklist I, question B.1. a-d, valid answers 46/47)

The majority of facilities evaluated provide accurate infrastructure-related technical equipment of the promotion of infection control within the isolation area. However, only some lack an adequate construction to provide a sealed room.

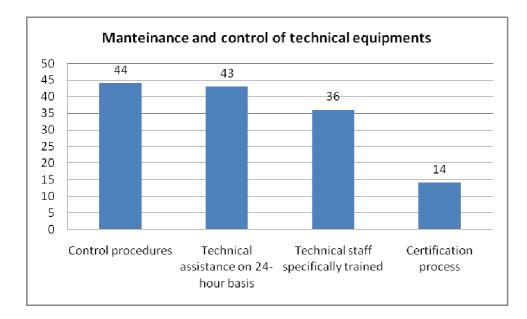


Figure 1.16 - Maintenance and control of technical equipment. (Deriving from: checklist I, questions B.2. a-c, valid answers 45)

National certification processes for the adequate function of technical equipment in the isolation facilities do rarely exist. Although the majority of centres do have protocols and procedures for the maintenance and control of technical equipment on a 24-hour basis, only few do provide specifically trained staff to conduct such work when operating. Staff for such work is most often recruited from the hospital and private sector (or in combination of both; data not shown).

1.3 Comments and recommendations

Logistic

The geographical location of clinical facilities for HIDs should be chosen with respect to incountry patient journey and specimen transport times not exceeding 6 hours, and should be colocated with a parent tertiary-care facility able to provide appropriate specialist support. Surveyed isolation facilities are usually intended to provide care only for small numbers of patients and once person-to-person transmission of a HID is occurring within a community, such centralized approach is not an alternative to planning for surge capacity (20).

In general, the **geographic location** of most centres fits areas where HID cases are most likely to occur or be referred to (in proximity to BSL-4 facilities and/or International Airports). However, some imported HID cases to Europe sought care in proximity to their private homes even if by-passing specialized care facilities on their journey. Thus, a network of specialized "front-line" care facilities should be considered useful for the assessment of suspected case, as standard care facilities may be expected not well prepared for such patients. In contrast, deployable teams from existing facilities, training and education of not specialized centres as well as sophisticated public health surveillance may compensate such situations (see chapter 6).

Being located on the same compound as other medical specialties most centres evaluated also ensure **access to medical specialties** others than Infectious Diseases as recommended by the EUNID project. Given the broad range of underlying medical conditions, complications and epidemiological factors (such as age, ethnicity, and sex) HID patients may present with, EuroNHID strongly recommends to ensure such access in all centres responsible for the clinical care of HIDs. If centres are not located within or in close proximity to general hospitals, specifically trained and pre-identified consultants should be on-call in case their expertise is demanded (see chapter 3).

Infection control regimen for the **contamination-free access of patients** should be reevaluated in many centres. In general, we recommend avoiding any transfer of HID patients within a hospital. Expert's clinical risk assessment must be the basis of any transfer of patients and a clear benefit for both the patient and the responsible team must be foreseeable. To ensure prevention of nosocomial infections and/or contamination of common areas within a hospital dedicated pathways to and/or within the facility should exist. Such dedication can be reached by either reconstruction of infrastructure or implementation and strict adherence to protocols ensuring the exclusiveness of routes and their consecutive decontamination or the use of stretcher isolators.

In order to gain maximum infection control outcome, about two third of all centres (n=31/46; 67.4%) should review their **functional dependence** from other hospital facilities. Generally spoken, any clinical care facility responsible for HIDs must ensure the functional separation of isolation rooms from other common areas either by architecture or functional barriers (e.g. controlled gates). Independence from other facilities should address problems such as doing and donning of PPE, decontamination of technical equipment used, and rooms for personnel dedicated to the isolation facility. Such independence may be gained by either reconstruction of

infrastructure or the implementation of protocols defining functional barriers to other hospital areas (restricted access, portable or non permanent barriers and doors).

Most centres evaluated are capable of admitting a patient within 5 hours of notification. However, EUNID recommends a maximum **alerting time** of 4 hours due to the maximum period of work in high-level PPE. Centres that are not able to function within this time frame should adopt their protocols and training of staff (see chapter 3). Furthermore, given the geographic location of most centres, shorter alerting times may be expected and centres should be prepared to admit patients within 1-2 hours (e.g. in case of laboratory exposure in a BSL-4 facility).

The **routine use** of isolation facilities for other patients or not is still controversial, because both solutions have advantages and disadvantages. Mainly, three different models can be used: (i) routine use for all patients; (ii) use for some patients only (those requiring isolation but not HIDs, such as patients with tuberculosis, meningitis, multi-drug-resistant pathogens); (iii) reserved use for HIDs only.

The main advantages of model (i) are:

- 1. As construction and maintenance is usually very expensive, routine use on daily basis can enhance economical efficacy;
- 2. when an HID patient is admitted, HCWs are already familiar with the isolation facility and equipment;
- 3. the facility is constantly monitored, and each technical/ functional inadequacy may be timely noticed and resolved.

On the other hand, the main disadvantages are represented by:

- 1. the need to evacuate the patient if a case of HID occurs;
- 2. the need of monitoring some technical features, such as negative pressure and HEPA filters, usually not used with all patients;
- 3. limited access to the rooms for the training of HCWs, in order to be prepared if a HID patient occurs;
- 4. the need to decontaminate the rooms prior to the admittance of an HID case if used for patients with contagious diseases such as MDR pathogens.

The main advantages of model (ii) are, besides the points 1 and 2 of (i);

- 1. the possibility to exercise frequently some of the procedures used also during the admittance of HID patients, such as the use of PPE and the procedures for their donning and removal;
- the frequent use of some technical devices, such as negative pressure and HEPA filter. Thus, only routine maintenance protocols and not specific technical interventions are needed,

while the disadvantages are the same listed before.

Finally, the main advantages of the reserved use (model iii) are:

- 1. the constant availability of the facility;
- 2. special attention to infection control protocols by HCWs;

while the main disadvantages are represented by:

- 1. the need of additional time for making the unit fully functional, if not already equipped;
- 2. the need of a constant training for HCWs, in order to exercise the specific procedures;
- 3. the need of a constant monitoring of technical devices;
- 1. a possible lack of experience in the use of the facility leading to avoidable mistakes, and the risk that these facilities may be "forgotten" if not used for long long time;
- 2. the economic aspect, indeed this model is not cost/effective given the high cost for the construction and maintenance of these facilities.

In conclusion, no clear recommendation can be done on the model to be used, and its choice remains upon the decision of each isolation facilities, after a careful assessment of risk and benefits.

Infrastructure-related technical equipment: fundamental issues

Infrastructure-related technical equipment such as HEPA filtration, negative pressure rooms, and the existence of an anteroom are considered indispensable for all clinical care facilities responsible for HIDs. Any material used within the isolation facility should be chosen with respect to decontamination procedures and centres should provide protocols for the maintenance of any technical feature in use. Additional functional independence from other hospital resources and facilities may be achieved by ensuring the availability of standard technical equipment for both supportive intensive care and bed-side diagnostics.

Preferably, **anterooms** for the safe doing and donning of PPE in newly built centres should be constructed in a 2-way fashion (separated entrance and exit rooms) to provide the highest level of infection control possible and allow safe, contamination free emergency entrance and exit solutions.

Although some existing centres evaluated have proven the well function of one-way anteroom management as well, such solutions are not recommended. However, alternate ways (1 room solutions) with protocols for infection control, waste pre-decontamination, constant one-way air-flow and the management of emergencies may be feasible. Nevertheless, non-permanent solutions such as decontamination tents in case a given infrastructure does not allow setting up permanent anterooms, may provide short- and mid-term solutions.

Air locks, providing a constant one-way airflow in the direction of the isolation room(s) via the anteroom(s), should (i) generate a minimum of -10/15 Pascal, and (ii) exhausted air must be HEPA-filtered. **Air-changes** per hour must be adapted to the size of rooms ventilated and support a constant one-way airflow towards the isolation room(s). As recommended by EUNID, any newly built isolation facility should provide non-porous **ceiling and walls**. If this aim cannot be reached, decontamination procedures and compounds used must be adapted to the existing infrastructure in accordance to national protocols. Personnel for the **maintenance and control** of all technical equipment used within the isolation room(s) should be available on a 24-hour basis and basically trained in PPE demanded.

Infrastructure-related technical equipment: additional issues

Internal communication systems should be adapted to isolation technique used (either high-level PPE or isolation beds) to ensure a constant and safe communication between the team members working at bedside without donning of PPE (clinician-clinician communication). In addition, constant communication must be provided to team members outside the isolation room(s) to prevent any delay in material or personnel support needed at bedside. If patients are alert and orientated, they must also be provided with a possibility to contact staff (patient-clinician communication).

In general, system that prevent scanning and interception are suggested to provide privacy and security of both patients and personnel. In order to maintain non-verbal communication **windows** to the isolation room(s), within doors as well as to the decontamination area are considered advisable. CCTV systems for both isolation rooms and entrances to the facility can support a security policy.

EuroNHID also recommends **negative pressure indicators** as an essential technical equipment to allow at least a visual control of the pressure gradient in the airlocks and the isolation room(s) and recommends either visual or audio alarm (or both) in case of gradient dysfunction.

Any mechanical (automated or manual) **self closing door** system ensuring doors to be kept close are recommended for the patient room and the decontamination area. In addition, non-hand operating doors shall support infection control procedures.

Separate **evacuation pathways** for staff and patients are advisable although evacuation strategies should follow the facilities' standard protocols.

Finally, among technical issues, despite not included into Evaluation Form at this point, we recommend that exclusive access to an **autoclave** should be provided within the restricted isolation area. Other solutions such as access to an autoclave on the hospital compound or in other locations should follow a strict policy for transport and should include the availability of specifically trained personnel, written protocols for pre-decontamination of material as well as en route accidents. (See chapter 11).

Facilities not, or only partially, providing those features should be carefully prepared and trained to deal with infection control issues on other ways. If those aims can not be achieved due to the given building structure, non-permanent solutions (e.g. inflatable isolation tents) can provide a desirable solution and can be well positioned in a national or regional response-system for HID management.

EuroNHID recommendations:

Optimal requirements (adapted from [20]):

Location of facilities for HID care

- 1. Facilities for HID care should be sited so that in-country patient journey and specimen transport times do not exceed 6 h;
- 2. They should be co-located with a parent tertiary-care facility able to provide appropriate specialist support;
- 3. Facilities should be sited in, or near to, the population centre nearest to the country's major international airport and/or in proximity to BSL-4 laboratories to provide rapid containment in case of occupational exposure.

Operational management and clinical care

- Regularly exercised standard procedure for becoming fully operational for management of a patient within 3–4 h must be ensured;
- 2. Facilities should have a controlled access system limiting access to essential, trained staff when fully operating;
- 3. The isolation facility should be able to operate as more as possible independently from other hospital areas;
- 4. Details of all individuals entering or leaving the unit should be documented;
- 5. Emergency evacuation protocols should exist and be tested regularly;
- 6. Facility security must be ensured by a protocol compatible with European and national legislation;
- 7. High-quality, secure communications systems should exist.

Ventilation systems and air handling

- 1. Ventilation systems used must be independent of the other building heating, ventilation, and air conditioning systems;
- 2. Each patient room should have an anteroom;
- 3. Air flows and pressure gradients run from the cleanest to the most contaminated areas with the patient room at negative air pressure relative to adjacent areas;

- 4. Air from the whole facility is not re-circulated, and exhaust air is vented 100% to the outside of the building with obligatory HEPA filtration of exhausted air;
- 5. Ventilation systems undergo functional ("in-use") testing; are connected to an emergency back-up power source; designed to fail safe; and to minimize cross-contamination in the event of system failure in the facility or elsewhere;
- 6. Ventilation systems incorporate current best practice performance checking tools; have a schedule for planned preventive maintenance, written protocols for performance-checking exist.

Choice and decontamination of equipment

- 1. Any equipment used within an isolation facility should be selected with decontamination in mind;
- 2. If an item of equipment cannot safely be decontaminated for reuse, a disposable alternative should be selected;
- 3. An inventory of all unit equipment stating the usual method of decontamination/disposal must be provided;
- 4. Patient care equipment (e.g., mechanical ventilator) can be decontaminated according to standard national/local protocols. Large, complex equipment that has been contaminated might require decontamination on site before disassembly;
- 5. Standard national/ local hospital protocols for cleaning and decontamination of environmental surfaces must be adhered to.

Minimal requirements:

- At least <u>functional</u>, if not structural, independence from other facilities is indispensable for any type of facility to promote infection control;
- At the same time, location near a general hospital is essential;
- Specialized treatment facilities should be fully operational within 4 hours after a case is notified;
- Basic technical requirements (negative pressure, anteroom, HEPA filtration of exhausting air, sealing of the room and appropriate material) must be fulfilled in any

facility responsible for HID patients to provide a safe working environment for primary assessment and care;

- Additional technical requirements should be fulfilled as more as possible in reference centres/ HLIUs to allow medical care under strict bio-safety and -containment regimen in the long term treatment of patients;
- National emergency response plans should include either deployment of specialised teams or the geographic distribution of primary assessment facilities for suspected cases.

1.4 Brief conclusive remarks.

The heterogeneity of data presented clearly reflects the lack of a harmonized EU legislation for the construction, design and "tactical" function within national emergency response plans of clinical care facilities for HIDs. Despite great financial input into the (re-)construction of such facilities in the aftermath of September 2001 nearly half of all centres evaluated can neither ensure contamination free access of suspected or proven cases to the facility nor functional independence from other common hospital facilities and areas. In addition, the capacity of beds broadly differs inbetween member-states evaluated, although evidence based calculation of such capacity is difficult and most often related to transport capacity and modes. In contrast, the geographic location of the facilities evaluated is mostly appropriate and access to specialist support as well as time until fully operational is achieved in the majority. Although adequate infrastructure and equipment to ensure appropriate infection control is found in the majority of centres enrolled, attention should be given to the lack of accessible and exclusively used autoclaves as well as an improvement of the maintenance procedures.

Chapter 2 – Medical issues

Main author: S. Schilling

2.1 Introduction

Despite the fact that the main focus of HID isolation facilities is infection control, the fact of providing care to HID patients should not lead to a restriction or reduction of diagnostic and therapeutic strategies although any procedure should be undertaken with respect to possible exposure and contamination of staff. As in any severe infection, access to supportive (intensive) care should be considered necessary as the clinical condition of HID patients may change and deteriorate depending on the causative agent and underlying medical conditions. Hence, the EUNID consensus states that: "HLIUs should therefore be equipped to provide the level of care available in an intensive care unit (...)" [20].

During the EuroNHID study, the general availability of Intensive Care support was assessed as adequate medical equipment in isolation facilities plays a vital role to ensure good clinical practice for the patient's outcome. Furthermore, access to specific medical equipment, either permanently stationed in the isolation facility or available on-call and on-time, enhances the functional independence of any such facilities thus supporting the aim of maximum care under maximum infection control regimen.

Nevertheless, access to trained intensive care personnel was assessed as well and is described in detail in chapter 3.

Medical equipment explored during the EuroNHID study included e.g. mechanical ventilators, or blood pressure- and cardiac- monitoring. Furthermore, the availability of bedside diagnostic equipment indispensable for the monitoring of interventions such as blood gas analysers for mechanical ventilation was evaluated.

2.1 Data from the surveys (aggregate and punctual data)

General item: 3.Medical assistance

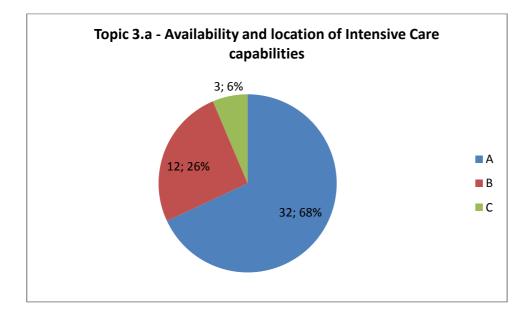
Topic 3.a) Availability and location of Intensive Care capabilities

The isolation facility is able to provide Intensive Care in place. (Deriving from: Checklist I, questions A.2.a, B.3.c, C.2.a)

Strength score: A

Evaluation score:

- A: Intensive Care capabilities available in the isolation facility.
- B: Intensive Care capabilities available in another area (i.e. isolation room in ICU).



C: Intensive Care capabilities not available at all.

Figure 2.1 – Availability and location of Intensive Care capabilities (valid answers 47)

Intensive Care capabilities within the isolation facility are provided in 68.1% (n=32/47) of centres evaluated and is considered the optimal solution. In 12 facilities (25.5%) Intensive Care is provided in dedicated isolation room within standard Intensive Care units: this solution is acceptable if strict infection control measures are applied, otherwise this solution may increase the risk for the HID patient and other patients to contract nosocomial infections. In 3 facilities (6.4%), no access to Intensive Care capabilities is available: this represents a strong inadequacy.

Topic 3.b) Availability and access to medical instruments and devices

The isolation facility has access to dedicated or pre-identified instruments and devices, to provide high quality and appropriate diagnostic and medical assistance. (Deriving from: checklist I, questions B.3.a-k)

Strength score: C

Evaluation score:

- A: Medical instruments/devices mostly (at least half of the explored) permanently present in the facility.
- B: Medical instruments/devices not permanently in the facility but "identified" instruments/devices available.
- C: Medical instruments/devices not permanently in the facility and "identified" instruments/devices not available.

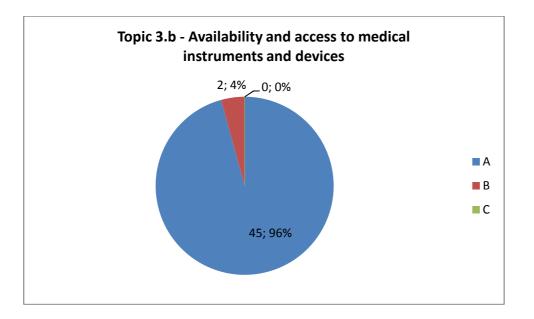
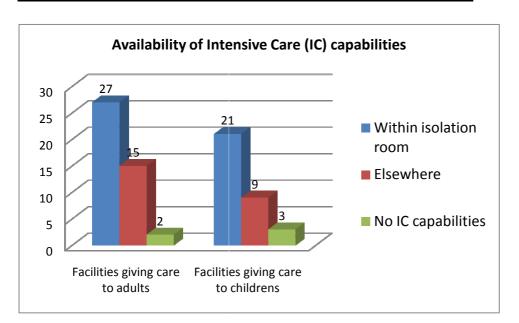


Figure 2.2 – Topic 3.b. Availability and access to medical instruments and devices (valid answers 47)

The availability of and the access to several medical instruments (including mechanical ventilator, portable/digital ultra-sonography and radiography instruments, equipment for renal replacement, ECG/ BP monitors, others) and devices (perfusors, blood-gas analyzer, minor surgery sets) have been explored. Very few facilities (2, 4.2%) have at least half of medical instruments/devices permanently located into the isolation facilities, and consequently always available. All other facilities (the remaining 45, 95.8%) adopted another solution, considered as

adequate: most important instruments/devices, despite not permanently located into the facilities, are pre-identified, and are at hand in short time if needed. This solution is considered most cost-effective, as it assures both availability of instruments and devices for routine medical care, and rapid access to these for HID patients if needed. For a good functioning of this approach, detailed and well-known procedures (including rapid disinfection of instruments/devices) must be in place.



Data from the checklists: specific evaluation aspects and outcomes.

Figure 2.3 - Availability of Intensive Care (IC) capacities for adult and paediatric patients. (Deriving from: Checklist I, question A.2.a, valid answers 47)

Out of all centres evaluated, care for both adult and paediatric patients is provided in 30, for adults or paediatric patients only in 14 and 3 centres, respectively (see chapter 1). The majority of centres providing care for adult patients is capable to apply IC within the respective isolation facility (n=27/44; 61.3%). One third (n=15/44; 34.1%) of those centres rely on transporting a patient to their hospital's standard intensive care unit, while 2 centres cannot apply IC, at all.

Out of 33 centres able to care for paediatric patients, 21 (63.6%) can provide paediatric IC within the isolation facility. 27.3% (n=9/33) rely on transporting paediatric patients to the standard intensive care and 3 can not provide IC at all.

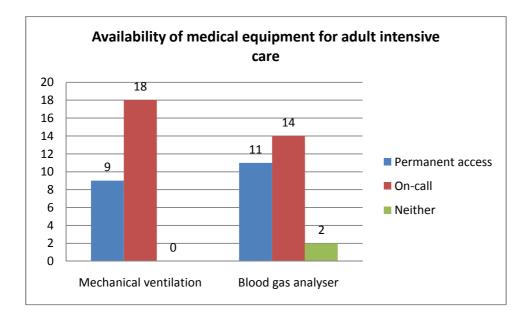


Figure 2.4 - Availability of medical equipment for adult intensive care. (Deriving from: Checklist I, question B.3.1, valid answer 27)

All centres indicating to perform IC for adult patients (n=27/44) within the isolation room(s) have access to mechanical ventilation, either permanently (33%) or on-call (66%). Permanently available blood-gas analyzers exceed the number of centres with permanent access to mechanical ventilation (40.74%; n=11/27), but not available at all in 2 centres. Surprisingly, two centers with access to mechanical ventilators do report no access to blood-gas analysers, at all.

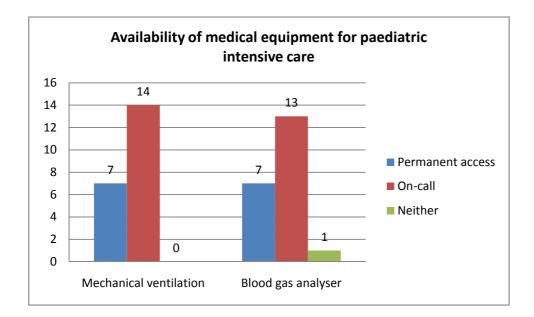


Figure 2.5 – Availability of medical equipment for paediatric intensive care. (Deriving from: checklist I, question B.3.2, valid answers 21)

All centres indicating to perform IC for paediatric patients within the isolation room(s) (n=21) have access to mechanical ventilation, either permanently (33%) or on-call (66%). Access to blood-gas analysers is equally distributed, but not available at all in 1 centre.

Table 4 – Availability of medical devices						
Availability	Ultra- sonography	Portable radiography	Mechanical ventilator	Minor surgery sets	Renal replacement system	
Permanently	8	17	12	12	2	
On-call	35	27	31	34	39	
Neither	4	3	4	1	6	
	ECG/BP monitors	Perfusors	Blood gas analyzers	Bronchoscope	Gastroscope	
Permanently	33	27	14	2	3	
On-call	14	19	27	38	42	
Neither	0	1	6	2	2	

 Table 4 - Availability of medical devices. (Deriving from: Checklist I, question B.3.1, valid answers 42-47 answers).

Numbers indicate the quantity of centres reporting access to specific devices. Facilities indicating both permanent and on-call availability of a single device were accounted for the group of "permanently", only.

Overall, medical devices for appropriate supportive (intensive) care are either available oncall or permanently stationed in the isolation facility in the majority of centres. Most often, blood gas analysers, renal replacement systems or endoscopic devices are not available at all, although in than 10% of all centres evaluated.

2.3 Comments and recommendations

The EUNID consensus states that: HID "...patients had needed a range of interventions, including transfusion of blood/blood products; cardiac, respiratory, and invasive haemodynamic monitoring; radiography; ultra-sonography; minor surgical procedures (eg, thoracocentesis); renal dialysis; and mechanical ventilation. (...) HLIUs should therefore be equipped to provide the level of care available in an intensive care unit (...)"[20]. Despite the fact that the EUNID consensus only refers to HLIUs the availability of sufficient technical equipment to provide supportive care within the isolation room is considered most desirable for all clinical facilities managing HID cases. However, the EuroNHID study only assessed the availability, not the quality of supportive care provided as such assessment would be far beyond its approach. Whether interventions at which level should be performed at all was partially addressed in another publication of the EUNID group but still lacks the level of a practical algorithm applicable to routine clinical care [19].

Overall, most centres evaluated have sufficient access to basic medical devices and it can be expected that short term stabilisation of the critically ill is possible when emergency equipment used for standard care is at hand (e.g. ECG monitors, perfusors and ultrasound). However, it should be mentioned that not all centres are able to provide supportive intensive care within the isolation facility but one third of centres relies on their standard intensive care units. Most important, not all centres indicating to provide intensive care within the isolation facility have permanent access to mechanical ventilators and blood-gas analysers and should thus review respective protocols.

Availability of Intensive Care

Intensive Care capabilities within the isolation facility are provided in two third of centres evaluated and considered the optimal solution. When intensive care is not available in the isolation facility itself most centres rely on transporting an HID patient to their hospital's standard intensive care unit. Despite risks and rigors of transport for both personnel and patients such alternative approach should only be considered if strict adherence to infection control procedures is guaranteed and periodically drill-trained. Any standard intensive care unit planned to provide care for HID patients must undergo a reliable risk-assessment process in order to adhere to demanded infection control measures only if a functional separation of isolation room is guaranteed (separate pathways, entrances, dedicated staff and equipments).

Nevertheless, the presence of a HID patient in a standard Intensive Care Unit (ICU) could pose additional risk of cross-infection: i.e. (i) For the patient him-/herself due to an increased risk of

exposure to MDR agents; (ii) for other patients, because ICU patients most often represent subjects with severe diseases and immunosuppression.

Availability of medical instruments/devices

In general, the availability of medical equipment should be planned depending on the facility's role in national emergency response plans and may be divided into permanently or short-term available equipment. HLIUs are considered to be in the position to provide long-term care for HID cases and should thus be equipped according to national standards for intensive care units with most equipment permanently available on-site. In contrast, other isolation facilities may be considered to function as assessment centres, only, capable of isolating an HID patient for a short term only until a tentative diagnosis is confirmed or ruled out. Thus, such assessment centres may not need to be permanently equipped but have material for intensive care available on-call.

Minimal requirements for the short-term stabilization of critically ill patients should be fulfilled by any centre responsible for HID care including permanent access to:

- 1. Equipment for the monitoring of vital signs;
- 2. Emergency care sets (including tubes for oro-tracheal intubation, anaesthetics, and bag valve masks).

In order to prevent transportation of HID patients within a hospital and with regard to reduced auscultation/palpation skills in the isolation setting, portable **imaging devices** (ultra-sonography and/or X-ray) are recommended. If **mechanical ventilation** is accessible, blood-gas analysers are indispensable. It is recommended to choose equipment that is used on daily basis, either on the isolation ward or other facilities of the respective hospital, to avoid additional training of staff, stockpiling, shortcoming in spare parts and to reduce costs.

Once inside the isolation room, all equipment must not be removed from the contaminated area until a patient is discharged and equipment decontaminated with respect to the causative agent. Decontamination procedures should be planned and performed in adherence to national and local infection control guidelines and the manufacturer's recommendations.

Centres functioning as **primary assessment sites** may not need to provide the full range of supportive intensive care equipment but should also have more sophisticated, pre-identified material available on-call in case a patient's medical condition prohibits transportation to centres equipped

for intensive care. Such plans should involve equipment from other (regional) care facilities or deployment of equipment from specialised centres. Permanently accessible material for **mid- or long-term critical and intensive care** of patients (such as endoscopic devices and renal-replacement equipment) may be restricted to highly specialised centres (HLIUs) constructed for and planned to provide mid- or long term care to HID patients.

In summary, EuroNHID recommends that (adapted from [19]):

- All care facilities for HIDs should be able to perform supportive intensive care within the isolation area;
- All care facilities for HIDs should have a minimal set of emergency care equipment permanently accessible in order to allow a short-term stabilisation of patients;
- All care facilities for HIDs should provide permanent access to adequate equipment for the monitoring of vital signs (such as ECG and blood-pressure monitors);
- When planned to apply intensive care, ventilators, perfusors and a blood-gas-analyser must be stationed within the isolation area/room(s) once a patient is admitted.

Chapter 3 - Personnel management

Main author: S. Schilling

3.1 Introduction

Appropriate management of personnel involved into the clinical management of HIDs is crucial for both HCWs safety and the patient's clinical outcome. Key issues are the composition of staff, appropriate multidisciplinary competencies, and the opportunity to work with a proper timeline and shifts.

In general, a "core team" of specifically trained and pre-identified medical and non-medical personnel is considered essential for any facility providing care for HID cases. Infectious disease and infection control specialists should be represented in such core teams and, due to possible life threatening clinical consequences of HIDs, the availability of intensive care specialists is required, also. Personnel composed in such teams should be available on-call and of sufficient quantity to ensure a fully operating isolation facilities within a few hours after case notification.

Isolation precautions such as PPE are an essential part of managing HID cases in the clinical environment and any member of a core team should be periodically trained in its use. With regard to the specific causative agent, different types/levels of PPE may be indicated but any kind of PPE poses an increased physic and psychological stress to HCWs. Thus, although only a minimum of HCWs should be exposed to HID cases, the quantity of staff needed to care for such patients is often increased compared to standard patients. In addition, surge capacity planning is considered an approved strategy in order to mitigate the impact of such increased demand of personnel on routine care. As HIDs may present with a broad range of underlying medical conditions, access to consultants from different medical specialties may be needed. Finally, specifically trained technicians should be available to ensure the well function of infrastructure and technical equipment, although data presented in the following focus on medical staff, mostly.

3.2 Data from the surveys (aggregate and punctual data)

General item: 5. Personnel management

Topic 5.a) Presence of specifically trained Infectious Diseases specialists

The isolation facility has a number of specifically trained Infectious Diseases specialist personnel (with competence in infection control procedures). (Deriving from: Checklist I, questions C.2.a, C.3.b, Checklist III, questions C.1.a, C.1.b)

Strength score: A

- A: The facility has specifically trained (with competence in infection control) Infectious Diseases specialists
- B: The facility has not specifically trained (with competence in infection control) Infectious Diseases specialists but specific procedures (i.e. supervision by Infection Control specialists) are in place
- C: The facility has neither specifically trained Infectious Diseases specialists nor specific procedures.

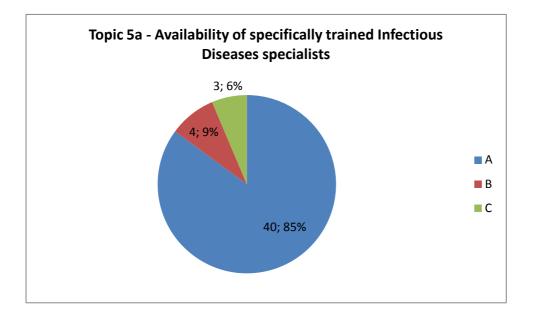


Figure 3.1 – Availability of Infectious Diseases specialists specifically trained for the management of HIDs (valid answers: 47)

The majority of centres evaluated (n=40/47; 85.1%) provides a team of specifically trained ID physicians, considered the optimal solution. The remaining centres do not have permanent access to such specialists but 4/7 do have procedures in place to gain input of such specialist when managing an HID case. Finally, 3 centres do not even provide such solutions and were rated inadequate.

Topic 5.b) Presence of specifically trained Intensive Care specialists

The isolation facility has specifically trained (with competence in infection control) Intensive Care specialists personnel. (Deriving from: Checklist I, questions C.2.a, C.3.b, Checklist III, questions C.1.a, C.1.b)

Strength score: A

- A: The facility has specifically trained (with competence in infection control) Intensive Care specialists
- B: The facility has not specifically trained (with competence in infection control) Intensive Care specialists but specific procedures (i.e. supervision by Infection Control specialists) are in place
- C: The facility has neither specifically trained Intensive Care specialists nor specific procedures

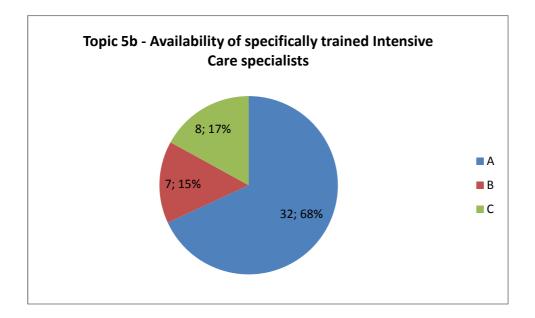


Figure 3.2 – Availability of Intensive Care specialists specifically trained in the management of HIDs (valid answers: 47)

The majority of centres evaluated do report access to specifically trained intensive care specialists (n=32/47; 68%). Furthermore, seven additional facilities provide specific protocols for the supervision of intensive care personnel. These two solutions were considered optimal and adequate as the clinical status of HID patients may deteriorate quickly and demand (supportive) intensive care. However, 8/47 centres (17%) do not provide access to any intensive care trained personnel and were thus rated inadequate.

Topic 5.c) Availability of other specialists

The isolation facility has pre-identified, specifically trained consultants in other medical specialties. (Deriving from: Checklist I, question C.3.b)

Strength score: C

- A: The consultants in other medical specialties are identified and specifically trained.
- B: The consultants in other medical specialties are identified but not specifically trained.
- C: The consultants in other medical specialties are neither identified nor specifically trained.

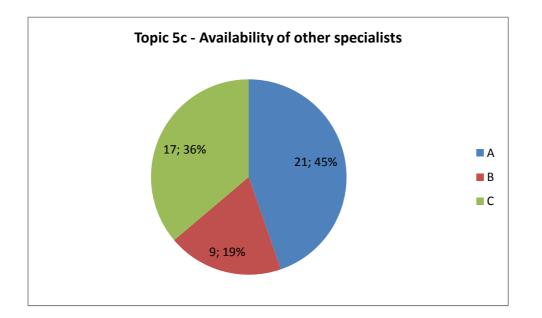


Figure 3.3 – Availability of other specialists for the management of HIDs (valid answers: 47)

Besides sex, age, and ethnicity, any HID case may present with a broad range of underlying medical conditions making the access to specifically trained and pre-identified consultants indispensible. In addition, treatment in an isolation facility may as well exacerbate underlying diseases, either psychological or physiological. Less than half of all centres evaluated (n=21/47; 44.7%) do provide access to pre-identified and specifically trained consultants form other medical specialties than infectious diseases and intensive care such as psychiatry, cardiology, or surgery. Training of consultants on demand (when managing an HID case) is considered adequate and reflects the current solution in 9 other centres, although 36.2% of centres (n=17/47) are not prepared for such situations at all.

Topic 5.d) Availability of protocols for contacting the staff

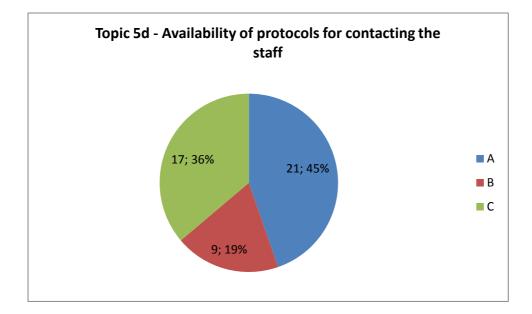
The isolation facility has in place protocols for contacting its staff, technical personnel, consultants and public health officials on 24h-basis. (Deriving from: Checklist I, questions B.2.b, C.1.b, C.3.a, C.3.c, Checklist II, question A.4.a)

Strength score: A

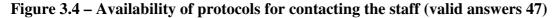
Evaluation score:

A: Protocols for the contacting exist for staff, technical personnel, consultants, and public health officials.

B: Protocols for the contacting exist, for some only.



C: Protocols for the contacting do not exist.



Management of HID cases demands an integrative approach including a broad range of medical and no-medical specialists. Short-term notification of HID cases must be expected, facilities should be fully operational within a few hours, and any technical problem posing a threat to both patients and HCWs must be solved in a minimum of time. Thus, protocols to contact either medical or non-medical staff are considered indispensable. 72.3% (n=34/47) of centres evaluated do fulfill requirements to contact both medical and non-medical staff responsible for the well-function of the facility on 24hour basis. Interestingly, 2 facilities do not even have protocols to contact their medical team, while the remaining centres (11/47; 23.4%) were most often lacking permanent access to technicians.

Topic 5.e) Existence of a specific shift plan

The isolation facility has an already developed shift plan to be used in the case of HID patients, that considers the specific needs (i.e. limitation of HCWs exposed, reduction of shift duration when working with PPE, shift plans to work in pair, "dedicated" staff). (Deriving from: Checklist I, question C.2.b, Checklist II, question I.1.b, Checklist III, questions A.2.e, B.1.b, B.1.e)

Strength score: B

Evaluation score:

- A: A special shift plan to be used in the case of HID patients that consider all of explored items is available.
- B: A special shift plan to be used in the case of HID patients is not available, but some of the explored items are available to address these specific needs.
- C: A special shift plan to be used in the case of HID patient/s does not exist, and explored items are not available to address these specific needs.

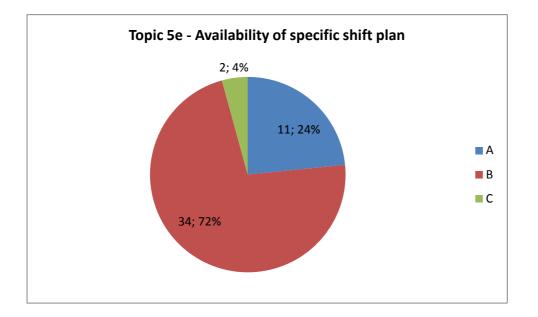


Figure 3.5 – Availability of specific shift plan in case of HIDs (valid answers: 47)

Shift plans are considered the optimal solution to address specific needs when managing HID cases such as an increased physiological and psychological stress when working in PPE and a consecutive need of increased quantity of staff. Overall, the majority of centres evaluated do fulfil or partially fulfil these aspects (n=45/47; 95.7%), but shift plans do not exist in the remaining centres.

Data from the checklists: specific evaluation aspects and outcomes.

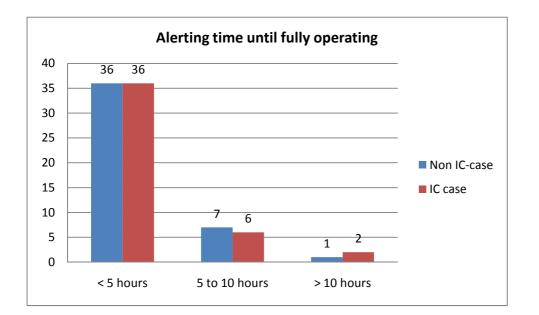


Figure 3.6 – Alerting time until the centres is fully operating and patients can be admitted. (Deriving from: Checklist I, question C1.a, valid answers 44)

The majority of centres evaluated are fully operating in less than 5 hours after case is notified (n=36/44) and ready to provide care for patients demanding intensive care or not. However, 9 centres demand more time to have all equipment installed and personnel on site. Overall, no difference is found regarding the time needed to admit patients demanding intensive care or not but depends on the individual facility evaluated.

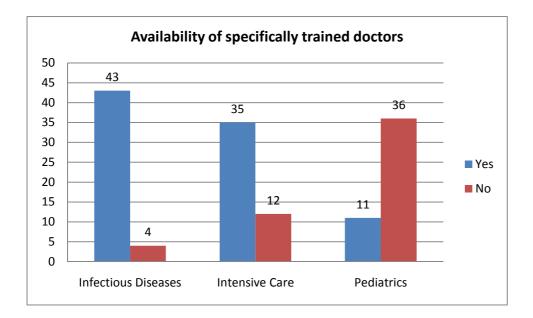


Figure 3.7 - Availability of specifically trained doctors by specialty. (Deriving from: Checklist I, question C2.a, valid answers 46)

In all but 4 centres evaluated Infectious Disease specialists are represented in the core team of the facility, and Intensive Care specialists permanently available in 76% (n=35/46). Overall, 42 centres indicated to be able to provide intensive care either inside or outside the isolation facility (see chapter 1), thus 7 centres lack appropriate permanent access to specialized medical staff for intensive care and do not have IC consultants on call (Question C3.b). In addition, paediatricians are permanently available and specifically trained in 23.9% (n=11/46) of centres, only. As 34 centres indicated to provide care for paediatric cases (see chapter 1), 33 of those lack an adequate access to specialized medical staff for paediatric care.

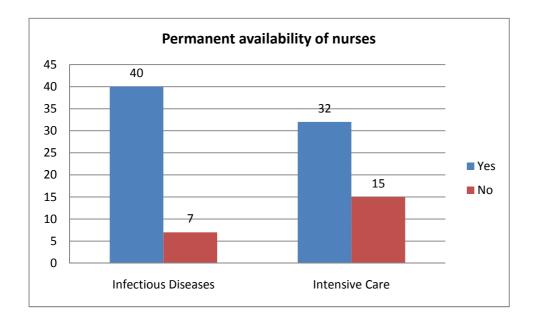


Figure 3.8 - Availability of specifically trained nurses by specialty. (Deriving from: Checklist 1, question C2.a, valid answers 47)

Infectious Disease nurse are specifically trained and permanently available in the majority of centres evaluated (n=40/46; 86.9%) although the percentage of centres having permanent access to Intensive Care nurses is lower compared to available doctors (68.1%; n=32/47). Thus, out of 42 centres indicating to provide intensive care either inside or outside the isolation facility (see chapter 1), 10 lack appropriate permanent access to specialised intensive care nurses.

Table 5 - Availability of specifically trained IC- and ID-doctors by EU member states.					
EU member state	Centre(s)	IC doctors/	IC doctors/ million	ID doctors/	ID doctors/ million
	surveyed	centre	of population*	centre	of population*
Austria	1	1	0,12	8	0,95
Bulgaria	1	1	0,13	19	2,51
Denmark	1	0	0	8	1,45
Finland	2	2,5	0,93	4	1,49
France	12	4,8	0,90	6,2	1,15
Germany	8	7,6	0,74	8,3	0,81
Greece	6	4,8	2,56	5,6	2,97
Ireland	2	0	0	1,5	0,67
Italy	2	7,5	0,25	27,5	0,91
Luxembourg	1	7	13,9	4	7,97
Malta	1	0	0	2	4,84
Poland	1	6	0,16	60	1,57
Slovenia	1	4	1,90	6	2,93
Spain	5	4,2	0,46§	4,6	0,50§
United Kingdom	2	3	0,05	4,5	0,15

*Total population calculated on the basis of most recent estimates from Eurostat web-site (access on December 6, 2010)

§Accurate calculation not possible because the surveys cover Catalonia region only

Table 5 - Availability of specifically trained IC- and ID-doctors by EU member states.(Deriving from: Checklist I, questions C.2.a, valid answers: 46)

The permanent availability of specifically trained IC and ID doctors responsible for the clinical management of HID cases broadly differ in-between the 14 EU member states evaluated within this study. Specialised ID doctors for HID management are found in all EU member states assessed but their quantity broadly differs (maximum 74, minimum 2, median 9). Specialised IC doctors are not available in 2 EU member states, at all, and also differ by quantity in other member states assessed (maximum 61; minimum 1; median 6). Overall, the median number of population covered by one specialised IC or ID doctor is 1228390.3 and 691842.2, respectively.

It must be taken into account that the number of centres evaluated in each EU member state correlates with the quantity of doctors available and does not reflect either geographic distribution

of centres within the EU member state, the existence of concepts for the transportation of patients or deployable teams.

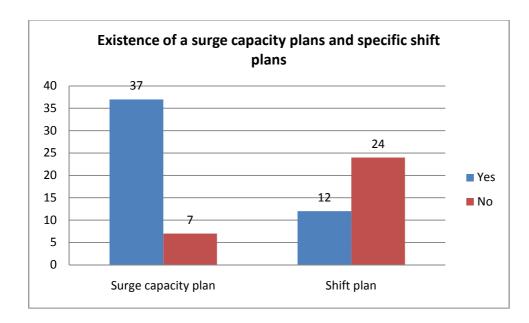


Figure 3.9 - Existence of a shift and surge capacity plan. (Deriving from: Checklist I, question C2.b, valid answers 44 and 34)

The majority of centres have surge capacity plans in order maintain routine care when a HID patient is admitted. However, 7/47 centres (14.9%) do not provide such plans. In contrast, only 76.9% of all centres evaluated provided information on the existence of shift planning. Out of those, two third do not provide any specific plans for the amount of personnel needed and working hours planned of HCWs.

All but one centre evaluated (n=46/47) are able to contact pre-identified staff, either nurses or doctors, on 24/7 basis, mostly by phone. As well, all centres evaluated are able to contact their responsible public health authorities on 24 hour basis. In contrast, only 18/47 centres (38.3%) have access to specifically trained consultants of different specialties not represented in the facilities core team (such as microbiology, endoscopy and intensive care) (Data not shown, deriving from Checklist 1, questions C.3.b, C.3.c).

3.3 Comments and recommendations

Optimal requirements for the operational management of HLIUs were published in the EUNID consensus and are listed at the end of this chapter. Despite this the well function of any facility responsible for HID care and the patient's clinical outcome strongly depends on the availability of pre-identified, specifically trained and dedicated personnel. Training personnel periodically in the use of PPE and any procedures demanded is both time-consuming and costly. In a hospital environment increasingly affected by economical factors, preparedness for such rare events as HIDs is more or less difficult; thus, facilities evaluated report a strong need of financial and political support to ensure access to a sufficient quantity of periodically trained personnel.

Although data presented reflect an overall adequate adherence of most centres to the recommendations, a lack of specialities others than infectious diseases is clearly documented. Actions of improvement should focus on the availability of both intensive care and paediatric personnel. In addition, an ongoing efflux of medical personnel in many EU member states underlines the problem of training more (inexperienced) personnel in the near future.

The **quantity of staff** involved into clinical care for HIDs must be thoroughly calculated and based on the individual needs of each facility (e.g. depending on the number of beds provided). In order to reduce secondary transmission risks, the number of staff with access to an HID patient should be as few as possible. However, given the burden of working under PPE, the number of staff involved must allow intervals for each team member to rest and recover. Independent from a patient's clinical condition, the presence of at least one nurse and doctor each in the isolation room (at the bedside) is considered indispensable. In addition, logistic support must be provided from outside the pressure-controlled area to the team inside the isolation room.

To avoid exhaustion of staff, **shift plans** are considered very important and must also be adapted to the number of beds available. Generic shift plans should exist to cover a minimum of one week allowing an independent function of any facility. It is recommended to implement and test such plans by table top exercise, including a reduction of planed access. As the duration of work in high-level PPE should be **4h maximum** in order to prevent physical exhaustion of HCWs, centres currently not fulfilling this recommendation should adapt their SOPs, exercises, and staff arrangements.

Surge capacity plans should exist in any centre responsible for HID care in order to ensure a continuum of routine care. As mentioned above, surge capacity planning should be incorporated

into legal contracts/ multi-centre protocols to put the affected facility into the position to call in personnel from others.

All centres should have sufficient staff **available every day throughout the whole year** within 4 hours after a case is notified to prevent shortages in personnel and provide a fully functioning unit. Centres not able to adapt this recommendation should re-arrange and exercise contingency planning. Furthermore, **contracts and protocols** for the co-operation with other units should be made available to ensure care capacities for HID patients. Such contracts or protocols may be established on either national (in case of more than one unit per member-state) or European level (in case of only one unit per member-state). Centres willing and able to provide **intensive care** or to treat **paediatric patients**, as well, must ensure the availability intensive care and/ or paediatric nurses and doctors throughout the whole year. Ideally, such staff should be specifically trained and include pre-identified senior nurses or doctors available on-call.

In order to mitigate nosocomial infections, exhaustion of staff and avoidable mistakes when handling technical equipment all team members with access to HID patients must undergo **periodical trainings**. Such drills are preferably conducted in the environment a patient would be taken care of (in the isolation room), to allow training conditions comparable to real missions. Besides the application of standard care in PPE drills should also focus on emergency situations such as Cardiac Life Support training.

Besides practical drills, training of staff should also include table-top exercises and fieldexercises in cooperation with health authorities and other levels of public health importance (e.g. paramedics/ fire brigade).

To provide optimal care for patients under minimal infection risks for HCWs, **composition of teams** in any facility should include different specialities. Although the number of HCWs exposed to a case should be as little as possible to prevent nosocomial infections, the quality of care should not be reduced. Thus, teams should be composed out of medical and non-medical staff with an expertise in their specialty. Infectious Disease doctors and nurses are considered the core element of each team. In addition, Infection control specialists and technicians responsible for the well functioning of equipment must be included. As a patient's condition may deteriorate quickly the availability of both Intensive care doctors and nurses familiar with the infrastructure and the equipment of the isolation facility is desirable if not indispensable. Other medical specialities may also be needed depending on the patient's condition and/or underlying diseases.

EuroNHID recommendations

Optimal requirements for the operational management:

- 1. A designated isolation facility director/lead clinician (usually the most senior and experienced doctor), with overall responsibility for coordination, training, liaison, and communication;
- 2. A designated isolation facility nursing director/lead nurse consultant/nurse manager, responsible forward management and training of nursing staff;
- 3. An effective mechanism for succession planning;
- 4. A specific training programme that is mandatory for all staff who will work in, or enter, the isolation area. This programme should have standardised curricula and competencies appropriate for each professional group (e.g., doctors, engineers), and should include both initial training and regular refresher training, with an accurate system for recording course attendance and performance;
- 5. An audit and quality assurance programme, and a system for monitoring adverse events;
- 6. Sufficient specifically-trained staff to provide 24-h availability to open and run the unit;
- 7. A regularly exercised standard procedure for becoming fully operational for management of a patient with a highly infectious disease within 3–4 h;
- 8. A clear and agreed method for providing cover for any usual duties (e.g., anaesthetic list) that staff cannot undertake because they are working in the isolation facility;
- 9. An agreed system of reward and remuneration for isolation facility work and training;
- 10. Support from other specialties (e.g., nephrology, paediatrics, cardiology) had also been needed, so specialist clinicians should also be pre-identified and train alongside the core isolation team.

Minimal requirements for the operational management:

- All centres should have sufficient staff available every day throughout the whole year within 4 hours after a case is notified;
- 2. The presence of at least one nurse and doctor each in the isolation room is considered indispensable and logistic support must be provided from outside the pressure-controlled area;

- 3. Shift plans are considered very important and must be adapted to the number of beds available;
- 4. The duration of work in high-level PPE should be 4h maximum;
- 5. Surge capacity plans should exist in any centre responsible for HID care in order to ensure a continuum of basic medical support;
- 6. Centres providing intensive care or care for paediatric patients must ensure the availability specific medical personnel throughout the whole year;
- 7. Composition of teams in any facility should include different specialties.

Chapter 4 – Management of diagnostic procedures

Main author: P. Brouqui

4.1 Introduction

Appropriate management of HIDs cases require high-level diagnostic capabilities. Indeed, in suspected HIDs patients, other common causes of disease should be explored as soon as possible, while it should be possible to perform specific tests for HIDs, that are not widely available.

Moreover, the management of diagnostic specimens arises specific infection control questions. Among class 3 and 4 agent, laboratory-associated infections have been reported with filoviruses, epidemic typhus, Q fever, Herpes B virus simiae, tularaemia, pulmonary plague, Lassa fever, RMSF, Hantan virus, murine typhus, tick borne encephalitis virus TBEV, sabia virus, melioidosis, West Nile virus and vaccine [23,24]. More recently SARS Co-Virus was laboratory acquired raising worries on bio-safety [25]. Experience shows that the recognition and isolation of a new infectious agent is often followed by a report of a laboratory-acquired infection caused by the new isolate [26] as reported in SARS [25]. Although laboratories that handled class 3 and 4 agents should comply with bio-safety regulations, laboratory leakage might happen any time when working with a known agent but also when attempting to isolate an unknown infectious agent such as mimivirus [27]. Infection of a single laboratory worker with a highly infectious agent is likely to be at the origin of an outbreak especially if the agent has the capability of human to human transmission such as happen with SARS CoV. Consequently handling highly contagious diagnostic specimens is risky and should comply with adapted guidelines [19]. This special attention should not rely upon laboratory workers and responsible only. Indeed, all the diagnostic process, from the specimen sampling to the transport to laboratories, should fill with adequate and careful procedures.

This chapter shows data about diagnostic capabilities and infection control procedures for an appropriate and safe handling of specimens in surveyed isolation facilities, and presents specific recommendations on these points.

4.2 Data from the surveys (aggregate and punctual data)

General item: 4. Diagnostic capabilities

Topic 4.a) Capabilities for and management of BSL-4 specimens

The isolation facility has access to BSL-4 labs or capabilities/protocols for the safe and appropriate handling of group 4 agents specimens for diagnosis. (Deriving from : Checklist I, Questions B.4.a, B.4.c)

Strength score: A

- A: The unit is located in the same hospital/city as a BSL-4 lab and has protocols for the safe and appropriate handling of group 4 agents specimens
- B: The unit is not located in the same hospital/city as a BSL-4 lab but has protocols for the safe and appropriate handling of group 4 agents specimens to another city/country
- C: The unit is not located in the same hospital/city as a BSL-4 lab and has not adequate protocols for the safe and appropriate handling of group 4 agents specimens to another city/country

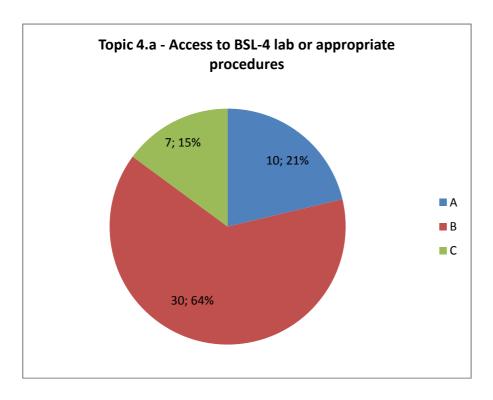


Figure 4.1 – Topic 4.a. Access to BSL-4 laboratory or availability of appropriate alternative procedures (valid answers: 47)

About a fifth of the surveyed isolation facilities throughout Europe are located nearby a BSL-4 lab, avoiding in such way long-distance transportation of HIDs diagnostic specimens. Among those not sited nearby a BSL-4 lab, the majority has written protocols for appropriate handling and sending of the specimens to a BSL-4 lab. On the other hand, 15% of surveyed facilities has no specific protocols. This represent an inadequacy, because un-standardized management of specimens may lead to concerns about infection control and delays in diagnostic process.

Topic 4.b) Capabilities for and management of BSL-3 specimens

The isolation facility has access to BSL-3 labs or capabilities/protocols for the safe and appropriate handling of group 3 agents specimens for diagnosis (Deriving from: Checklist I, Qs B.4.b, B.4.c)

Strength score: A

- A: The unit is located in the same hospital/city as a BSL-3 lab and has adequate protocols for the safe and appropriate handling of group 3 agents specimens
- B: The unit is not located in the same hospital city as a BSL-3 lab but has adequate protocols for the safe and appropriate handling of group 3 agents specimens to another city
- C: The unit is not located in the same hospital city as a BSL-3 lab and has not adequate protocols for the safe and appropriate handling of group 3 agents specimens to another city

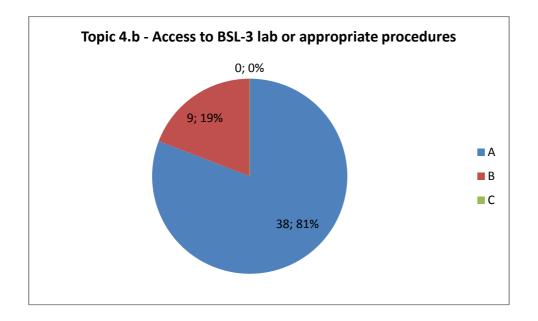


Figure 4.2 – Topic 4.b. Access to BSL-3 laboratory or availability of appropriate alternative procedures (valid answers: 47)

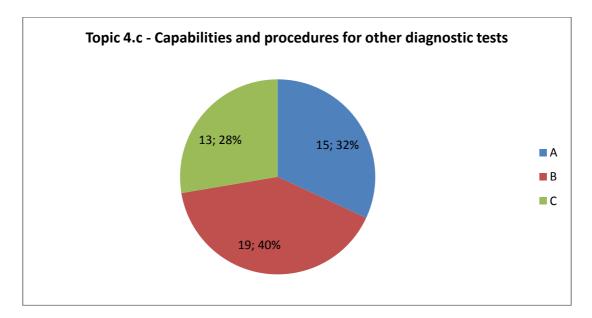
81% of the surveyed isolation facilities throughout Europe are located nearby a BSL-3 lab allowing easy and quick decontamination of sample and safe laboratory analysis. This allows, in presence of adequate procedures, to release in one hour time a safe routine analysis of blood/urine basic constants, and other microbiological tests. In another 19% of the surveyed centres, which do not have such lab facilities, protocols for secure handling of sample, protecting their HCWs from possible accident, are available. Time for data release in such situation is longer due to the need of transportation.

Topic 4.c) Capabilities for and management of other diagnostic tests

The isolation facility has capabilities/procedures for the safe and appropriate management of other tests/routine analysis in HID patients (i.e. use of bed-side tests inside isolation area, or use of central hospital lab after inactivation of samples, or without inactivation, but given appropriate measures of bio-security and bio-safety including the use of automatic, closed-type system analyzer) (Deriving from: Checklist I, Questions B.4.b, B.4.c)

Strength score: A

- A: Optimal use of bed-side testing inside the isolation area OR use of the central hospital lab after inactivation of samples OR use of the BSL-3 lab
- B: Use of the central hospital lab, also without inactivation, given special measures of bio-security and bio-safety including the use of automatic, closed-type system analyzers



C: Use of central hospital lab, without special measures of bio-security and bio-safety

Figure 4.3 - Topic 4.c. Capabilities and procedures for other diagnostic tests (valid answers: 47)

A third only of isolation facilities have access to secure handling of contagious specimens either by direct routine analysis of specimens in a nearby BSL-3/4 lab or by bedside decontamination of sample or by bedside point-of-care tests. 40 % of isolation facilities perform routine analysis (such as biochemistry and haematology) in the central hospital lab, without inactivation, but using closed-type auto-analyzers. This solution, despite far from being optimal, is considered acceptable. Other 13 facilities refer to perform routine tests in the central laboratory, without any specific protocol.

Data from Checklists: Specific evaluation aspects and outcome.

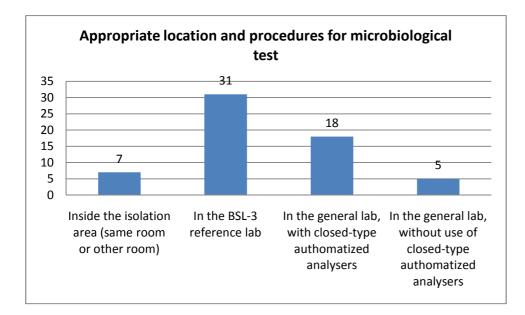


Figure 4.4 – Location and procedures for microbiological tests. (Deriving from: Checklist I, question B.4.b, valid answers: 47 answers, multiple answers possible)

Most of the facilities are directly connected (in the same town) with a BSL-3 and performed microbiological testing such as blood culture or smear for malaria there. Few isolation facilities are equipped with small microbiology apparatus (such as for blood culture) inside the isolation area, while for 23 centres the standard microbiological diagnostic is sent to the routine central laboratory which mostly performed the analysis in a closed-type automatic analyzer. Some centres use different procedures according to risk assessment.

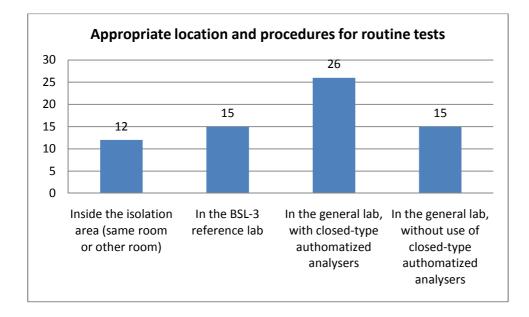


Figure 4.5 - Location and procedures for routine tests (Deriving from: Checklist I, question B.4.c, valid answers: 47, multiple answers possible)

The easy availability of transportable devices makes 27 centres able to perform biochemistry and routine haematology as well as blood gas analysis either at bedside within the isolation unit or directly in a nearby BSL-3 laboratory, while the remaining facilities are using the central laboratory for routine testing, in 15 cases without using closed-type auto-analyzers. Some centre use different procedures according to risk assessment.

4.3 Comments and recommendations

Among isolation facilities surveyed in Europe, most of them are in good safety conditions for sampling and analyzing highly contagious specimens. However some of them should improve the handling of their specimens in setting up protocols allowing safe sampling, handling and shipping to the referral laboratory. Some inadequacies have emerged in particular about specimens to be managed in BSL-4 ambient (15% of facilities refer to have not a standardized procedure for the handling of specimens from sampling to shipping to BSL-4 pre-identified referral centre), and about routine tests (that are referred to be managed in the central hospital lab without special biosafety measures in many facilities).

According to our panel, it is important that an isolation facility is located in the nearby of a BSL-3/4 lab. This logistic assure both rapid availability of safe and appropriate diagnostic testing in HIDs patients, and an appropriate isolation area for lab workers accidentally exposed to biological accidents.

To reduce the risk of transmission to HCWs, patients' sampling should be done in the isolation room at the emergency department or in the isolation facility depending on availability. All diagnostic test should be processed if possible in a BSL-3/4 laboratory [28,29]. Once decontaminated, the sample can be processed in routine clinical laboratory for PCR or blood film for example. Under certain handling precaution, the use of certified auto-analyser in routine has been suggested to be safe. To reduce transmission of a highly contagious agent from a victim of a laboratory accident to other HCW, a medical follow-up of laboratory personnel's as well as other HCW with occupational traceability during all crisis should be done.

It is important to remember that the first aetiology of fever in tropical traveller is malaria, followed by other common infections, and that these diagnosis are far more likely than an HID [23]. This emphasizes on the mandatory routine testing for differential diagnosis. As routine laboratory analysis of contagious samples might be risky for the unaware laboratory technician, an alternative is that routine test is done in the isolation facility at patient's bedside (as for malaria for example). The routine laboratory analysis can also be performed in the BSL-3/4 diagnostic laboratory that should be located as near as possible from the isolation facility to avoid unnecessary transportation and a quicker analysis and response in care time delay [19]. If not available, laboratory routine analysis of these specimens can also be performed in a core routine laboratory either after decontamination if possible or under the condition that specimens are handled following written bio-safety protocols in a verified secure close auto analyzer. We advocate the fact that everything should be done to exclude the most frequent differential diagnosis without delay.

EuroNHID recommendations

Recommendations for appropriate management of diagnostic issues. Optimal requirements:

Sampling HID patients for laboratory analysis

- 1. Should be performed in the isolation room of the ED or in the Isolation facility following written protocols;
- 2. Should use if possible bedside laboratory test analysis (ex malaria test).

Testing HID samples

- Should be performed if possible in the nearby BSL-3 laboratory including routine laboratory (blood, urine, other fluid analysis and chemistry, haematology ...). If a nearby BSL-3 laboratory is not existing, specific procedures should be in place for the appropriate and safe handling and shipping of specimens to the pre-identified BSL-3 referral centre as soon as possible;
- Viral cultivation must be performed at bio-safety level 4, according to the requirements of the EU Biological Agents Directive 1. If a nearby BSL-4 laboratory is not existing, specific procedures should be in place for the appropriate and safe handling and shipping of specimens to the pre-identified BSL-4 referral centre as soon as possible;
- 3. Once decontaminated samples can be tested in routine laboratory for PCR or other testing;

- 4. Tests which must be performed by an operator at the laboratory bench (such as specimen preparation, light microscopy and agglutination tests) must be performed at BSL-3 or higher;
- 5. Protocols must exist for laboratory operator training and for adequate quality assurance of laboratory results.

Recommendations for appropriate management of diagnostic issues. Minimal requirements:

Sampling HID patients for laboratory analysis

- 1. Should be performed in the isolation room according to bio-safety written protocols;
- 2. Decontaminated samples can be tested in routine laboratory;
- 3. Under the condition that specimens are handled by informed trained technician and following written bio-safety protocols, closed auto-analyser can be used for routine laboratory analysis in the central laboratory.

Chapter 5 – Management of HIDs in Emergency Departments

Main author: F. M. Fusco

5.1 Introduction

Infection control procedures in Emergency Departments (EDs) dramatically changed after the SARS experience. With the appearance and global spreading of SARS, it clearly emerged that EDs represented the "weak point" in the infection control chain: indeed, despite the fact that some EDs had in place adequate procedures for infection control and isolation, in the majority of them these measures were inconsistently applied. This inadequacy clearly emerged during the Canadian experience with SARS. On March 7, 2003, two men with undiagnosed SARS were admitted to hospitals in two Canadian cities. In Toronto, where the patient waited in emergency room for 16 hours, this event caused an outbreak of disease that killed 44 people and infected a further 330. In Vancouver, instead, the staff removed the patient from the common waiting area within five minutes, he was put on "full respiratory precautions", and no secondary cases were recorded. This experience shows that should a patient affected by an highly contagious pathogen arrive in an ED, the occurrence or not of a large outbreak would depend largely on what hospitals do when this patient is admitted. If hospitals have effective infection control procedures in place, an epidemic might be contained.

Among health care settings, EDs are preferential sites of disease transmission. Indeed, they are usually very crowded places, where potentially infectious patients and several susceptible individuals are present in the same limited place. Moreover, the identification and isolation of potentially infectious patients may be delayed, because of over-working, lack of specific training/skills, or unavailability of adequate isolation procedures or areas.

We included EDs in our surveys, when present in the same centre as the isolation facility, because EDs may be involved in the initial management of patients with HIDs. In general, patients with suspected or confirmed HIDs may refer to EDs in 2 different situations:

 Patients self-referring to the EDs for an evaluation of their clinical symptoms. It is more likely in the EDs placed in the same centre as the isolation facilities, because these are usually located in hospitals well-known by the general public for their competence in infectious and tropical diseases, often in the main Infectious Diseases centre of the country/region; • Patients with suspected HIDs referring to other health care facilities, and transferred to the centre for the specific competence in infectious diseases. In these cases the patient may be admitted directly into the isolation facilities, or, alternatively, in some centre the patient is evaluated in the ED before to be transferred, if appropriate, to isolation facility.

Among the 48 isolation facilities surveyed, 41 of them refer to have an ED operating in the same centre. Complete data are available for 39 EDs only. This chapter present data about infection control capabilities and procedures in these EDs.

5.2 Data from checklists (aggregate and punctual data)

General item: 6. Infection Control in emergency Departments

Topic 6.a) Availability of isolation area

The Emergency Department associated with isolation facility, if any, has an adequate isolation area (at least one single room with a dedicated route and direct access) (Deriving from: Checklist I, questions D.1.a, D.1.b)

Strength score: B

- A: The Emergency Department associated with isolation facility is equipped with a single room (ideally with negative pressure) for isolation with a direct access and a dedicated route
- B: The Emergency Department associated with isolation facility has a specific area for isolation, but without specific technical/logistic features
- C: The Emergency Department associated with isolation facility has not a specific area for isolation

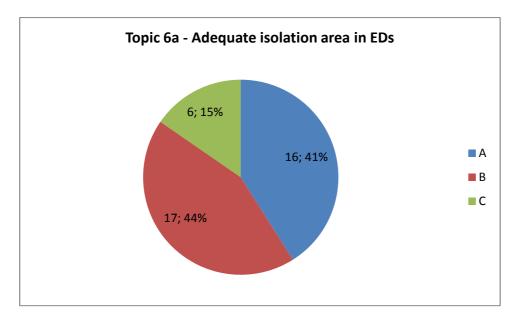


Figure 5.1 – Topic 6.a. Availability of an adequate isolation area in EDs (valid answers: 39)

The presence of one or more rooms for isolation in the ED is fundamental for the rapid isolation and the safe initial evaluation of suspected patient. Optimally, these rooms should have special logistic features (such as a separated access directly from outside, avoiding the contamination of common areas) and should be equipped with special technical equipments (e.g. negative pressure and HEPA filtration of exhausting air).

Single room(s) for isolation, logistically separated by other areas of ED (with a separated access directly from outside and a dedicated route to the isolation facilities, even if external) is present in 16 EDs (41%). Among these, 11 EDs have room(s) with an anteroom, in 11 EDs these isolation room(s) are equipped with negative pressure, while in 9 EDs the exhausting air is HEPA filtered. Isolation room(s) with all explored logistic and technical features are available in 6 EDs only. Isolation room(s), but without special logistic and technical features and equipments are present in 17 EDs (44%), while 6 EDs report to have not rooms for isolation.

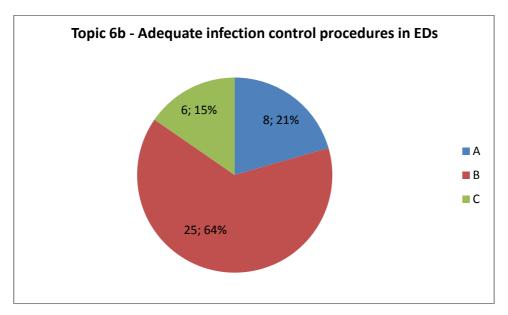
Topic 6.b) Infection control procedures in EDs

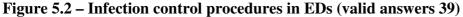
The Emergency Department associated with isolation facility, if any, has adequate structural/logistic/procedural solutions for the limiting of spreading of Infectious Diseases in general (waiting area large enough for distancing the patients, presence of a separated waiting/evaluation rooms for patients with suspected contagious diseases, availability of PPE, existence of plans for the implementation of emergency waiting/ triage areas in case of overcrowding, availability of protocols for the rapid isolation of suspected patients) (Deriving from: Checklist I, questions D.2.a-e, D.3.a)

Strength score: A

Evaluation score:

- A: The Emergency Department has all the structural/logistic features and procedures for the limiting of spreading of Infectious Diseases
- B: The Emergency Department has partially adequate structural/logistic features and procedures (at least 3 explored items in place)
- C: The Emergency Department has not adequate structural/logistic features and procedures (less than 3 explored items in place)





Appropriate infection control in EDs is based on several factors, including the proper logistic of waiting/triage rooms, that ideally should be large enough to keep the right distance among waiting persons, or be separated for patients with probable contagious diseases, such as those with fever and cough. We explored different logistic solutions for EDs, including the presence or not of plans for enlarging waiting/triage areas if necessary. Moreover, the availability of PPE has been explored, such as the presence of written protocols for the management of suspected HIDs patients. All explored features and procedures are available in 8 EDs, while at least 3 of them are reported to be present in 25 EDs (64%). Six EDs (15%) report to have in place less than 3 among explored items. In particular, all EDs report to have availability of PPE, while all except 2 report to have written procedures for the management of HIDs: these procedures always include criteria for initial diagnostic suspect, infection control measures to be applied, and protocols for the notifying/alerting about the case, some of these procedures also include the diagnostic work-up to be applied, while only few include indication for medical treatment, also. About explored logistic features, 28 EDs report to have plans for the rapid implementation of waiting/triage areas in case of

overcrowding, while 22 and 13 report to have a dedicated waiting/evaluation area for patients with suspected contagious diseases and waiting areas large enough for the right distancing among waiting patients, respectively.

Topic 6.c) Specifically trained personnel for the management of HIDs in EDs

The Emergency Department associated with isolation facility, if any, has continuous access to specifically trained personnel for the management of HIDs (Deriving from: Checklist I, question D.2.e)

Strength score: A

Evaluation score:

- A: A specifically trained triage HCWs is available on 24h-basis
- B: A specifically trained triage HCWs is available, but not on 24h-basis
- C: A specifically trained triage HCWs is not available

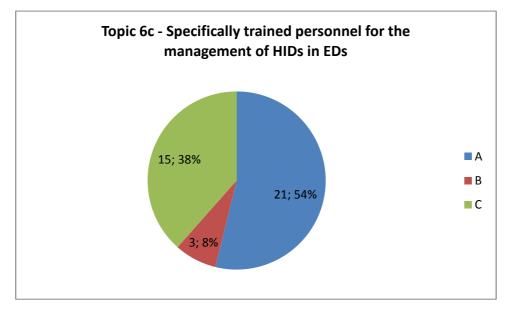


Figure 5.3 – Availability of specifically trained personnel for the management of HIDs in EDs (valid answers: 39)

Good logistic and appropriate protocols are not enough in absence of a trained workforce able to recognize a suspected patient and to apply procedures consistently. HCWs in EDs, especially those in charge of the initial triage procedures, should have a basic training in the management of suspected HIDs patients. Most of the surveyed EDs (24, 62%) have the staff, or part of it, specifically trained in the recognition and initial management of HIDs cases. Among these, in 21 EDs this specifically trained staff is available on 24h basis. Specifically trained staff is not present in 15 EDs (38%).

5.3 Comments and recommendations

Patients with HIDs may be present in EDs, for the evaluation of their symptoms. At the same time, EDs may be used as the first point of contact and evaluation by HCWs for suspected patients. If not adequately managed, the presence of these patients in ED may cause nosocomial and community outbreaks, as already happened for SARS and tuberculosis (30-34)

After the September 11 and SARS, most EDs adopted or developed local and national preparedness plans, in order to improve their capabilities to deal with emergencies and large-scale events, such as with a bioterrorism attack. This plans always include suggestions for the appropriate logistic solutions, and the isolation procedures. Moreover, the current infection control guidelines, updated after the SARS epidemic, stress the importance of incorporating into routine practice simple measures designed to contain respiratory droplets and secretions, to reduce the possibility of transmission of other febrile respiratory infections. These measures, called 'respiratory hygiene' or 'cough etiquette', have been recently added by WHO to standard precautions (infection control procedures that should be applied in health care settings at all times and in all areas) for all patients presenting to healthcare settings with fever and cough [34]. In particular about HIDs the risk of spreading can be reduced only through the application of different measures, from appropriate logistic features to adequate procedures and education of HCWs.

Despite the existence of these preparedness plans, as more years passed from the emergencies, as less attention to infection control has been given into EDs: some surveys, performed in EDs in UK, USA and Canada [35-37] revealed that the application of these plans and procedures, including the respiratory hygiene/cough etiquette measures, was low.

The preparedness in EDs has been once again tested during the 2009 H1N1 pandemic, during which EDs have been strongly stressed by a huge number of patients, with divergent results. Indeed, despite lesson learned by previous experiences, many EDs still reports the use of non-permanent, extemporized solutions, such as the use of curtains for separating patients, triage procedures in external areas, or in ambulances [38].

Results emerged from our surveys confirm that the general level of preparedness to Infectious Diseases emergencies, and to HIDs in particular, is not adequate. The EDs surveyed in EuroNHID project should represent the most prepared in infection control, because the fact that they are located in the same centre of an isolation facilities make the referral of patients with suspected/confirmed HIDs more likely. Moreover, the surveyed EDs are usually located in the major hospital of the country/region. Despite that, overall results are not encouraging: only few of them reports to have room(s) technically adequate for isolation, logistic is often not appropriate, and in about one-third no specifically trained staff is available.

Different level of interventions should be promoted for an appropriate infection control management in EDs. General respiratory hygiene and cough etiquette measures, summarized in the table 6, should be implemented as more as possible. It means that:

- Waiting areas should be large enough to allow people to set at least one meters each other or dedicated areas for people with suggestive symptoms should be present;
- Visual signals should be present, and well visible, in common waiting areas;
- Disposable tissues and/or surgical masks should be available and should be offered to coughing and sneezing persons (including patients and visitors);
- Places for the disposal of used tissues should be present;
- Stations for hand hygiene, with all things needed, should be disseminated as more as possible in the EDs, including in waiting rooms;
- An HCWs should have the responsibility to apply these measures to the largest number of persons as possible.

Table 6 - Respiratory hygiene/cough etiquette measures.

Measures targeted to patients:

Persons with respiratory symptoms should apply the following measures:

- cover their nose and mouth when coughing/sneezing with tissue or surgical mask;
- dispose of used tissues and masks;
- perform hand hygiene after contact with respiratory secretions.

Measures targeted to common areas in Healthcare Settings:

- seats in common areas at least 1 metre apart;

- strategies in place to promote Respiratory Hygiene/Cough Etiquette measures (visual alerts,

pamphlets, information given by nurses);

- a supply of disposable tissues and masks, a trash can for used tissues and masks, and a facility for hand-hygiene should be present.

Measures targeted to HCWs:

- correct selection, donning and removal of PPE

For the rapid identification of suspected patients, the first point of contact and the triage procedures are very important: these should not only include an assessment of disease severity/urgency, but should as more as possible consider also the risk of disease transmission posed by the patient. A brief epidemiological investigation of patients with symptoms suggestive to be caused by an HIDs may help in the rapid identification of suspected patients: this investigation should include (i) history about travels in endemic areas for HIDs, (ii) occupational history of exposure to risk factors (the patient is an HCWs, a veterinarian, a laboratory worker, a farmer...), (iii) contact history of exposure to other persons with similar illness, particularly those with unknown disease; and (iv) history of being part of a clustering (the presence of multiple ill patients arising from the same area, school, workplace or residence). Simple standardized forms to be rapidly checked should be developed and used by triage personnel, in order to simply identify suspected patients. These patients should be placed in separate waiting/evaluation areas, if available, or removed as soon as possible by common areas.

Once identified a suspected patient, clear procedures, well-known by HCWs, should be applied. These procedures should include at least the basic steps for rapid management of the suspected patient, that include the infection control measures to be applied (isolation, PPE to be used, disinfection issues if needed), and the actions for the activation and alerting and command chain. Responsible persons for the management of these patients, such as the health authorities, should be alerted as soon as possible. These procedures could also include, if appropriate, the basic diagnostic work-up to be applied. Other measures, such as therapeutic interventions, if not urgent, and epidemiological investigation as the contact tracing, should not be responsibility of EDs staff. For the full application of these protocols, adequate PPE and hospital-approved products for disinfection should be available and easily accessible.

The availability of well technically equipped and logistically adequate isolation rooms is fundamental, in order to isolate and evaluate suspected patients self-referring or sent from other facilities. This room should have a separate access directly from outside or being logistically isolated by other common areas, in order to avoid environmental contamination. The way-in, if logistically adequate, may be also used as a reserved pathway, even if external, for transferring the patient safely to isolation facility. Alternatively, a pathway to isolation facility should be identified and exercised. This pathway should be, if possible, dedicated, alternatively other solutions, such as the temporary evacuation of areas going through should be planned and exercised. As all isolation rooms, also this should have an anteroom, in order to give a safe area to HCWs for the donning and removal of PPE and stockpiling of material. Ideally, the room should have negative pressure, HEPA filtration of exhausting air, sealing of windows and door, and material inside should be easy to decontaminate. All these procedures could not be appropriately applied if the staff is not adequately trained. All HCWs should be familiar with general procedures and alert and command chain. All HCWs, or some part of them depending on EDs policies, should be familiar with PPE use, donning and removal, isolation procedures and disinfection issues. Triage HCWs, in particular, should be specifically trained in the rapid identification of suspected patients. It also imply a continuous updating on ongoing outbreak around the world. Operatively, one HCW should take the responsibility to monitor at least weekly the major on-line epidemiological alerts sites and bulletins, such as Promed-mail and CIDRAP (www.promedmail.org; www.cidrap.umn.edu), and disseminate the news to all other triage staff (by e-mail, or other methods).

EuroNHID recommendations

Recommendations for appropriate infection control in EDs dealing with HIDs. Optimal requirements:

- 1. Implement as more as possible the application of respiratory hygiene/cough etiquette measures, and select an HCW dedicated to monitor and implement their application;
- Institute separate waiting areas for potentially contagious patients (all persons with fever and cough/sneeze) or use common areas large enough to allow the right distancing among waiting persons;
- 3. Develop triage procedures also including an assessment of transmission risk. This procedures should include a brief epidemiological investigation, that should be performed on the basis of standardized forms;
- 4. An isolation room should be available for the rapid isolation and initial assessment of patients with suspected HIDs. This room should be logistically and technically adequate (way in and out not passing through common areas, better if directly from/to outside, anteroom, negative pressure, HEPA filtration of exhausting air, sealing of door and windows, material used easy to be decontaminated);
- 5. Staff should be adequately trained. Ideally, all ED staff should be familiar with isolation and infection control procedures, and with correct management of PPE. HCWs dedicated to triage should be specifically trained in the rapid recognition of suspected patients, and a simple system for the updating of epidemiological information should be in place.

Recommendations for appropriate infection control in EDs dealing with HIDs. Minimal requirements:

- Respiratory hygiene/cough etiquette measures should be applied in all EDs, at every moment. If it is not possible to dedicate an HCWs to their application and monitoring, implement as more as possible visual signals suggesting them;
- 2. If the use of dedicated waiting room is not possible, ask to people with fever and cough/sneeze to seat at least 1 meter away from other patients, and plan surge capacity plans for the implementation of triage/waiting areas in case of over-crowding;
- 3. Include a basic epidemiological evaluation into triage procedures, in order to identify patients more likely to be affected by HIDs;
- 4. Identify a room that could be used for isolation. Prefer those rooms that are located marginally and near to alternative entrances, if available, in order to functionally isolate the area if necessary;
- 5. A core number of HCWs should be trained in the correct management of suspected HIDs' patients. Shift plans should be developed in order to have some trained HCWs available in every moment, or procedures for their rapid alerting should be in place. Triage personnel should have a basic training in the rapid recognition of suspected HIDs, and should have access to an epidemiological update about the main outbreaks ongoing in the world.

Chapter 6 – Transport of HIDs

Main author: S. Schilling

6.1 Introduction

Despite growing concerns and training efforts focussing on front-line care clinicians, HID patients are rarely admitted to specialised treatment facilities initially and often are identified when standard treatment regimen fail [21]. Moreover, as depicted in chapter 1 (infrastructure issues), treatment facilities for HIDs are very few in many EU Member States (MS) and most often located in highly populated areas indicating a lack of facilities in more rural areas. Facilities not planned and equipped for long-term HID care should thus provide protocols for the re-location of confirmed or suspected cases to more specialised isolation facilities. As cases may occur in close proximity to other EU MS a patient may have to be relocated to the closest isolation facilities available – even if not in the same MS as the one where the case was initially identified. Hence, both domestic and cross-border relocation of such patients should be included into any national and regional response plan [39].

As any transportation of HID cases poses a risk to patients, HCWs and the environment, specific, case-by-case needs and benefits of relocating the patients must be well balanced. The mode of transport (e.g. ground vehicle versus aircrafts) is defined and limited by vehicle availability, national legislation and the geographic distance to the next isolation facility. High risks of secondary infections in a care facility not prepared for HIDs or the absence of adequate supportive care may amplify the decision to relocate patients to other facilities. In contrast, the absence of a reliable transport infrastructure, inaccessible care en route and the patient's clinical condition may contraindicate relocation.

Within checklist 2, the existence and adequacy of ground-vehicle transport capacities for HID patients was analysed. Information on transport capacities was assessed using four subsets of questions focusing on (i) legal issues; (ii) technical and infrastructure issues; (iii) management procedures; and (iv) promotion and monitoring of procedures. Aspects addressed derived from consensus guidelines published elsewhere [19,20,40]. One centre was excluded from this analysis as no information was provided.

Definitions

National regulations:

National regulations are defined as laws and recommendations issued by either Ministries (e.g. Ministry of health) or national institutions (e.g. for occupational health) that must be adhered to by hospitals included into the analysis.

Local protocols:

Local protocols are defined as written "Standard Operation Procedures" (SOPs) defining the management of HID transport within, to or from the respective isolation facility including clinical care, infection control, disinfection and team management. SOPs are written, regularly updated protocols and instructions covering operations which lend themselves to a definite or standardized procedure without loss of effectiveness. SOPs should be accessible to all staff at any time point to allow adherence to established procedures.

Specifically designed ground ambulance:

Ground ambulances are defined as "specifically designed" for the transportation of HID patients if the ambulance itself and any fixed equipment used can be effectively decontaminated (by wiping, spraying, or fogging with an effective disinfectant) according to national policy. Specific technical features on board shall include controlled ventilation, negative pressure, HEPA filtration, intercom systems, aerosol tight storage containers and separation of driver's from patient's cabin. [20]

Reserved ground ambulance:

"Reserved" ground ambulances for the transportation of HID patients are defined as standard ambulances without additional technical features (see above) but available on call when demanded. "Reserved" ground ambulances may have easy to decontaminate cabin walls and equipment. Strategies should be in place to protect both paramedics and drivers from infectious agents.

Stretcher isolators:

Stretcher isolators are defined as portable self containment isolation beds, generating negative pressure inside the patient's cabin/ area and exhausting HEPA-filtered air.

6.2 Data from the surveys (aggregate and punctual data)

General item 10: transport of HID patients

Topic 10.a) Existence of procedures on transport

The isolation facility has procedures for the transport of patients, outside and within the facility. (Deriving from: Checklist II, questions E.1.a, E.2.d, E.2.e)

Strength score: A

Evaluation score:

- A: Procedures for the external and internal transport are available.
- B: Procedures are available, but only for the external or internal transport.
- C: Procedures not available.

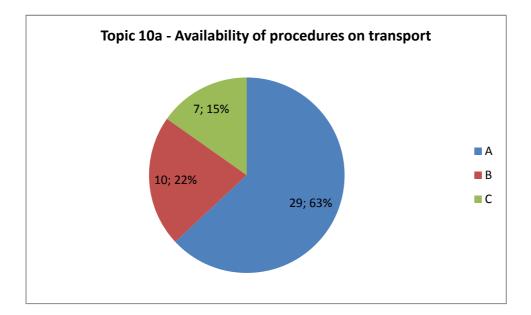


Figure 6.1 – Availability of procedures for the transport (valid answers: 46)

Two third (n=29/46; 63%) of all centres evaluated do provide adequate protocols for both external and internal transport of patients. Although representing the minority, 7 centres do not have

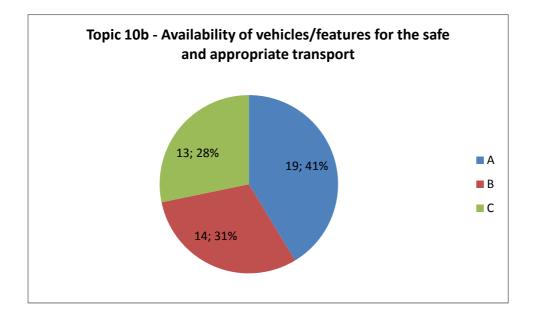
any procedures in place for either internal or external transport of patients indicting a high risk for secondary spread of agents when patients are admitted to the facility or re-located within the hospital. Topic 10.b) Availability of vehicles/features for the appropriate and safe transport

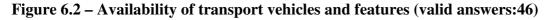
The isolation facility has access to specific technical features for the transport of patients (access to suitable vehicles adequately equipped, availability of a stretcher isolator, existence of separate entrance, existence of separate pathway(s), area for the decontamination of ambulances). (Deriving from: Checklist II, questions E.2.a-e, E.3.c)

Strength score: C

Evaluation score:

- A: 4-5 of explored items available.
- B: 2-3 of explored items available.
- C: Less than 2 of explored items available.





41.3% of centres evaluated (n=19/46) fulfil more than 4 criteria considered adequate for the safe transportation of patients. About 30% each fulfil more or less than 2 criteria evaluated. Criteria most often fulfilled were the existence of dedicated entrances (n=32/46) and pathways (n=30/46), although 11 centres did not provide either of them.

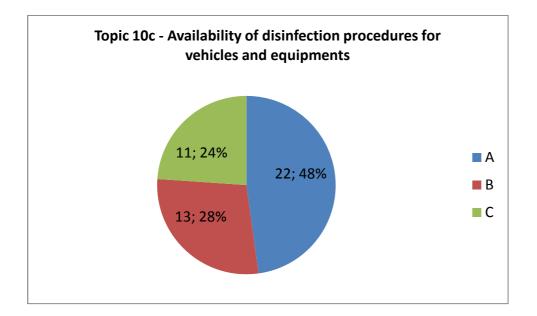
Topic 10.c) Availability of disinfection procedures for vehicles and equipments

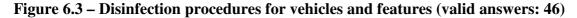
Procedures for the disinfections of vehicles and equipments used during the transport of patients are available. (Deriving from: Checklist II, question E.3.a, E.3.b, E.3.d)

Strength score: A

Evaluation score:

- A: Disinfection procedures available for all of explored items (disinfection procedures for the ambulance, the ambulance equipment and the stretched isolator).
- B: Disinfection procedures available for 1-2 of explored items.
- C: Disinfection procedures not available.





Adequate procedures for the disinfections of vehicles and equipment as well as the existence of a dedicated area for ambulance or stretcher disinfection are available in 47.8% of centres (n=22/46). Overall, the number of centres with protocols for the disinfection of equipment used en route (n=30/46) exceeded the number of those with access to ground vehicles and/ or stretcher isolators (n=25). Finally, 16 centres did not provide protocols for the disinfection of equipment used en route or a dedicated area for the disinfection of ambulances (n=23; respectively), and only one centre providing a ground vehicle did not have a dedicated area for its disinfection.

Topic 10.d) Existence of procedures for the promotion and monitoring of transport procedures

Adequate procedures for the promotion of the safe transport of patients are available. (Deriving from: checklist II, questions E.4.a-c)

Strength score: B

Evaluation score:

- A: Presence of periodically employed procedures for the promotion of the safe transport of patients, regularly monitored.
- B: Presence of periodically employed procedures for the promotion of the safe transport of patients, not regularly monitored.
- C: Procedures for the promotion of the safe transport of patients not in place.

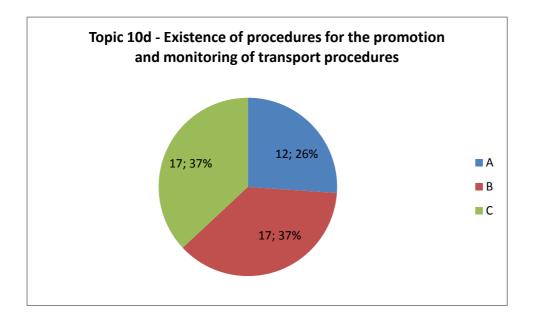
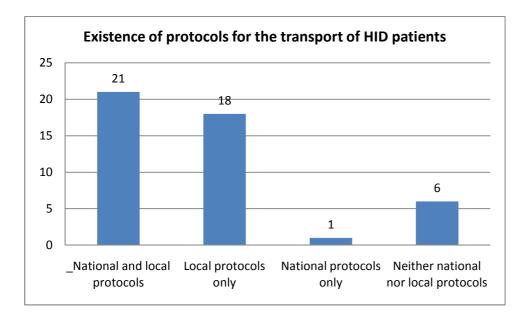


Figure 6.4 – Availability for procedures for the promotion and monitoring of transport procedures (valid answers: 46)

Periodically employed procedures for the promotion of the safe transport of patients are implemented in n=29/46 centres (63%), but regularly monitored in n=12/46 (26%), only. More than one third of all centres do not provide such procedures, at all (n=17/46; 36.9%).



Data from checklists: specific evaluation aspects and outcome

Figure 6.5 – Existence of local and national protocols for HID transport. (Deriving from: checklist II, questions E.1.a and E.1.b, valid answers 46)

Half of all centres evaluated (n=21/46) are located within 3 MS that do have access to national recommendations and local protocols for the safe transport of HID patients within or to the respective isolation facility. All of those centres are located in France, Germany, and Italy. Despite a lack of national regulation, local protocols are at hand in 18 centres. Neither national nor local protocols regulate the transport of HID patients in 6 centres assessed (representing 5 MS). One centre only does have access to national regulations but has not yet implemented local protocols.

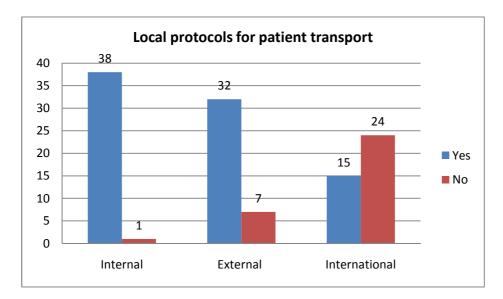


Figure 6.6 - Existence of local protocols for HID transport. (Deriving from: Checklist II, question E.1.a, valid answers 46)

Nearly all centres indicating to provide local protocols for the transportation of HID patients (n=38/39) do have regulations for in-hospital transport. In addition, 32 of those also have regulations for transporting a patient to or from the isolation facility while the minority only provides regulations for international repatriation of patients (centres from France, Germany, Italy, Spain and the United Kingdom).

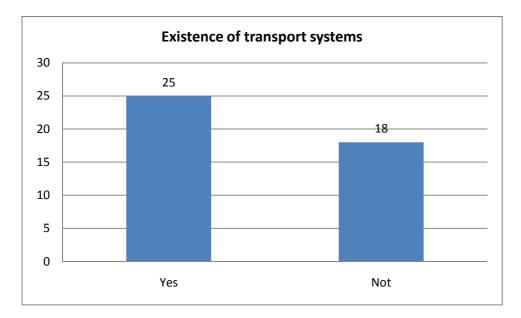


Figure 6.7 - Existence of specific equipment for the transportation of HID patients. (Deriving from: Checklist II, questions E.2.a-c, valid answers: 43)

Overall, ground vehicles (either reserved or specifically designed) or specific equipment (stretcher isolators) for the transportation of HID patients within or to/from the isolation facility do exist in more than half of all centres evaluated (n=25/44; 54.3%). 18 centres from 9 EU member states do not provide any specific equipment for either internal or external transportation of HID patients.



Figure 6.8 - Adherence to requested existence of specifically designed ground vehicles. (Deriving from: Checklist II, question E.1.b, E.2.a, valid answers: 42)

Overall, 12 centres could provide specifically designed ground vehicles. Among these centres, 8 are located in countries where the use of such vehicles is recommended by National Regulations, while 4 are available in countries where the use of these vehicles is not specifically required. In the countries where the use of these special ground vehicles is required, one isolation facility only is unable has no access to them.

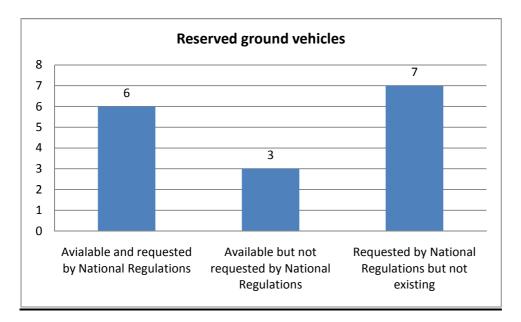


Figure 6.9 - Adherence to requested existence of reserved ground vehicles without specific design. (Deriving from: Checklist II, question E.1.b, E.2.b, valid answers: 42)

Overall, the existence of reserved ground ambulances for HID transportation is requested by national health authorities in 13 centres. In contrast to Figure 6.8, adherence to requested existence of reserved but not specifically designed ground vehicles is low. Less than 50% of centres (n=6/13) do adhere their national regulations. It should be mentioned that 2 centres of those do provide stretcher isolators, instead, and 3 other centres do have reserved ground vehicles although not requested. However, 8 centres with access to specifically designed ground vehicles also have additional reserved vehicles as "back up" equipment in case of technical failure.

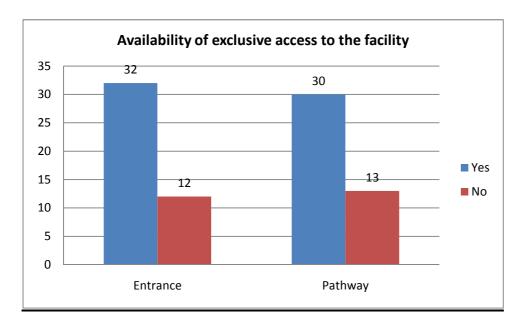
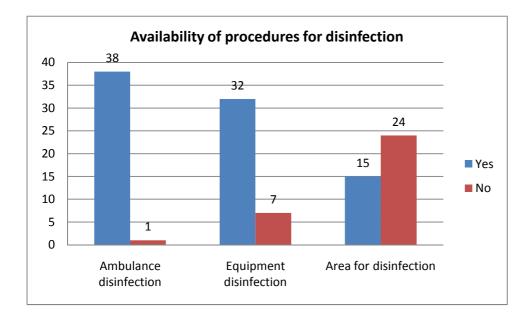
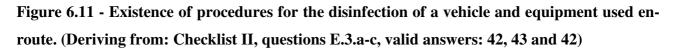


Figure 6.10 - Existence of pre-defined and exclusive entrances to the facility and pathways for patient transport. (Deriving from: checklist II, question E.2.d, E.2.e, valid answers: 44 and 43)

Overall, the majority of centres evaluated provides pre-defined and exclusive access routes for ground vehicles to their facility (n=32/44; 72.7%). In addition, exclusive, specifically reserved pathways for the transportation of patients within the hospital or the isolation facility itself are found in 71.5%.





Written protocols for the disinfection of vehicles and equipment used en-route do exist in the majority of centres (80.9 and 69.76%, respectively). For ambulance cabins and equipment, surface decontamination and fumigation are most often used in accordance with national guidelines (data not shown). In contrast, only 54.7% of all centres have dedicated areas to conduct both interior and exterior vehicle decontamination. If stretcher isolators are available (Question E.3.d), procedures for its disinfection are available in 69.23%, only (n=9/13).

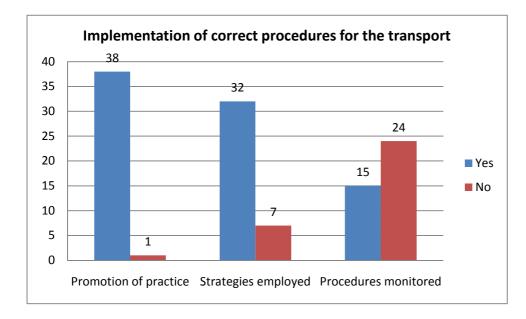


Figure 6.12 - Promotion and monitoring of correct practice for patient transport. (Deriving from: Checklist II, questions E.4.a-c, valid answers 41, 37 and 37)

73.2% of centres to promote the correct practice of HID transport, e.g. loading/ unloading of patients and vehicle/ equipment disinfection procedures. Strategies employed for the promotion of such practices most often include practical exercises (n=21/37), lectures (n=19/37), and educational campaigns (n=11/37). Most of those are periodically employed twice per year (data not shown). However, monitoring procedures of correct practices for HID transports such as supervision or video documentation is lacking in most centres.

6.3 Comments and recommendations

Optimal requirements for the transportation of HID patients were described in the EUNID consensus statement and are enlisted at the end of this chapter. As mentioned before, the EUNID consensus refers to HLIUs only and does not consider all requirements feasible for secondary or tertiary care facilities. However, if such less specialised facilities are considered to provide care for HID patients even for a few days only, EuroNHID strongly recommends to have procedures and equipment for the relocation for HID patients at hand.

Transportation of HID patients to or from any clinical care facility should strictly adhere to both **national laws and regional guidelines** when existent. The distance to be travelled, the transport system used and the benefit for the patient must be taken into account. As the closest specialised care facility may be located within another EU MS than the one where the case was initially suspected/diagnosed, formal agreements between neighbouring states for cross-border transfer may help to overcome such problems.

A patient's **clinical condition** represents the strongest limitation of any transport approach. If stable and cared for in a safe clinical environment, transport to the next specialised facility may be postponed until a tentative diagnosis is verified and clear decisions for the level of PPE and the need of transport can be made. If stable but deteriorating, contingency relocation under validated infection control condition may be demanded in order to reduce the risk of nosocomial spread. If a patient is clinically unstable, transport may not be possible, at all, and specifically trained **deployable teams** from the next specialised care facility may have to care for a patient on site. Such approach of deployable teams may also be considered feasible when no secure transport system is available or other conditions (e.g. climate and geography/topography) make any relocation difficult.

Generally spoken, pre-identified and dedicated **transport systems** for HID patients should be co-located with any clinical care facility responsible for HIDs. Such transport systems may include

stretcher isolators, ground vehicle and either fixed- or rotary-wing aircrafts depending on population density as well as the geographical location and quantity of specialised care facilities within the respective EU MS. While ground vehicles cover only a small range of distance, longterm experience on their value in pre-hospital care exists and they are widely accessible. In contrast, rigors of transport are more severe when using fixed- or rotary-wing aircrafts but great distances can be covered in a short amount of time.

Any transport system in use and equipment on board must be carefully chosen with respect to **disinfection procedures** afterwards. Protocols for the disinfection of the patient's cabin and any equipment use en route must exist in accordance to national regulations. Furthermore, dedicated areas for the disinfection of both must be pre-identified and secured in order to prevent any secondary infections.

When an HID patient is transported to or relocated from a clinical facility, dedicated, preidentified and secured **entrances and pathways** must be used. Such entrances and pathways do not necessarily need to be represented by additional infrastructure by may be defined in functional manners (e.g. by blocking access to the pathway while a patient is transported and decontamination of the pathway, thereafter).

Whatever transport system is considered feasible, **periodical training** of teams on board (e.g. for use of equipment, disinfection procedures and management of accidents en route) and teams at the respective care facility (e.g. for loading/ unloading procedures) are indispensable. Practical exercises to enhance self-confidence, management of accidents and communication strategies have proven most success and should be conducted at least twice a year.

EuroNHID recommendations

Thus, the following **minimal requirements** for the transportation of HID patients should be fulfilled by any centre responsible for HID care:

- 1. The mode of transport (by road or air) must be adapted to (inter-) national laws;
- 2. Pre-identified standard or specifically equipped vehicles should be co-located with any facility responsible for HID care;
- 3. Procedures for the disinfection of the vehicle and equipment used must be in place, even if no reserved or specifically designed vehicle is co-located with the respective facility;
- 4. Pre-identified entrances and pathways should exist;

5. Loading and unloading teams should undergo periodical education and drills.

Safe and appropriate transport of HID patients. Optimal requirements (Adapted from [20])

- 1. The decision to transport a patient as well as transport mode and vehicle type must be based on expert clinical risk assessment;
- 2. PPE for transport must be based on expert risk assessment;
- 3. Staff exposed to the patient en route during the journey should wear appropriate PPE should be subject to the same health surveillance after the journey as potentially exposed staff within the isolation facility;
- 4. The vehicle and any equipment used must be able to be effectively decontaminated according to national policy;
- 5. The vehicle crew must be trained in the protocol for transport of patients with HIDs;
- 6. The isolation facility should have an external, securable, area for ambulance parking and decontamination, and procedures for safe decontamination of ambulance equipment, including safe storage before decontamination;
- 7. The isolation facility should have an admission route from the ambulance area to the unit entrance that can be controlled and secured, and that is wide enough to permit transfer of patient, staff, and equipment;
- 8. An ambulance used to transport HID patients should not be returned to normal use until the vehicle has been decontaminated;
- 9. Duration of transport should not exceed 4-6 hours.

6.4 Brief conlcusive remarks

The data collected clearly depict the awareness of centres for the problems of safe transport solutions even when vehicles are not available. Besides investment into equipment, a harmonised EU-wide approach including the definition of minimal technical requirements of ground vehicles and a jurisdiction defining a legal frame for cross-border relocations is needed.

Chapter 7: Infection control procedures. Management of Personal Protective Equipment (PPE)

Main author: G. De Iaco

7.1 Introduction

The protection of healthcare personnel from infectious disease exposures in the workplace requires a combination of controls, one of which is the use of PPE. It is important to recognize that HCWs protection also involves other prevention strategies. Biological safety is based on a series of controls to include engineering controls, administrative controls, primary barriers, PPE, and workplace practices to achieve safety for the worker and the environment. These controls work in concert and each is designed to reinforce the others.

Correct selection and use of PPE is crucial for the safe management of HID patient. Indeed, despite the presence of good technical and logistic features, the strict contacts between HCWs and patients, in particular during some procedures, remain at high risk.

The proper selection of control measures is based on a hierarchy of elimination and minimization by engineering controls, followed last by PPE when exposures cannot be eliminated. Once it is decided that PPE is needed, the process of selecting appropriate PPE requires an understanding of the work activities associated with potential exposure. In particular, type of exposure and foreseeable conditions of use should be considered.

Several definition are available to describe PPE. Here we report some of them:

- "any device or appliance designed to be worn or held by an individual for protection against one or more health and safety hazards" (89/686/EEC);
- devices that "provides a physical barrier between micro-organisms and the wearer. It offers protection by helping to prevent microorganisms from: contaminating hands, eyes, clothing, hair and shoes; and being transmitted to other patients and staff" (WHO);
- "specialized clothing or equipment worn by an employee for protection against infectious materials" (OSHA).

Several items about PPE have been explored during EuroNHID survey through the checklist 2:

- presence of procedures for PPE selection, donning and removal;
- policies about fit-test and seal-check,
- presence of strategies for implementing and monitoring the correct use of PPE;
- presence of protocols for the maximum length of time PPE should be worn;
- policies for PPE supply.

Particularly 3 areas were explored and summarized in the assessment form as follow:

- 1) Availability of procedures for PPE selection, donning and removal (requirement 7.a)
- 2) Availability of procedures for the promotion of correct use of PPE (requirement 7.b)
- 3) Availability of procedures for the supplying of PPE (requirement 7.c)

The aim of this chapter is to describe the results of the survey conducted in 47 centers belonging to the EuroNHID network for HID, and to provide recommendations on selection, use and supply of PPE in healthcare settings dedicated to HID.

7.2 Data from checklists (Aggregate and punctual data) and specific evaluation aspects and outcome

As a general consideration, all facilities but 2 protect HCWs during direct contacts with HID patients through the use of PPE. In 2 facilities, both in UK, another approach is used: the patient is isolated in a single-bed flexible-film unit (the Trexler Unit). The plastic isolator is completely sealed, and is equipped with 4 protective suites directly attached to the longer sides of flexible-film, with front side within the isolator. All medical procedures can be performed without direct physical contacts between the HCWs and the patient. Moreover, among isolation facilities using PPE, some report to use always complete suites for suspected/confirmed HIDs, consequently some procedures are not applicable in these facilities. On the other side both strategies (use of separate PPE or complete suites) can be used in the same centre. These situations explain the presence of some data expressed as not applicable, and also explain why some data could appear inconsistent.

General item 7: PPE

Topic 7a) Procedures for PPE selection, donning and removal

The isolation facility has procedures for PPE selection, donning and removal (Deriving from: Checklist II, questions B.1.a, B.1.b) Strength score: A

Evaluation score:

- A: The facility has procedures for PPE selection, donning and removal
- B: The facility has procedures for one explored item
- C: The facility has not procedures for PPE selection, donning and removal

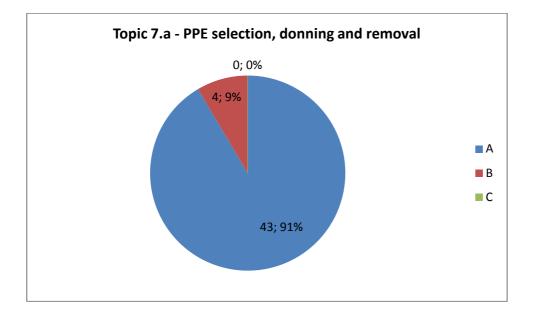


Figure 7.1 – Availability of procedures for PPE selection, donning ad removal (Valid answers: 47)

The vast majority of surveyed facilities have both procedures for selection and donning and removal of PPE. Among those scored as B, 1 report to have not procedures for PPE selection, while 3 report to have not procedures for PPE donning and removal. Out of these 46 centres which have procedures for PPE selection it has been also asked if different procedures are in place according to the type of exposure (routine care vs. high-risk procedures, such as bronchoscopy and sputum induction): in 6/46 no different protocols are followed for PPE selection according to the type of exposure; in 3 centres maximum protection is always used independently from the type of exposure; and 37/46 facilities use different PPE according to the exposure.

It has been also asked who is in charge for the development of the selection procedures. Possible answers are Infectious Diseases (ID) specialists, Infection Control (IC) specialists, Occupational Medicine (OM) specialists. Results are shown in the graphic 7.2.

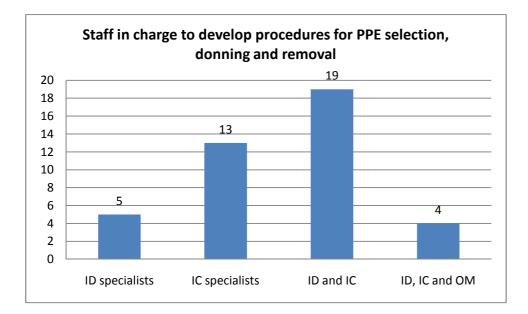


Figure 7.2 – Staff in charge to develop PPE procedures (Deriving from: Checklist II, question B.1.a, valid answers: 41)

In most facilities (19, 40.4%), ID and IC specialists are in charge to develop procedures for PPE selection, donning and removal. Procedures have been developed by IC specialists alone and ID specialists alone in respectively 13 and 5 facilities. In 4 facilities only, OM specialists are involved, also.

Topic 7b) Promotion of correct use of PPE

The isolation facility has procedures for the promotion of correct use of PPE (Deriving from: Checklist II, questions B.2.a-e)

Strength score: A

Evaluation score:

- A: The isolation facility has adequate procedures for the promotion of correct use of PPE (presence of 4-5 of explored items)
- B: The isolation facility has partially adequate procedures for the promotion of correct use of PPE (presence of 2-3 of explored items)
- C: The isolation facility has not adequate procedures for the promotion of correct use of PPE (presence of 1 or less of explored items)

Explored items are: (i) Performing of fit-test; (ii) Protocols for periodical repetition of fit-test; (iii) Protocols/procedures for the seal/fit check before entering in the patient's room; (iv) Strategies for implementing and monitoring the correct use of PPE; (v) Protocols for the maximum length of time PPE should be worn.

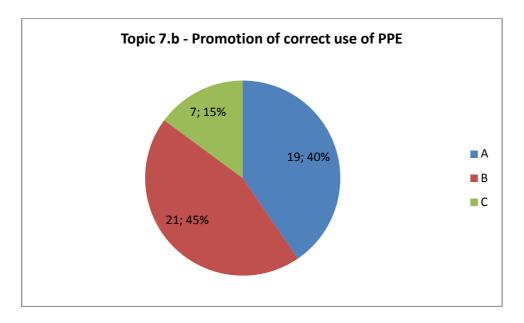


Figure 7.3 – Promotion and correct use of PPE (valid answers: 47)

Correct use of PPE is very important and it is fundamental that all HCWs are specifically trained to use effectively their PPE. Among the 47 surveyed facilities, 19 (40%) report to have adequate procedures for the promotion of correct use of PPE (presence of 4-5 of explored items). 21 facilities report to apply only 2-3 among explored procedures, while 7 facilities have not adequate procedures for the promotion of correct use of PPE (presence of 1 or less of explored items). In particular about fit test, 23 facilities refer to have procedures to perform it, while other 10 facilities report to not use fit-test of respirators because complete suites with respirator incorporated are used, so fit-test is unnecessary. Among facilities where fit-test is performed, 11 have procedures in place for its periodical repetition, also. Mostly fit-test is repeated at fixed intervals (for example annually), but some centres plan to repeat it only when new respiratory condition of facial changes in the wearer occur. Similar picture emerges about performance of seal-check before entering into patient's room: 22 centres refer to do it. As before, in 10 facilities the use of complete suites for HIDs patients make this procedures not useful. Merging the data available on performance of both fit test and seal-check it results that only 15 out 47 centres have both procedures available for performance of fit test and seal-check.

The presence of strategies for implementing and monitoring of correct use of PPE are present in 41 facilities (87%). Strategies referred include the presence of visual signals, the cross-check between HCWs, the supervision by an expert, the presence of a mirror for a self-assessment. Strategies applied are shown in the graph below (more than one strategy is applicable).

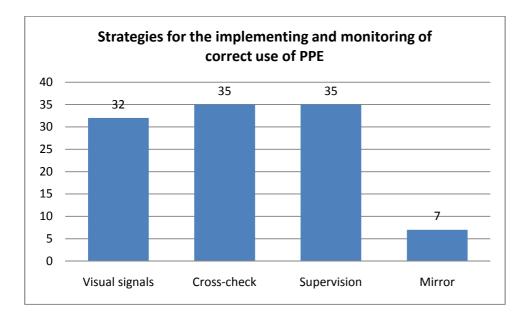


Figure 7.4 – Strategies for the implementing and monitoring of correct use of PPE (Deriving from: Checklist II, question B.2.b, valid answers 47, multiple answers possible)

Finally, last explored issue among procedures for a correct use of PPE has been the presence of protocols for the maximum time a PPE (especially respiratory protection) may be worn. Given that some isolation facilities use different type of PPE, and that this information is usually provided by the manufacturer, 28 isolation facilities report to have such protocols.

Topic 7c) PPE supplying

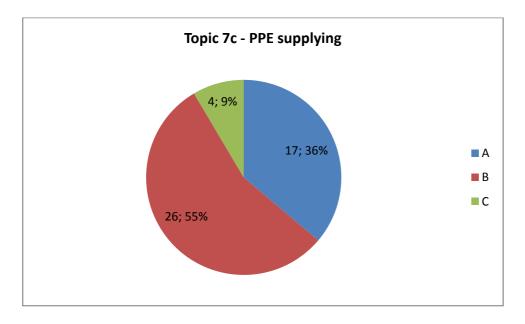
The isolation facility has procedures for the supplying of PPE (Deriving from: Checklist II, questions B.3.b-d)

Strength score: A

Evaluation score:

A: The isolation facility has adequate procedures for the supplying of PPE (procedures for the supplying, monitoring of expiration dates, decontamination for the re-use of some PPE)

B: The isolation facility has partially adequate procedures for the supplying of PPE (2 of explored items)



C: The isolation facility has not adequate procedures for the supplying of PPE (1 or less of explored items)

Figure 7.5 – Procedures for PPE supplying (valid answers: 47)

As a result 17/47 facilities have adequate procedures for the supplying of PPE (procedures for the supplying, monitoring of expiration dates, decontamination for the re-use of some PPE), 26/47 facilities have partially adequate procedures for the supplying of PPE (2 of explored items), and 4/46 facilities have not adequate procedures for the supplying of PPE (1 or less of explored items).

Overall 42 centres have procedures for supplying PPE. On the other side, 4 facilities have no procedures available at all (specific data is not available for one facility). This is an important gap that should be addressed and overcome. Concerning the strategy used for supplying the majority of the centres (32, 68%) used both internal and external stockpile of PPE, while internal stockpiling or external supplying is used in 4 and 6 facilities, respectively.

A positive picture come out also from the question about the presence of a responsible person for monitoring the expiration date of PPE: almost 90% of the centres surveyed (42/47) answered positively. Only few facilities (13, 27.6%) report to have procedures for the decontamination of PPE in case of shortage, while the majority of facilities use disposable PPE

only. Among PPE that can be decontaminated, glasses and facial masks or helmet were the most frequently reported.

7.3 Comments and recommendations

All care facilities for HIDs should have:

- procedures for PPE selection;
- different protocols/procedures for the selection of PPE depending on the type of procedure (routine care versus aerosol-generating procedures, such as bronchoscopy and sputum induction);
- procedure for PPE donning and removal.

The **process of selecting an appropriate PPE** requires an understanding of the work activities associated with potential exposure and should therefore take in account several considerations. Careful risk-assessment balance between the need of protection and the "workability" should be done. Indeed, high-level PPE, such complete suites, provide higher protection, but may be impervious to work with, can be used for short shifts only, and may decrease the manual dexterity, increasing the risk of needle-stick injuries. Moreover, verbal communication among HCWs may be hampered by the use of complete suites. Despite these concerns, sometimes an high-level protection is needed, and appropriate training sessions and operative procedures may help to overcome these matters.

To summarize, when selection of PPE is needed, we have to consider three key concepts. **First** is the type of anticipated exposure. This is determined by the type of anticipated exposure, such as touch, splashes or sprays, or large volumes of blood or body fluids that might penetrate the clothing. PPE selection, in particular the combination of PPE, also is determined by the category of isolation precautions a patient is on. **Second**, very much linked to the first, is the durability and appropriateness of the PPE for the task. This will affect, for example, whether a gown or apron is selected for PPE, or, if a gown is selected, whether it needs to be fluid resistant, fluid proof, or neither. **Third** is fit. PPE must fit the individual user, and it is up to employer's duty to ensure that PPE are available in appropriate size for staff protection.

Sequence for the removal of PPE is important, too. The sequence for removing PPE is intended to limit opportunities for self contamination. Several proposed sequence for appropriate

PPE removal already exist, so we limit to recommend only general rules: (i) avoid the contact of contaminated gloves or hands with facial protection (goggles, face shield, respirators); (ii) goggles and face shield should be removed early in the sequence (with clean hands or gloves) because they are cumbersome and can impair vision during the PPE removal; (iii) always wash your hand after the removal of the gloves, and after each contact with potentially contaminated PPE. The location for removing PPE will depend on the amount and type of PPE worn and the category of isolation a patient is on, if applicable. If only gloves are worn as PPE, it is safe to remove and discard them in the patient room. When a gown or full PPE is worn, PPE should be removed at the doorway or in an anteroom. Respirators should always be removed outside the patient room, after the door is closed. Key-points about PPE donning and removal are summarized in the table 6.

Table 6 – Key-points about PPE donning and removal procedures

• a detailed and pre-defined sequence to remove PPE after their use has to be known by HCWs, who should be trained in removing PPE;

• the sequence depends on the PPE chosen, which ultimately depends on the HID managed;

• the HCW should be extremely careful in removing protection from the mucous membranes of the face with decontaminated hands, in order to prevent self-contamination with contaminated PPE or hands;

• PPE should be worn outside the patient room and should be removed in the anteroom, if present.

The use of pre-prepared PPE personal kits, already including all required PPE for a single entrance in the isolation facility, is in general advisable although have the limitation of not being able to fit everybody.

About appropriate and safe use of PPE, EuroNHID recommends:

All isolation facilities were single PPE including respirators are used (not complete suites including respirators) should:

- Regularly perform fit testing of all HCWs potentially involved in the management of a HID patient;
- Have protocols for the periodical repetition of fit-test.

Ideally, fit test should be repeated at a fixed interval (e.g evry 6 months or yearly) or in the following situations:

- when there is a change in facial features of the wearer;
- on demand of HCW when seal check does not work;
- when a medical condition that would affect respiratory function of the wearer emerges;
- at each change in supply of PPE (eg. different respirators...).

Manufactures have to be asked to provide fit test.

Alternatively, as a minimal requirement, fit-test should be performed during training session for HCWs before being admitted to work in the isolation setting

Moreover, EuroNHID recommends to:

- Perform seal check every time before entering in the patient's room;
- Have strategies for implementing and monitoring the correct use of PPE. Among these strategies, the supervision by an expert or the cross-check among HCWs are considered the best options, while self-assessment procedures (visual signals or mirror for self assessment) are considered as additional, not preferable options;
- Establish a maximum length of time before substituting each type of PPE.

Another aim of the survey concerning PPE was to address if the isolation facilities have strategies in place to ensure correct **supply of PPE**. Indeed, it is important to establish procedures for PPE selection, use, supply, replacement, maintenance, training, instruction, storage and keeping of appropriate records. All PPE should be used, maintained and stored in accordance with instructions from the manufacturer/supplier. Part of staff should be in duty to regularly inspect PPE and order replacements if required. Users of PPE must store the equipment in the accommodation provided. The equipment must be cleaned regularly and cleaned prior to use if shared.

PPE needs to be checked regularly both during storage and use and should be easily accessible when needed. Supervisors must carry out regular inspections to ensure that PPE is on hand and is maintained in good condition to ensure its continued effectiveness and must keep records on any acquisition, cleaning and training in relation to the equipment. Individuals must inform their Supervisor if there are deficiencies in the supply or condition of any PPE required to carry out work safely.

According to EuroNHID all isolation facilities should:

• have procedures/protocols in place for correct supply of PPE even in case of shortage. It is considered as optimal to have access to both internal and external stockpile;

- identify a person responsible of monitoring of PPE expiration date;
- use the same PPE as other city/region if possible (to offer a back up solution in case of need in order to facilitate procedure for supply/surge plan);
- draft some protocols for PPE disinfection and decontamination, to be used in the case of sudden increase of demand or shortage.

EuroNHID emphasize that reuse should be considered an option only in circumstances in which adequate supplies simply cannot be obtained. In case of shortage or increase in demand first priority should be given to HCWs performing aerosol-generating procedures, and the number of HCWs that will have access to HIDs patients should be limited as more as possible.

Main points about PPE management in isolation facilities managing HID patients are summarized in the table 8.

Table 8 – EuroNHID recommendations. Main points about PPE management in					
isolation facilities managing HID patients					
Selection of PPE	To ensure that the item of PPE will provide the level of protection that it is designed to, PPE should:	 be appropriate for the type of work and give appropriate protection for the risk give adequate protection to the user not create additional health or safety risks be compatible with other PPE being used (eg ear muffs with a hard hat) fit properly not interfere with any medical conditions of the user be comfortable comply with relevant European standards Consult with workers when selecting PPE and consider a person's individual characteristic and 			
Using PPE	Make sure that:	style preference. o PPE is used in accordance with the manufacturer's instructions o the PPE fits correctly o individuals are instructed and trained in how to use it o appropriate signs should be displayed to remind employees and students where PPE must be worn. o Training covers arrangements for the			
		provision, correct use, storage and maintenance of PPE and it is done when new employees, when you get new PPE, to refresh employee's memories			

		from time to time
	Minimum training shall include:	
		1. When the use of PPE is necessary
		2. What PPE is appropriate
		3. How to properly put on, adjust, use, and remove PPE
		4. Limitations of PPE
		5. Where to get PPE
		6. The proper care, maintenance, useful life, and disposal of PPE
Supplying PPE	Make sure that:	procedures/protocols are in place for correct supply of PPE even in case of shortage

Chapter 8 - Hand hygiene procedures

Main author: H.C. Maltezou

8.1 Introduction

Hand hygiene is the cornerstone for the prevention of health-care associated infections, as it decreases spread of pathogens within health-care facilities. Most nosocomial pathogens may survive on the hands of HCWs for several days and through them, in case hand hygiene and standard precautions are not employed appropriately and consistently, may transfer from hospitalized patients to other patients and HCWs, and cause nosocomial infections and outbreaks. Microorganisms may also survive on surfaces and inanimate objects for several days or weeks and transfer through HCWs hands to patients. In case of hospitalized patients with HIDs, prompt implementation of hand hygiene by HCWs is crucial for the safety of both patients and HCWs.

Definitions that refer to hand hygiene are listed below [41-43]:

- Hand hygiene: the process of hands washing with soap and water, antiseptic wash, or spread with antiseptic.
- Hand washing: washing of hands with liquid (non-antiseptic) soap and water. It removes dirt and part of the transient microbial flora from HCWs hands.
- Hand antisepsis: wash with an antiseptic or spread of antiseptic agents on hands.
- Antiseptic agents: antimicrobial agents that are applied in skin in order to reduce the microbial burden of skin (e.g. alcohols, chlorexidine).
- Alcoholic agent: alcohol-containing agent for application on hands. Usually contains 60-90% ethanol or isopropanol. Often, an agent (e.g. glycerol) is added in order to minimize skin dryness and irritation.
- Visibly soiled hands: hands that have visible dirt or are visibly contaminated with biologic materials (e.g. blood, urine, stool).
- Plain soap: soap used for the mechanical removal of visible dirt does not provide antiseptic action.

Normally a high bacterial number $(3.9 \times 10^4 - 4.6 \times 10^6 \text{ CFUs/cm}^2)$ of bacteria is found on HCWs hands. Skin flora consists of transient and permanent flora. Transient flora colonizes the superficial skin layers and consists of microorganisms transferred to HCWs hands following contact with patients or contaminated inanimate objects. These microorganisms are almost always pathogenic for humans, are transmitted easily to other patients, and constitute the main source of nosocomial infections. In contrast, permanent flora colonizes the deeper skin layers, consists of microorganisms that are permanently isolated from the hands of HCWs (e.g. Coagulase-negative *Staphylococcus, Corynobacterium*), and does not cause systemic infections, except in immune-compromised patients. Hand hygiene is applied in order to eliminate transient flora on HCWs hands.

There are two categories of antiseptics available currently: alcohol-based antiseptics (usually containing 60-95% ethanol or isopropanol) and chlorexidine. Alcohol-based antiseptics offer advantages for clinical use, including easy application, minimal time required, high and rapid efficacy (removal of high proportion of transient flora from HCWs hands). Alcohol-based antiseptics demonstrate excellent activity against Gram-positive and Gram-negative bacteria, including multi-resistant strains, fungi, and mycobacteria, and also at the above mentioned quantities, against hepatitis B and C viruses. Alcohol-containing gels are less effective compared with other alcohol-based antiseptics. Alcohol-based antiseptics have minimal efficacy against *Clostridium difficile*, although higher that those demonstrated by other antiseptics. Glycerol at 1-3% is usually added in order to prevent skin irritation. Hand hygiene agents should be accepted by HCWs, in order to achieve and sustain increased compliance rates with hand hygiene.

Antiseptics in general have minimal or negligible action against *C. difficile*. In such cases, infection control should rely on mechanical removal of spores from HCWs hands through meticulous hand washing with water and soap after removal of gloves and strict implementation of contact precautions.

Compliance rates with guidelines for hand hygiene range from 5-81% globally (mean rate: 40%). Low compliance rates have been associated with:

- skin irritation;
- difficult access to water basin;
- absence of soap, antiseptic, and/or hand towels;
- not enough time for hand hygiene;
- prioritization of patients care;

- feeling protected by wearing gloves;
- limited responsibility for the safety of patients;
- ignorance of guidelines;
- ignorance of indications for hand hygiene.

The World Health Organization (WHO), as part of its First Global Patient Safety Challenge "Clean Care is Safer Care", recommends implementation of multi-faced strategies to increase compliance with guidelines for hand hygiene among HCWs.

Strategies to increase compliance with hand hygiene include:

- continuous training of HCWs;
- systemic surveillance and feedback;
- easy access to sinks, soap, towels, antiseptics;
- use of posters and leaflets to educate and remind hand hygiene;
- training of patients to remind hand hygiene to HCWs;
- reward of HCWs who comply systematically;
- provision of protective products (emollients);
- ensuring an adequate ratio of HCWs to patients.

8.2 Data from checklists (aggregate and punctual data)

Questions about hand hygiene are available in Checklist Part B: Hospital Procedures, questions 8.a, 8.b, 8.c. Questions, answers, and comments referring to hand hygiene are presented below.

General item 8: Hand hygiene procedures

Topic 8.a) Availability of procedures for hand hygiene

The isolation facility has procedures for hand hygiene. (Deriving from: Checklist II, questions C.1.a-c)

Strength score: A

Evaluation score

- A: procedures for hand hygiene available
- B: option not present
- C: procedures for hand hygiene not available

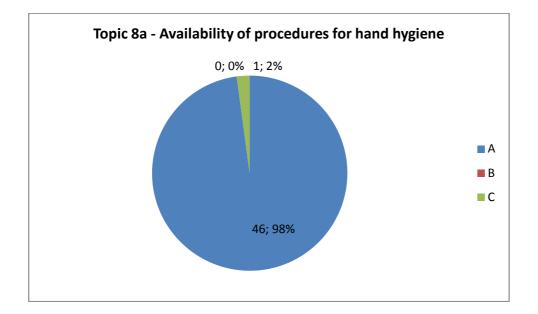


Figure 8.1 – Availability of procedures for hand hygiene (valid answers: 47)

Regarding availability of procedures for hand hygiene within Isolation Units, the situation is considered adequate all over Europe.

Topic 8.b) Presence of adequate technical features for hand hygiene

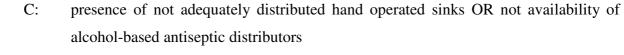
The isolation facility has adequate technical features for hand hygiene (adequate number of sinks and appropriate distribution, availability of non-hand operated sinks, availability of alcohol-based antiseptic distributors). (Deriving from: Checklist II, questions C.2.a, C.2.b)

Strength score: A

Evaluation score:

- A: presence of adequately distributed non-hand operated sinks and availability of alcohol-based antiseptic distributors ;
- B: presence of adequately distributed non-hand operated sinks and not availability of alcohol-based antiseptic distributors OR presence of adequately distributed hand operated sinks and availability of alcohol-based antiseptic distributors OR not

adequately distributed non-hand operated sinks and availability of alcohol based antiseptic distributors



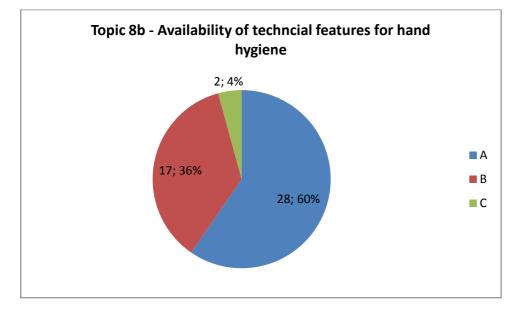


Figure 8.2 – Availability of technical features for hand hygiene (valid answers: 47)

The presence, and the adequate distribution of basins, preferably non hand-operated in order to prevent contamination by contaminated hands and gloves, is very important in order to facilitate the access to hand hygiene procedures by HCWs. Similarly, also distributors of alcohol based solution are crucial. Although adequate technical features for hand hygiene were disclosed in most (60%) interviewed isolation facilities in Europe, in 40% of them technical features were partially or mostly inadequate.

In particular about availability and location of basins, 36 facilities report to have non handoperated basins, while 35 report to have hand-operated ones. The most frequent locations of these basins have been reported to be, respectively, the anteroom, the isolation room, and the staff room.

Topic 8.c) Existence of procedures for the promotion and the monitoring of hand hygiene The isolation facility has procedures for the promotion of the procedures hand hygiene. (Deriving from: Checklist II, questions C.3.a-c)

Strength score: A

Evaluation score

- A: presence of procedures for the promotion of hand hygiene, periodically employed, and regularly monitored
- B: presence of periodically employed procedures for the promotion of hand hygiene, not regularly monitored
- C: procedures for the promotion of hand hygiene not in place

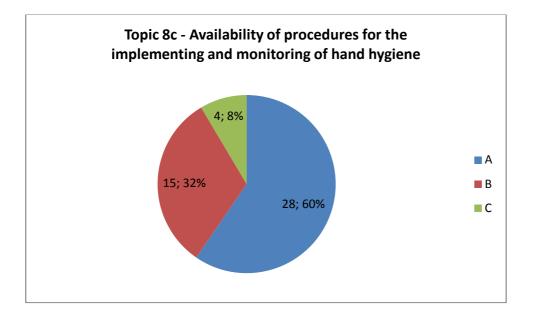


Figure 8.3 – Procedures for the implementation and monitoring of hand hygiene procedures (valid answers: 47)

Hand hygiene procedures are regularly implemented and monitored in most surveyed facilities. Otherwise, these practices are not monitored in 19 facilities.

Data from checklists: specific evaluation aspects and outcome

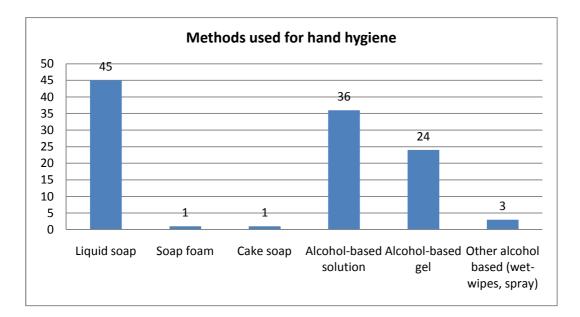


Figure 8.4 – Methods used for hand hygiene (Deriving from: Checklist II, questions: C.1.b, C.1.c, valid answers 47, multiple answers possible)

Liquid soap and alcohol-based solution are the most used methods for the performing of hand-hygiene in the surveyed isolation facilities. Alcohol-based gel is widely used, also, while other methods, such as soap foam, cake soap or wet wipes and spray containing alcohol, are used in few facilities.

8.3 Comments and recommendations

Within an Isolation Unit, hand hygiene should always and strictly practiced:

- before and after all contacts with a patient, which, in the case of a HID, means before wearing and after removing gloves (please refer to the section on PPE);
- between patients.

HCWs should wear (non-sterilized) gloves during:

- patient contact;
- any contact with biologic material (e.g. blood, urine);
- procedures that carry a risk for contact with biologic material (e.g. during blood sampling);
- contact with mucus membranes;
- contact with skin lesions;
- contact with contaminated objects or surfaces;

- when there is a skin lesion or disruption at their hands;
- during cleaning-decontaminating procedures.

Hand hygiene and use of gloves concern all patients, all HCWs categories that may be at risk for contact with a biologic material or an infectious agent, and all potentially contaminated objects and surfaces. HCWs with ulcerative or exudative skin lesions should be strictly excluded from caring of immune-compromised patients and young infants. In case of a patient with HID, gloves constitute part of PPE (please refer to the relevant section for details). Gloves should be changed when they are damaged.

Hand hygiene is a fundamental part in the appropriate process of PPE removal (please refer to chapter 7). Attention should be paid during gloves removal: the inside surface should turn to outside, while contact between skin and outer surfaces of gloves should be avoided. Gloves should be thrown immediately after removal and never reused in the same or another patient. After removal of gloves, hand hygiene should always be practiced. HCWs should keep in mind, that gloves do not protect from needle sticks or accidents with sharp objects, and that they are not a substitute for hand hygiene.

Regarding the practice of hand hygiene, the following apply:

- When there is visible dirt, hands should be washed thoroughly under running water and soap;
- In all other cases, an antiseptic agent should be preferred;
- The appropriate quantity (3-5 ml, in accordance with the manufacturer) should be applied and all surfaces (between fingers, wrists, under nails) should be covered for at least 15 seconds;
- Plain soap should not be used;
- Hands should be dried using disposable paper towels. Air dryers should not be used in isolation facilities;
- If non-hand operated sinks are not available, disposable paper towels should be used in order to close the drain;
- HCWs nails should be kept short;
- Artificial mails and jewelries should be avoided;
- Warm water should be avoided for hand washing.

Posters using pictures in order to promote appropriate techniques for hand hygiene should be posted near sinks and antiseptic solutions. Written protocols about hand hygiene should be in place.

All HCWs who may be in contact with infectious agents or biologic material (e.g. HCWs in direct patient care, laboratory personnel, housekeeping personnel, personnel working in the laundry) should be trained in hand hygiene regularly. Monitoring and audit procedures should be also in place. Attention should be paid in order to ensure that employees working under no permanent conditions (e.g. through one-year contracts with private laundry and housekeeping companies) have been trained appropriately. Alcohol-based antiseptic distributors should be available at the bed site and sinks.

EuroNHID recommendations

Optimal requirements are included in the comment section

Minimal requirements

In order for an isolation facility to manage a patient with HID without compromising safety of HCWs and other patients, written protocols about procedures for hand hygiene should be in place. Posters and pictures indicating the appropriate techniques should be posted above sinks and alcohol-based distributors. One sink (preferably non hand operated) should be available per anteroom. Alcohol-based antiseptic distributor should be available by the sink.

Isolation units should promote hand hygiene through campaigns and educational events in order to train HCWs and promote hand hygiene. These should be done on a regular, continuous basis (e.g., annual "Hand Hygiene Week"), in order high compliance rates among HCWs are achieved and sustained. Compliance with recommendations for hand hygiene should be regularly monitored and audit should be available.

Chapter 9: Prevention of Needle-Stick Injuries

Main author: H.C. Maltezou

9.1 Introduction

Transmission of infectious agents through needle stick injuries constitutes a serious and real threat for HCWs during every-day clinical practice. Needle stick accidents and accidents with sharp objects have been implicated in the transmission of hepatitis B and C viruses, and human immunodeficiency virus (HIV) within health-care settings. In particular, the risk of transmission and seroconversion is 30% for a needle stick from a HbeAg+ patient, 3% for an anti-HCV+ patient, and 0.3% for a HIV+ patient [44-47]. Written protocols for prompt management of cases of needles stick injuries and accidents with sharp objects should be in place, and appropriate agents (e.g. specific hepatitis B immunoglobulin and hepatitis B vaccine for a hepatitis B case, antiretroviral treatment for a HIV case) should be available on a 24-hour basis. However, **in case of a patient with a viral hemorrhagic fever, a needle stick could be detrimental for the HCWs life** [48].

9.2 Data from checklists (Aggregate and punctual data)

Questions about needle stick injuries are available in Checklist Part B: Hospital Procedures, questions 9.a, 9.b, 9.c. Questions, answers, and comments referring to prevention of needle stick injuries are presented below.

General item 9: Prevention of needle-stick injuries

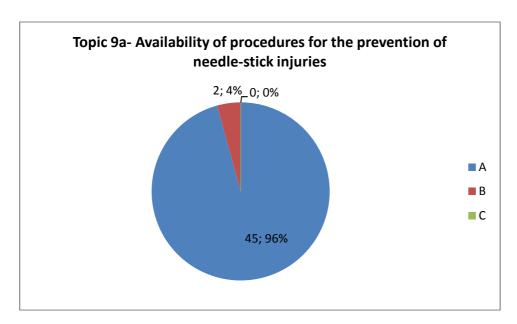
Topic 9.a) Availability of procedures for the prevention of needle stick injuries.

The isolation facility has procedures for the prevention of needle stick injuries. (Deriving from: Checklist II, questions D.1.a-c)

Strength score: A

Evaluation score

- A: procedures available both for the prevention of needle stick injuries and for the management of accidents
- B: procedures available for only one of explored items



C: procedures not available

Figure 9.1 – Availability of procedures for the prevention of needle-stick injuries (valid answers: 47)

The overall situation around Europe about the explored topic is considered adequate. All surveyed facilities but 2 report to have procedures in place for both management of needle-stick injuries and accidents. Among those resulted to be partially adequate, 1 report to have not protocols for the prevention of needle-stick injuries, while the other one report to have not written protocols in case of needle-stick accidents.

Topic 9.b) The isolation facility ordinarily use technical devises for the prevention of needle stick injuries. (Deriving from: Checklist II, questions D.2.a, D.2.b)

Strength score: A

Evaluation score:

A: At least half (7) of explored medical devices in use

- B. from 3 to 6 explored medical devices in use
- C: less than 3 of explored medical devices in use OR specific sharp boxes not available, independently from the number of explored items in use

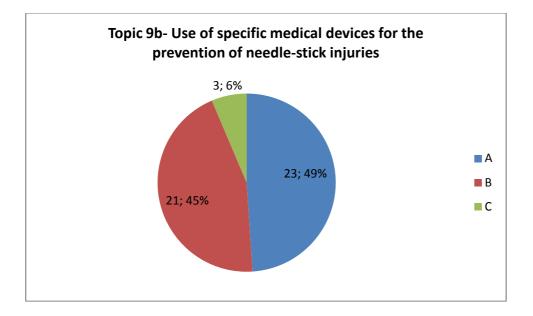


Figure 9.2 – Use of specific medical devices for the prevention of needle-stick injuries (valid answers: 47)

Although adequate technical devices for the prevention of needle sticks were available in about half of interviewed isolation facilities in Europe, in the other half availability of specific medical devices (safety-engineered needles and other devices) is partially adequate or inadequate. All facilities report to use specific, secure sharp box, some of them report to do not use of to use very few specific safety engineered devices.

Topic 9.c) Availability of protocols for the promotion and monitoring of prevention of needle stick injuries

The isolation facility has procedures for the promotion of the prevention of needle stick injuries.

Strength score: A

Evaluation score:

- A: presence of periodically employed procedures for the promotion of the prevention of needle stick injuries, regularly monitored
- B: presence of periodically employed procedures for the promotion of the prevention of needle stick injuries, not regularly monitored
- C: procedures for the promotion of the prevention of needle stick injuries are not available

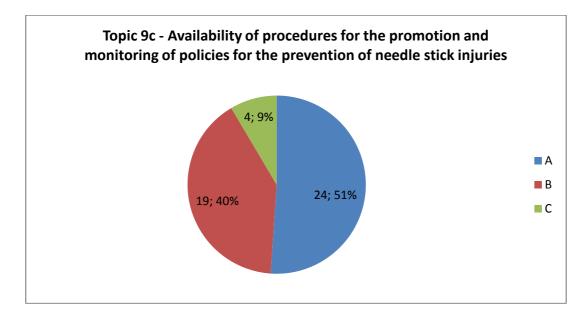


Figure 9.3 - Availability of protocols for the promotion and monitoring of prevention of needle stick injuries (valid answers: 47)

The protocols for the prevention of needle stick injuries are promoted and regularly monitored about in the half of surveyed facilities. In the remaining, these procedures are not monitored, or not promoted al all.

Data from checklists:	specific evaluation	aspects and outcome
Dutu II OIII CHEEKIISISI A	pecific cratation	aspects and outcome

Table 9 – Needle stick prevention devices in use in surveyed facilities				
Device	Ν			
Hypodermic needles and syringes (sliding sheath / sleeve; needle guards)	30			
Needleless jet injection systems	17			
Retractable needles / syringes	27			
Pre-filled syringes	23			
Needleless IV access – blunted cannulas	17			

Prefilled medication cartridge with safety needles	12
Shielded or retracting peripheral IV catheters	28
Central venous catheter kit with integral needle protection	11
Peripherally inserted central catheter kit with integral needle protection	13
Epidural / spinal needles with safety epidural needle	6
Arterial blood gas syringes	22
Safety engineered blood collection needles	22
Safety engineered blood collection needles with tube holders	22
Winged steel needle (butterfly) blood collection sets	37

In the surveyed facilities, the most used engineered medical devices for the prevention of needle stick injuries are the butterfly blood collection sets, followed by various type safety engineered needles and syringes. Safety engineered devices for invasive procedures (central venous catheter and epidural/spinal needle) are used less frequently.

9.3 – Comments and recommendations

Handling of needles and other sharp objects should be done cautiously. Since most accidents occur during handling of already used needles or sharp objects, each stick or contact of non-intact skin or mucus membrane with a contaminated needle or sharp object may result to infection. Glass tubes should be strictly forbidden for collection and storage of HID agents.

HCWs working in isolation facilities that are involved in blood sampling, should be trained regularly about the appropriate safe procedures. Written protocols should be in place, while reminding written material with pictures should be posted at the bed site.

Continuous training of HCWs, including those involved in indirect patient care and potential exposure to biological materials (e.g. laboratory personnel, housekeeping services) about the modes of transmission of infectious agents with emphasis on HIDs, and the appropriate implementation of standard precautions, should be provided. Written protocols about the management of accidental spoilage of blood and other biological material should be in place and updated regularly.

EuroNHID recommendations

Optimal requirements

The basic principles for safe and secured handling of needles and sharp objects are presented below:

- HCWs handling biologic specimens, needles and other sharp objects should always wear (non sterilized) gloves. In case of a patient with a HID, gloves are part of PPE (please refer to the relevant chapter for details);
- 2. Gloves do not protect from needle stick injuries;
- 3. Needles and other sharp objects should be handled **carefully** and **never in hurry**;
- 4. Non-reusable (disposable) needles should be used only;
- 5. Needles should be thrown after their use to the closest sharp box;
- 6. A sharp box should be available on a trailer, at the bed site of a patient with a HID;
- 7. The use of a routinely secured arterial line and central line access by a HID-trained physician, will allow safe serial blood sampling and drug administration without using needles;
- 8. Never throw a needle or a sharp object on waste bags;
- 9. Never recap a needle;

10. Used needles should never been left on the patient's bed, linens, or anywhere else;

- 11. Needles and sharp objects should never been removed from the sharp box;
- 12. Sharp boxes should be checked regularly, and replaced when they are ³/₄ full;
- 13. Only needles and sharp objects are thrown in sharp boxes;
- 14. In case of accidental exposure to blood or other biologic material from a patient with a HID, the HCW should immediately wash meticulously the affected body site with affluent running water and soap. No evidence exists that using antiseptics for wound care or expressing fluid by squeezing the wound further reduces the risk of blood-borne pathogen transmission; however, the use of antiseptics is not contraindicated. The application of caustic agents (e.g. bleach) or the injection of antiseptics or disinfectants into the wound is not recommended. In case mucus membranes are exposed (e.g. eyes), these should be immediately washed with affluent running water.

Minimal requirements

In order for an isolation facility to manage a patient with HID without compromising HCWs safety, written protocols about procedures for the prevention of needle stick injuries and for the prompt management of accidents should be in place. Reminding material with pictures indicating the appropriate techniques should be posted at the bed site. One sharp box and as more as possible devices for safe sampling of blood and other biologic material should be available. A sharp box should be at the bed site of a patient with HID. Isolation units should employ procedures for the promotion of the prevention of needle-stick injuries periodically. Practical training is fundamental, because a good "practical skill" is important for the safe use of theses devices. Reminding posters and pictures indicating the appropriate techniques should be posted by the bed site of a patient with HID.

Chapter 10 - Hygiene and Disinfection Issues

Main author: H.C. Maltezou

10.1 Introduction

Hospitalization and management of a patient with HID constitutes a challenge, since it almost always requires the provision of high-level, sophisticated medical services without compromising safety of HCWs and other hospitalized patients. Routine hygiene and disinfectant issues are critical in order to eliminate the possibility of spread of a HID in the hospital setting and the community [49,50].

Written protocols about procedures and appropriate liquid disinfectants for the routine hygiene and final decontamination of isolation rooms and other spaces (e.g. emergency room, laboratory department) in case of a HID patient should be in place and updated regularly. Such protocols should be syndrome-specific (e.g. VHFs) or pathogen-specific (e.g. smallpox, *C. difficile*), and provide in details the procedures and appropriate disinfectants for high-level decontamination of equipment/objects that are in contact with blood, the cardiovascular and respiratory systems. Written protocols about procedures for the routine hygiene, final decontamination or discarding should be available for decontamination of all non-disposable items/ equipment/ devices. Written procedures about the management of accidental spoilage of blood or other biological material should also be in place.

10.2 Data from checklists (Aggregate and punctual data)

Questions about hygiene and decontamination are available in Checklist Part B: Hospital Procedures, questions 11.a, 11.b, 11.c, 11.d. Questions, answers, and comments referring to hygiene and decontamination are presented below.

General item 11: hygiene and disinfection

Topic 11.a) Availability of procedures for hygiene and disinfection

The isolation facility has procedures for the routine hygiene and final disinfection of its rooms. (Deriving from: Checklist II, Questions F.1.a, F.1.b)

Strength score: A

Evaluation score:

- A: procedures available both for routine hygiene and final disinfection
- B: procedures available for routine hygiene or for final disinfection
- C: procedures for routine hygiene and final disinfection not available

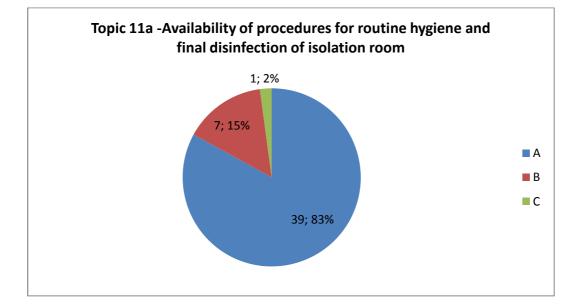


Figure 10.1 – Availability of procedures for routine hygiene and final disinfection of isolation room

Routine hygiene, to be performed during the admittance of a HID patient, is very important, such as the existence of procedures for the final disinfection of the isolation room before its re-use for routine patients or another patient with a suspected/confirmed HID. Although most (83%) isolation facilities have procedures available both for routine hygiene and final disinfection, a significant (17%) number of European isolation facilities has not. In particular, in 5 facilities procedures for final disinfection are not available.

In particular about final disinfection, the used methods may be summarized in two categories: surface cleaning and disinfection, or fumigation, using different disinfectant agents. These information are summarized in the figure 10.2

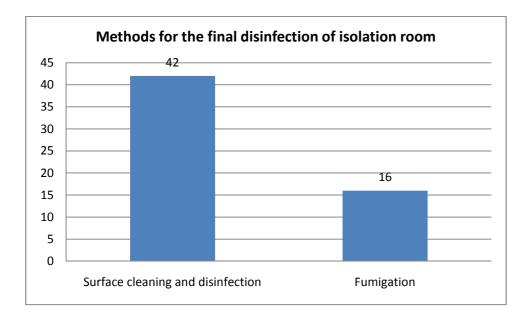


Figure 10.2 – Methods for the final disinfection of isolation room (valid answers: 42, multiple answers possible)

Topic 11.b) Availability of procedures for hygiene and disinfection of other areas (Deriving from: Checklist II, questions F.1.c)

Procedures for the routine hygiene and final disinfection of other areas (emergency and diagnostic departments, others) are available.

Strength score: A

Evaluation score

- A: procedures available both for routine hygiene and final disinfection
- B: procedures available for routine hygiene or for final disinfection
- C: procedures for routine hygiene and final disinfection not available

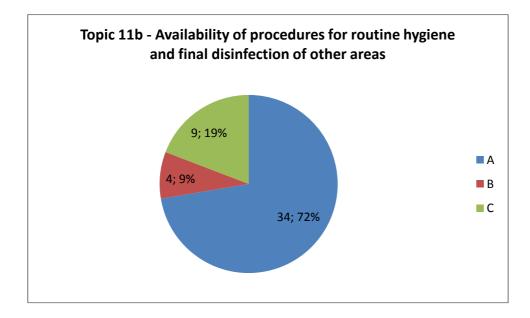


Figure 10.3 - Availability of procedures for routine hygiene and final disinfection of other areas (Valid answers: 47)

HID patients, before diagnosis, may be admitted in other areas (emergency department, general ward), or other areas may be utilized during the admission in the isolation facilities (radiology and diagnostic departments, intensive care unit). Consequently, specific procedures for hygiene and disinfection should be available for other areas, too. These procedures are totally or partially lacking in 28% of surveyed centres. Among the facilities reporting procedures for the routine hygiene and final disinfection of other areas, no one report to use fumigation, while some of them (3 facilities) report to have procedures for final disinfection only.

Topic 11.c) Disinfection and discharge of non disposable items/instruments/devices (Deriving from: Checklist II, questions F.1.d)

Specific procedures for the routine hygiene, final disinfection or safe discarding of all non disposable items/ instruments/ devices used are available.

Strength score: A

Evaluation score

A: procedures for the routine hygiene, final disinfection or safe discarding of non disposable items/instruments/devices available

B:

C: procedures for the routine hygiene, final disinfection or safe discarding of non disposable items/instruments/devices not available

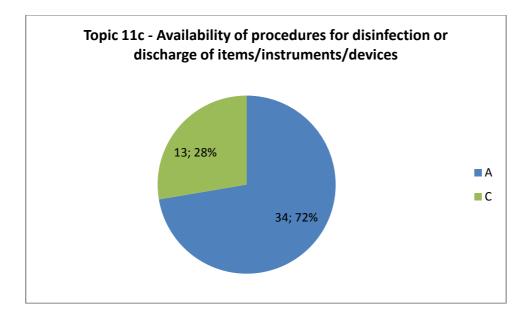


Figure 10.4 – Availability of procedures for disinfection or discharge of contaminated items/instruments/devices (Valid answers: 47)

Some items, diagnostic instruments, medical devices must be decontaminated before re-use. For example, specific procedures are needed for the disinfection of bronchoscope, or haemodialysis machine, after their use with a HID patient. Similarly, these procedures are needed for the decontamination or non-disposable, re-usable PPE. The majority of centres (34, 72%) report to have developed such procedures. Among the 24 facilities reporting further details about these procedures, almost all report to use them for all non-disposable items, 4 report to use these procedures for endoscopies only, while other 2 report to cover all used items/instruments/devices in plastic draping and wait for an adequate time before routine disinfection.

Topic 11.d) Personnel performing the hygiene and decontamination is adequately trained. (Deriving from: Checklist I, questions C.2.a)

Strength score: A

Evaluation score

A: housekeeping personnel is specifically trained OR other procedures are in place (housekeeping performed by doctors and nurses)

- B: -
- C: housekeeping personnel is not specifically trained and no other safe procedures are in place

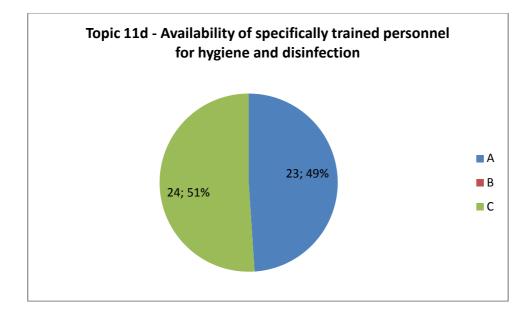


Figure 10.4 – Availability of specifically trained personnel for hygiene and disinfection (Valid answers: 47)

Both routine hygiene and final disinfection of isolation room should be performed wearing adequate PPE, and using special attention in avoiding aerosolization by shaking of contaminated objects. Consequently, these operations should be performed by a team with a basic training about these issues. Such workers are reported to be available in about half of surveyed facilities.

10.3 Comments and recommendations

The principles of routine hygiene and final decontamination for HIDs are listed below:

- The isolation room should be designed in order to promote routine hygiene and decontamination procedures;
- The materials used in the construction of the isolation room (walls, furniture), should be easily cleaned and disinfected, resist frequent and intensive disinfection, be non-porous, and repel dust;

- Decontamination should be a principal factor for selection of equipments and medical devices in these facilities. Disposable items/ devices or items/ devices that can be safely decontaminated should be preferred;
- In case of a patient with a HID, non-disposable medical equipment (e.g. **bronchoscope**) **should be dedicated to the care of this patient only and during his entire hospitalization.** In case this is not feasible, medical equipment may be used in other patients, only after high-level disinfection using a disinfectant with wide-spectrum antibacterial and antiviral action has been accomplished, and only after the nature of the HID is taken under consideration;
- Spillages of blood and other biologic material should be immediately removed and decontaminated;
- All surfaces and equipments within the patient's isolation room should be cleaned and decontaminated twice per day (routine hygiene);
- Meticulous cleaning and decontamination should be applied after discharge of a patient with a HID (final decontamination);
- Final decontamination should cover all objects/devices/ equipment/ furniture of the isolation room, including filtering system;
- Cleaning and decontamination of horizontal and vertical surfaces and furniture of the isolation room should be accomplished with appropriate hospital detergents;
- In case hypochlorite Na solution (1000ppm) is used, it should be produced on site in real time;
- In order to eliminate the possibility of nosocomial spread of a HID agents, **dry mopping and household vacuum should be forbidden within isolation facilities** - wet vacuum should be preferred;
- The disinfection procedure of items/ equipment should be performed in the anteroom of the isolation room;
- For decontamination of large and complex equipments, a pre-identified, dedicated area within the isolation facility should be available;
- For mechanical devices that cannot be immersed within a disinfectant, appropriate procedures of disinfection of environmental surfaces should be implemented. In case this is not feasible, it is advisable to use an autoclave;
- Large and complex equipment may require decontamination site before disassembly, and a fumigation procedure may be applied;

- Fumigation (preferably using 5% H2O2) may be applied following terminal decontamination;
- Integral autoclave facilities or safe access to pre-identified, dedicated autoclave facilities should be in place;

Housekeeping personnel and other HCWs involved in routine hygiene and final decontamination in HLIUs, should be trained appropriately and on a regular basis, including the use of PPE (please refer to Chapter 7). Monitoring and audit in order to investigate compliance of HCWs with written procedures should be conducted periodically.

EuroNHID recommendations

Optimal requirements are included in the comment section

Minimal requirements

In order for an isolation facility to manage a patient with HID without compromising HCWs safety, written protocols about procedures for routine hygiene and final disinfection should be in place, including other areas (e.g., emergency and diagnostic departments). Written protocols about procedures for routine hygiene, final disinfection or safe discarding of non disposable items/devices/instruments should be in place as well. When possible, disposable items/devices/instruments should be used. Housekeeping personnel should be specifically and routinely trained, or other procedures (as those presented in the questions) should be in place. HCWs should be familiar with procedures about hygiene and decontamination procedures. Periodical monitoring and audit is recommended.

Chapter 11 – Management of clinical waste

Main author: P. Brouqui

11.1 Introduction

The most common source of infection from clinical waste is from needle stick injuries, transmitting blood-borne virus infections. However, contamination of mucosa or intact skin, or inhalation of droplets or aerosols from infectious material can also lead to infection [20]. An outbreak of tuberculosis in waste workers exposed in an industrial setting has been reported, and even small-scale compaction of waste can generate pathogen-containing aerosols [51]. Moreover, HCWs are at risk of infection from exposure caused by splash, spillage, or aerosol generation during handling or disposal of infected fluids, and there is a theoretical risk for engineers or others working on drainage or sewage systems within or close to the unit.

According to the European Hazardous Waste Directive and related, waste from the management of patients with a known or suspected infectious disease, where the causal pathogen or toxin is present within, must be identified, separately packaged, and incinerated. Particularly about waste from HIDs patients, decontamination of solid waste by autoclaving is suggested by experts. The European Hazardous Waste Directive was originally underpinned by the European Waste Catalogue (EWC 1994) and Hazardous Waste List (HWL). These have been updated, combined and significantly extended [20].

Some countries have built on the guidance of the Directive to identify low-risk medical (clinical) waste and to categorize it as non-hazardous [52]. This philosophy differs from the belief in the USA that universal waste handling precautions are more likely to ensure the safe handling of all potentially hazardous clinical waste [51]. Waste which may contain hazard group 3 and 4 pathogens clearly must be handled as hazardous waste.

11.2 Data from the surveys (aggregate and punctual data)

General item: 12. Waste management

Topic 12.a) Management of solid clinical waste

The isolation facility has procedures for the decontamination of solid waste (Deriving from: Checklist II, Question G.1.a)

Strength score: A

Evaluation score:

- A: Procedures for the management of solid waste are available, and include the decontamination inside the facility
- B: Procedures for the management of solid waste are available, but do not include the decontamination inside the facility
- C: Procedures for the management of solid waste are not available

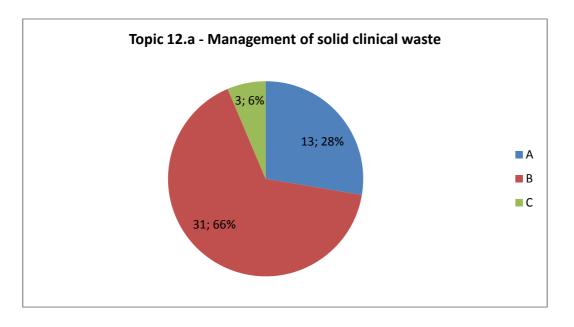


Figure 11.1 – Procedures for the management of solid clinical waste

If 28 % of the surveyed isolation facilities are capable of solid waste decontamination inside the units, the majority have protocols and use nearby autoclaving in the same hospital or secure transportation, in special containers, to incineration in an external facility. In 3 centres no protocols are available for solid waste management.

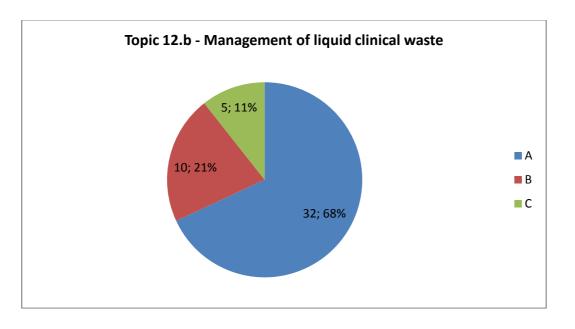
Topic 12.b) Management of liquid waste

The isolation facility has procedures, according to risk assessment, for the management of liquid waste (Deriving from: Checklist II, question G.1.b)

Strength score: A

Evaluation score:

- A: Procedures for the management of liquid waste are available, and include the decontamination before the disposal
- B: Procedures for the management of liquid waste are available, but do not include the decontamination before the disposal



C: Procedures for the management of liquid waste are not available

Figure 11.2 – Procedures for the management of liquid clinical waste

32 over the 47 centres have procedures and decontaminate the liquid waste before disposal in the hospital drain, 10 centres have specific procedures not including decontamination of the liquid waste before disposal, while 5 have no procedures for liquid waste.

Topic 12.c) Technical features for appropriate waste management

The isolation facility has adequate technical features for the management of solid and liquid waste (autoclave, secure containers if transport is needed, chlorination basins, other collectors

for decontamination treatments). (Deriving from: Checklist I, question A.4.f; Checklist II, questions G.1.a, G.1.b, G.2.a, G.2.b)

Strength score: A

Evaluation score:

- A: Optimal technical features are available both for solid waste (autoclave) and for liquid waste (autoclave after jellification or collectors for decontamination processes)
- B: Optimal technical features are available only for solid or liquid waste OR suboptimal technical features (transport in secure containers without prior decontamination) are available
- C: Technical features for the management of solid and liquid waste are not available

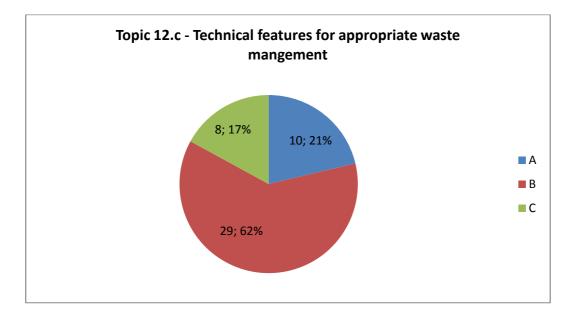


Figure 11.3 – Existence of technical features for appropriate management of clinical waste

39 facilities (83%) have an optimal or sub optimal decontamination process of both the liquid and solid waste by either autoclaving within the isolation area or collecting and disinfecting the liquid waste or solidifying and autoclaving the liquid waste or by incineration after secure packaging their solid waste. In 8 facilities, technical equipments for the safe management of waste (autoclaves and chlorination basins or other specific drain systems) are not available.

Data from Checklists: Specific evaluation aspects and outcome.

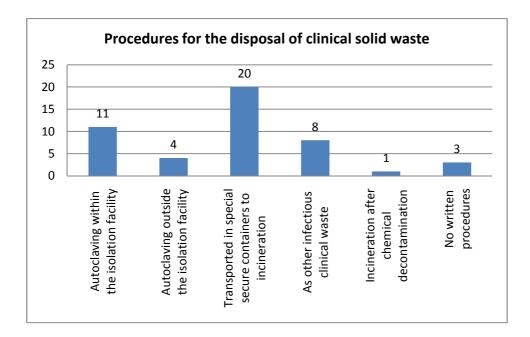


Figure 11.4 - Procedures for the disposal of clinical solid waste (Deriving from: Checklist II, question G.1.a, valid answers: 47)

All but 3 centres have a reasonable decontamination process of their solid waste, although some process such as transportation of non-decontaminated materials even in secure containers to the incinerator is not supported by regulation in some European states.

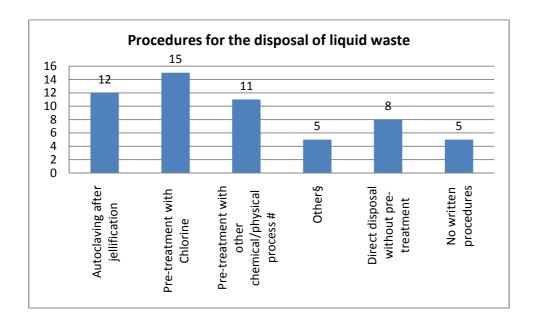


Figure 11.5 - Procedures for the disposal of liquid waste (Deriving from: Checklist II, question G.1.b, valid answers: 47)

The majority of centres have procedures and decontaminate their liquid waste before disposal in the hospital drain. Most centres use decontamination with either chlorine or other chemical or physical process. Some facility use more than one solution on the basis of risk assessment, or on the basis of the liquid to be disposed. In 8 facilities, the problem of decontamination of liquid waste is expressly faced in their infection control procedures, but they may choose, on the basis of a risk assessment, to not decontaminate liquid waste before disposal. Only 5 centres report to have not written procedures on this point.

11.3 Comments and recommendations

Current methods of disinfecting solid waste includes **incineration** which usually involves burning the waste at temperatures of 450-550°C, followed by further incineration of the resulting smoke and vapor at temperatures around 1100°C to destroy dioxins. **This has been shown to kill vegetative organisms, cells and bacterial spores** [53]. In an increasing number of countries, environmental legislation discourages incineration of clinical waste at the site where it is generated, making it necessary to transport waste to large, industrial incineration sites. It is the most frequently used method by many isolation facilities in Europe for highly contagious waste as it follows the Hazardous Waste Directive. However, in some circumstances, waste may be stored, transported and handled by the lowest-paid and most transient hospital staff, or by contractors, leaving the process at risk of a variety of mistakes and omissions [51]. One may consider that the risk of contamination with a Class 3 or 4 agent is similar on this clinical setting than in laboratory conditions and the rule reported in the last edition of the BLBM should likely apply "Infectious waste from BSL-3 laboratories should be decontaminated materials even in secure container to the incinerator is not supported by regulation in some European states.

Other methods used to disinfect waste have included microwaving, autoclaving or electro thermal deactivation (heating by passing electrical energy through the waste). Microwaving as a mean of heat-treatment can effectively sterilize waste, but the seal on the equipment must be secure to avoid release of aerosols generated by small explosions during heating [54]. More recently, local treatment of waste has been attempted by a process of grinding the waste and then injecting the oxidizing agent, ozone. This process reduced the bacterial count by a factor of 10 [55], which is not sufficient for heavily contaminated with hazard group 4 pathogens. In fact the method of choice for solid waste decontamination in many European countries is autoclaving, as this can be

controlled by recording the time and temperature of the autoclaving process, and by measuring temperatures within the waste load to ensure that they reach levels known to destroy the pathogens. Most hospitals have a number of autoclaves in various departments, so that regular maintenance and validation is part of the hospital engineers' routine work [20]. Although bulky, the equipment can usually be accommodated within or near to the clinical facility. However, the process of autoclaving is time-consuming because the volume that can be treated at a time is small compare to the important volume of material to be decontaminated. Consequently, packaging and other nonclinical material, such as information leaflets, should be let outside of the Isolation Unit and could then be disposed of in the domestic waste system. Thus the amount of clinical waste which required autoclaving is reduced by approximately half [56]. There is a logistic problem with the local use of a special treatment process. This is the need to maintain the engineering and function of a system which may be complex, and is often not in continuous use. A lack of readily-available expertise and spare parts, together with deterioration of equipment which is not regularly used, both contribute to reduced functionality and safety. For such equipment, shared use, for instance with an intensive care department or a pathology department may be a better option, if the sharing departments and the facilities are close enough to one another.

Clinical solid wastes may also be compacted. There are some advantages in **compacting clinical waste**. The resulting bales or packages are stable and easy to pack and transport. They may also produce better burning properties than loose waste, or conduct electricity better. However, the compacting process may be hazardous, as it easily generates infectious aerosols [57-59]. Combining compaction with chemical treatment may prevent infectious aerosol release [59], but the chemicals involved, such as hypochlorite, are themselves subject to health and safety controls when used in large quantities. A number of studies have been carried out to evaluate methods of waste decontamination at the site where it is produced.

<u>Current Methods of disinfecting liquid waste</u>: most of the liquid waste from general hospital units is discharged into the local wastewater collection. It is widely known that wastewaters, even from domestic sources, carry a significant load of pathogenic organisms, mostly of human origin [56]. Many species of virus can survive for some time in untreated wastewater; these are mostly non-enveloped viruses, adapted for survival in the human bowel. They include the whole range of enteroviral human pathogens, such as Coxsackie viruses, reoviruses, vaccine-derived polioviruses and wild polioviruses, enteric strains of adenoviruses, noroviruses, hepatitis A virus and hepatitis E virus. Small outbreaks of viral infections have been related to locally-prevalent types of virus in sewage [60,61]. In contrast to the situation with non-enveloped enteric pathogens, there is little

evidence that infectious enveloped viruses survive for more than a few hours in the wastewater environment. In a study of waste waters from two hospitals receiving SARS patients in Beijing [62], no living SARS virus could be demonstrated in hospital sewage samples, though SARS coronavirus RNA could be demonstrated before sewage treatment. Significant survival of live virus could be achieved in 'spiked' sewage samples, with survival of two days at 20°C. Chilling the sewage to 4°C permitted more prolonged survival of virus, as for other pathogens. Most types of sewage treatment cause the rapid decline of virus numbers in the solid phase (sludge) of sewage [63]. The situation with one or two highly infectious patients in a specialist unit is very different from the effect of many excretes in a domestic or general hospital setting. Patients with VHFs usually excrete large amounts of virus in stools and urine, and have heavily-contaminated blood and other body fluids that can be assimilated to highly concentrated inoculums as those worked in BSL-3 or 4 laboratories. Disposal of dressings and receptacles containing such infectious fluids fall within the requirements of the HWD. Consequently, the significant hazards of liquid waste not contained in absorbent dressings mainly result from a risk to HCWs handling and disposing of infected fluids within the isolation unit (from splash, spillage or aerosol generation) and a smaller but real risk to engineers and workmen undertaking urgent repairs and maintenance to sewage and effluent drainage systems within or immediately adjacent to the isolation unit. Similarly, discharge of urine and feces by the normal route, using urinals and toilets connected to the hospital wastewater system could lead to the presence of significant concentrations of viruses or other pathogenic agents in local drainage systems within the Isolation Unit. The situation seems different for waste from showers and hand washing. Enveloped viruses are readily destroyed by the action of soaps and detergents. Even without exposure to these agents, the viruses survive only for a short time in the environment. These effects are combined with a major dilution effect from the water used for washing and rinsing. There is therefore no requirement for any special management of water resulting from washing or showering of the unit staff.

Virus and other infectious bacterial agent concentrations in liquid waste can be reduced by the **addition of chemical disinfectants, especially chlorine**. Pre treatment before disposal in the hospital drain system is the most widely used methods in bio-safety laboratory and European clinical units. However, this can itself cause an additional hazard to HCWs who handle large volumes of disinfectants. Additionally, disinfectants' effects may be significantly reduced by the presence of organic matter. Another option is to deactivate the viruses by **heat treatment** of the liquid waste. This process consumes large amounts of energy. It also requires complex equipment and engineering controls, as waste must be stored until treated, heat distribution must be even and adequate, and the waste must be agitated by an impeller to ensure this. The liquid waste containers, impellers and control systems must be regularly maintained and validated. Handling of liquid waste can be simplified by using some medical products which irreversibly absorbs large volumes of fluid, converting it to a gel from which the fluid cannot be released, once absorbed [20]. Jellification crystals can be added to blood, vomit, urine and other fluids. The resulting gel can be bagged or binned, and is easily autoclaved because of its high fluid content. There is no risk of spillage once a fluid has been converted to gel. The absorbent crystals can be added, as degradable sachets, to disposable containers or urinals before the fluid is introduced.

EuroNHID recommendations

Optimal requirements:

- Solid waste should be decontaminated by autoclaving before being released out of the isolation facilities;
- Solid waste volume should be reduce by leaving packaging and other non-clinical material, such as information leaflets outside of the isolation area;
- At the exception of fluids resulting from hand washing and showers all other fluids should be decontaminated before being released in the hospital wastewater drain;
- Liquid waste can be decontaminated by chlorine and other efficacy proven chemical or physical treatments;
- Solidification of the liquid waste is an option before being decontaminated as solid waste;
- A policy must be available for special circumstances, such as the emergency repair of drains and pipe work in the facility;
- Appropriate supervision and PPE must be available for workers performing these tasks.

Minimal requirements:

- Solid waste must be securely packed and decontaminated by autoclaving in a nearby autoclave (shared autoclave in the same hospital);
- Solid waste must be securely packed and decontaminated by incineration in the hospital system if this comply with national transportation rules of infectious substances;
- Compacting solid waste is an option before autoclaving or transportation to incinerator but should be carried out with caution;
- Liquid waste resulting from care or body fluids must be decontaminated by chlorine addition in the receptacle before being released in the hospital drain.

11.4 Brief conclusive remarks.

We recommend isolation facilities not equipped to invest in autoclaving, best within the isolation unit, or at least in a nearby autoclave in the hospital before transportation of infectious solid waste to incinerator. For liquid waste we recommend chemical or physical deactivation before disposal in the hospital drain system.

Chapter 12 – Post-mortem procedures

Main author: S. Lanini

12.1 Introduction

The general item of this chapter focuses on the investigation of topics for preventing and controlling infection risks with regard to management of human remains and post-mortem practices. Indeed, while involved in the management of potentially highly infectious dead bodies, HCWs should be aware of the actual risk they take and may rightly expect to be provided with the state-of-art technology to be protected from hazardous biological compounds and for preventing the risk of infection.

Post-mortem handling of infected bodies is always a potential risk for transmission [64-66]; in fact, the capability of known infectious agents to uphold their viability in death body widely range, according to the type of the pathogen and the environmental conditions, between hours to months. Since the actual time-lag while a death human body may maintain its infectiousness is often unclear, the potential risk of transmission should be assessed with to the highest degree of prudence when subjects died, or they are supposed to have died, because of an HID.

To assess this item the panel decided to explore 3 different topics in the 47 surveyed facilities: (i) the availability of written procedures for management of human remains; (ii) the availability of procedures for the safe performance of autopsies and (iii) the availability of appropriate location and/or devices for post mortem examination.

12.2 Data from the surveys (aggregate and punctual data)

General item 13: Post-mortem procedures

Topic 13.a) Availability of written procedures for management of human remains

The isolation facility has procedures for the appropriate and safe management of human remains (Deriving from: Checklist II, Question H.1.a)

Strength score: A

Evaluation score:

- A: procedures for the management of human remains are available
- B: ·
- C: procedures for the management of human remains are not available

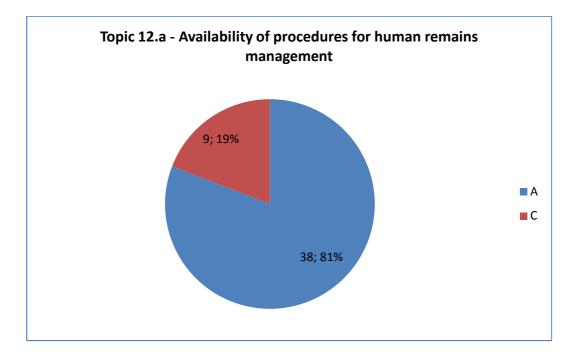


Figure 12.1 – Availability of procedures for the management of human remains

For this item the panel considered only 2 levels of adequacy i.e. written procedures available (A) or written procedures not available (C). Thirty-eight out of 47 units (81%) referred to be provided with written procedures for human remains management while the other 9 (19%) units reported to have no written procedures/protocols for human remains management. The option to be provided with written procedures is considered by our panel the only acceptable solution.

Topic 13.b) Procedures for the safe performance of autopsies

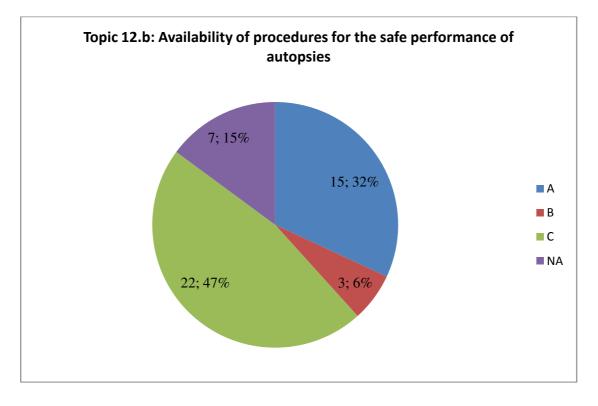
The isolation facility have proper procedures for the safe performance of autopsies (Deriving from: Checklist II, question H.1.b)

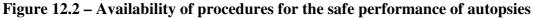
Strength score: A

Evaluation score:

- A: Optimal procedures for the safe performance of autopsies are available (autopsies are performed by a specifically trained pathologist)
- B: Sub-optimal procedures for the safe performance of autopsies are available (autopsies are performed by a not-specifically trained pathologist under the supervision of an Infection Control expert)
- C: Procedures for the safe performance of autopsies are not available

Please note: in case of autopsies not performed for safety reasons, the question is not applicable – NA





Facilities procedures to perform post-mortem examination have been explored and in particular fifteen units (32%) have optimal procedure for autopsy (A), three (6%) have acceptable procedures (B) and twenty-two (47%) have no procedures (C); in the seven (15%) reaming units it is recommended to avoid autopsy in case of subjects died as consequence of HID (NA). The panel recommend, as optimal solution, that in case of post-mortem examination on a subject died from HIDs the autopsy should be performed by a specifically trained pathologist, thought performing autopsy by a not-specifically trained pathologist under the supervision of an infection control expert may be acceptable. The panel consider that this question is not applicable to units where it is recommended not to perform autopsy on and gave no score for them.

Topic 13.c) Availability of adequate technical features for the performing of an autopsy (i.e. special BSL-3 autopsy room, special devices)

The isolation facility has adequate technical features for the performing of an autopsy (i.e. special BSL-3 autopsy room, special devices) (Deriving from: Checklist II, question H.2.a)

Strength score: B

Evaluation score:

- A: Optimal technical features for the safe performing of an autopsy are available (i.e.: the facility is equipped with a BSL-3 autopsy room)
- B: Sub-optimal technical features for the safe performing of an autopsy are available (e.g.: the facility is not equipped with a BSL-3 autopsy room, but special devices for the safe performance of autopsies are available)
- C: Technical features for the performing of an autopsy are not available

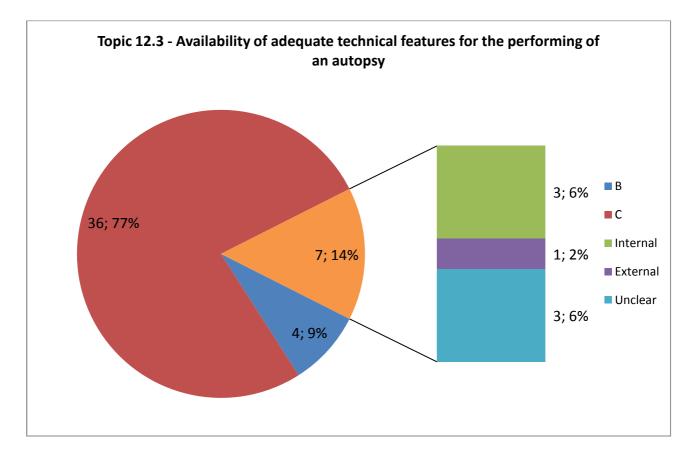


Figure 12.3 – Availability of adequate technical features for autopsies

Availability of appropriate device and technical features for autopsy performing have been explored and unit were raked according 3 degrees of appropriateness as usual. In particular seven units (14%) have optimal technical features to perform autopsy on subjects died as consequence of HIDs (A), four (9%) have acceptable special device and/or technical features (B) while in thirty-six units (77%) the facility technical features were not appropriate to perform autopsy on subjects died as consequence of HIDs (C). With regard to the seven units provided with optimal technical features, three reported that the BLS-3 autopsy room was within the unit, one that the BLS-3 autopsy room.

12.3 Comments and recommendations

The safe handling of deceased body is an important and sometimes underestimated issue. Indeed, body fluids may represent a source of infection also after the death. The procedures for the protection of HCWs are particularly important in case of HIDs, because deceased patients with HIDs are likely to have had severe form of disease, and consequently to be highly viraemic at the moment of death.

EuroNHID recommendations

About the post-mortem procedures, the EuroNHID panel recommends, as optimal standards, that:

- written procedures, well-known by HCWs, must be available and accessible;
- all handling of the corpse should be performed by personnel wearing appropriate PPE, and direct contact with the body must be discouraged;
- all isolation facilities should have an area for the temporary safe-keeping of deceased patients, large enough to contain and decontaminate sealable coffins and other mortuary equipment;
- if another place where to keep the corpses safely is not available, it is better to do not move them from isolation room;
- if a separate pathway/entrance is available, it should be used also for the transport of the corpses.

EuroNHID also proposes minimal requirements, that include:

• a general procedure (how to handle and prepare the bodies) must be available;

- all handling of the corpses must be performed wearing appropriate PPE;
- keep the corpses in the isolation room and move them only in a secured transport bag.

In general, EuroNHID panel discourage the performance of **autopsy** in these patients. Indeed, the handling and transporting of the body, and especially the use of saw for the cutting of the rib cage, represent high risk procedure, because contaminated fluids may be easily aerosolized.

If there is a need to perform the autopsies (lack of diagnosis, legal issues, research purposes...) it is suggested to prefer procedures not producing aerosols (e.g. exploration of abdomen only, or performance of needle biopsies) must be preferred. If there is a need to perform autopsy, written procedures, in line with national/local policies, must be available including:

- the risk assessment, also including consideration of alternatives such as use of pre-mortem specimens or needle biopsies;
- agreed procedures with a pathologists, better if specifically trained in autopsies with PPE;
- procedures for the safe transport, handling and keeping of tissues and other specimens.

Moreover, the panel recommend that post-mortem examination on a subject died from an HIDs should be done in a BSL-3 autopsy room, with special engineering controls. A BSL-3 autopsy room includes a minimum of six (old construction) to twelve (new construction) air changes per hour, negative pressure relative to adjacent areas and direct exhaust of air to the outside or passed through a HEPA filter if air is re-circulated. Exhaust systems around the autopsy table should direct air (and aerosols) away from HCWs performing the procedure (e.g., exhaust downward). For autopsies, local airflow control (e.g., laminar flow systems) can be used to direct aerosols away from personnel; however, this safety feature does not eliminate the need for appropriate PPE. Indeed, all HCWs performing an autopsy must wear high-level PPE. Optimally, the autopsy should be performed by a specifically trained pathologist.

If these technical features are not available, and there is the absolute need to perform autopsy, it should be performed with high-level PPE under the supervision of an infection control expert.

Chapter 13 – Appropriate bio-security measures in isolation facilities

Main author: F.M. Fusco

13.1 Introduction

Bio-security aspects are well known in laboratory settings. Indeed, global events in the recent past have highlighted the need to protect laboratories and the materials they contain from being intentionally compromised in ways that may harm people, livestock, agriculture or the environment. It is very important to understand the difference between bio-safety and bio-security:

- bio-safety is the term, usually specifically related to laboratory settings, used to describe the containment principles, technologies and practices that are implemented to prevent unintentional exposure to pathogens and toxins, or their accidental release.
- Bio-security, instead, refers to institutional and personal security measures designed to prevent the loss, theft, misuse, diversion or intentional release of pathogens and toxins.

The concept of bio-security may be easily applied in isolation facilities settings also. Indeed, some patients with HIDs may represent an significant source of infectious agents, and several specimens collected from them may represent potential material to be used for intentional release.

Moreover, the isolation facility settings are usually more stressful than laboratory, because medical care procedures are in place, and this may increase the risks.

The checklists tried to address this item, collecting some data about bio-security procedures.

13.2 Data from checklists (aggregate and punctual data)

General item 14: Bio-security procedures

Topic 14a) Availability of adequate features for bio-security

The isolation facility has procedures for bio-security (a controlled and secure entrance for authorized personnel, the availability of security personnel/circuit) (Deriving from: Checklist I, questions A.4.c, A.4.h)

Strength score: B

Evaluation score:

- A: Bio-security procedures (controlled and secure entrance, availability of security personnel/circuit) are available
- B: Bio-security procedures (controlled and secure entrance or availability of security personnel/circuit) are partially available
- C: Bio-security procedures (controlled and secure entrance, availability of security personnel/circuit) are not available

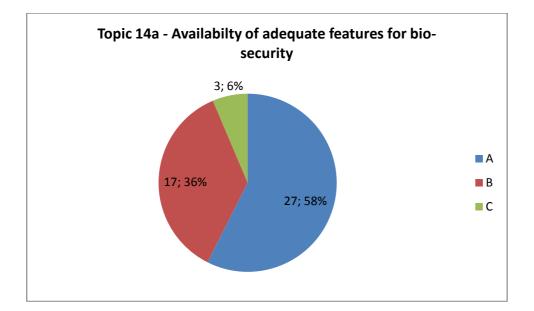


Figure 13.1 – Availability of adequate features for bio-security

Among surveyed facilities, 27 have adequate features: they have planned to control in some way the access into the isolation area, in order to limit the access to authorized persons only, and at the same time some security service (e.g. specific security personnel) are available. Among the 17 isolation facilities considered partially adequate, 6 have restricted access only, while the remaining 11 have security personnel or a security circuit (fences, or other barriers) around the isolation facility. The remaining 3 facilities do not report to have in place any features for the bio-security.

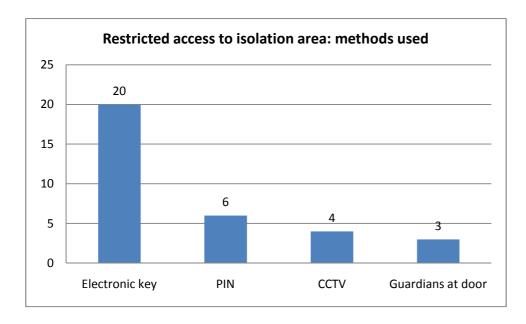


Figure 13.2 – Methods used for the monitoring of the access to isolation area (Deriving from: Checklist I, question A.4.c, valid answers:33)

Among the facilities reporting to have some control at the access of isolation area, some type of Electronic key is the most used method, in 20 facilities, followed by the digitations of a PIN number, the authorization through a Closed Tele-Video Circuit (CCTV), or by guardians at the door. Some facilities apply more than one methods, or different methods on the basi of a specific risk-assessment.

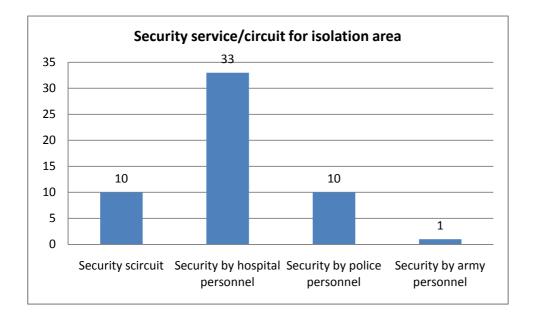


Figure 13.3 – Availability of security service and/or circuit for isolation area (Deriving from: Checklist 1, question A.4.h, valid answers:44, multiple answers possible)

Among surveyed facilities, 10 report to have some security circuit around the isolation facility (a gate, or a fence, or some other barrier), while many other report to have some security personnel at the isolation area accesses, at least during the admittance of a HID patient. This security service is furnished, in 33 facilities, by hospital-employed security personnel, in 10 cases by police, and in one case by army. As before, some isolation facilities have more than one procedures, or apply different procedure on the basis of a risk assessment process.

13.3 Comments and recommendations

Bio-security issues are important in isolation facilities, in order to:

- avoid that some specimens from HID patients, that may contain an high concentration of the responsible pathogen, could be intentionally taken by non authorized patients;
- avoid, in general, that any persons other than authorized staff (including visitors, patient's relatives, and journalists) can access in the isolation area.

This problem may be especially important in case of HID patients, because these cases may stimulate a great interest in the general public, thus mass-media operators may be interested to enter into isolation area.

Generally speaking, effective bio-safety practices are the very foundation of laboratory biosecurity activities. Bio-security measures should be based on comprehensive protocols that should include identification of personnel authorized to access, a registry of all HCWs entering and exiting from high-risk isolation area (this registry may also been used for an appropriate post-exposure surveillance of HCW, see chapter 14), documentation of internal and external movements of specimens and all potentially contaminated items. All this material should always be easily identified and transferred according to procedures that consider the bio-security risks. Responsible persons for bio-security should be clearly identified, and the involvement and roles and responsibilities of public health and security authorities in the event of a security infraction should be clearly defined. Basic bio-security training, together with bio-safety and infection control training, should be provided to all personnel: such training should help personnel understand the need for protection of such materials and the rationale for the specific bio-security measures, and should include a review of relevant national standards, if any, and institution specific procedures. Procedures describing the security roles and responsibilities of personnel in the event of a security infraction should also be presented during training.

EuroNHID recommendations

According the EuroNHID panel, **optimal recommendations** on bio-security in isolation facilities should include the following points:

- all entrances to the isolation area should be secured, and only authorized personnel should enter into high-risk area;
- the use of personal electronic key is the most used solutions, but these keys should be lost, or stolen. Consequently, other methods such as the presence a code access (Personal Identification Number, PIN) are considered optimal. The presence of a security personnel giving authorizations (by person or through a CCTV) is an optimal solution also, but it require many human resource;
- all access to isolation area should be recorded in a registry, or through a CCTV system;
- the presence of a security circuit (fence, gate, other kind of barrier) is useful in case of standing-alone buildings, but is not strictly required;
- all materials potentially containing the pathogen, al especially clinical specimens, should be managed according to protocols that also consider the bio-security risks, and all movements of these materials should be, if needed, carefully traced.

As minimal requirements, the EuroNHID panel proposes:

- if not secured through alternative systems, all accesses to isolation area, during the management of a HID patients, should be continuously monitored by security personnel, or with a CCTV system;
- keep a registry of personnel going in and out from isolation facilities;
- if a transportation is needed for specimens deriving from patient, clearly mark them, make sure to trace the transport, and use reliable hospital personnel.

Chapter 14 – Healthcare Workers safety: administrative, psychological and medical issues

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14.1 Introduction

An isolation facility, and in particular a HILU, cannot function without an appropriate level of expert staff, who are fully competent in the management of both the patient, and the facilities of the unit. Staff safety has to be of paramount importance in such an environment. Their safety will be dependent on a number of protocols and controls; administrative, engineering and the use of personal protective equipment (PPE). HCWs have died as a result of infection during nosocomial amplification of highly infectious diseases e.g. ebola, CCHF and SARS-CoV. According to a pending review [67] the majority of documented instances of VHF transmission have occurred following contact with undiagnosed cases during the early stages of an outbreak, when resources and infrastructure were not in place to determine causative agents. A high association was also found between infection and receipt of injections, through reuse and sharing of syringes. The review concludes that pre-emptive action is necessary, from effective triage strategies, basic infection control training to the establishment of isolation wards and rapid diagnostics, to contain outbreaks of these potentially deadly viruses and to ensure a safe environment for both staff and patients.

Risk management protocols.

No activity involving dangerous pathogens is entirely without risk. Staff need to know that there is a policy to identify and address all predictable risks, and that their health and safety will be monitored and supported before, during and after any deployment or event. The quality of the staff and the training protocols will equip staff with the capability to perform risk assessments and hazard identification, and to introduce mitigation procedures. These skills, together with a secure knowledge of basic principles will help them to manage unpredictable situations.

Every facility where dangerous pathogens are handled should have a comprehensive risk management programme.

Nowadays, most European Countries have a national legal requirement for adequate risk management where dangerous pathogens are handled. The European Commission Biological Agents Directive lays down a clear framework for working safely with such pathogens, concentrating on laboratory handling and transport of material containing pathogens. The European Hazardous Waste Management legislation also addresses part of this issue. Protocols for the clinical areas of hospitals are less clear. Most of the HLIUs in Europe aim to maintain clinical areas at least to the standard of bio-safety level 3. BSL-4, which is a protocol particularly designed for closed containment of laboratory specimens, equipment and procedures, presents significant difficulties in specific aspects of patient care and safety. In particular, it is not always practicable to contain individual patients closely in a very limited space. The requirements for airflow and filtration-and for regular disinfection of individual working areas are not easily reconciled with the need for patients to have a psychologically supportive environment, to be visited by family members, or to receive certain modalities of advanced care and investigation. Although these needs can be approached in some circumstances, it requires detailed planning, and highly trained teams to identify the expected difficulties and to develop methods of working, appropriate space and equipment, which can be used to safely manage the situation.

All of this helps to create a safety culture and climate which may help to ensure compliance with the measures required and therefore, help to keep the staff safe from infection. For a number of years it has been well recognised that in the industrial setting, employee perceptions regarding their organization's commitment to safety (ie, safety climate) have been shown to be important correlates to both the adoption and maintenance of safe work practices and to workplace injury rates. Gershon has studied the safety climate in the health care setting for over a decade. In an article which used a scale to try to quantify the safety climate [68], she and the other authors concluded that employees' perceptions about the safety of their hospital significantly influences their adoption of safe work practices, which could range from the use of barrier protective devices to consistent and correct use of safety needle devices, to adherence to vaccination recommendations and much more.

Staff health (occupational health) issues.

Those with responsibility for the health of staff must understand the hazards faced by the staff, and the actions needed to respond to them. The advisors should have an understanding of the structure and operational policy of the isolation facilities. These may not only include patient care, facilities operation and maintenance, but also the need to work in stressful circumstances, sometimes using personal protective equipment which is demanding of energy and technique, in a setting which is relatively isolated from other hospital staff.

The confidence and morale of staff depends on them having a thorough understanding of the unit and its operational policies.

However, other factors such as the death of a young patient, a very prolonged and stressful patient stay or an unavoidable accident in the unit, may have a severe effect on the psychological status of staff, especially those directly involved in the difficult situation, and those who have not encountered such events before. Discussion and support from other involved staff, and appropriate team debriefing, play a major role in providing psychological support and emotional relief. However, independent psychological support and advice are also valuable, especially when distress after an event causes disproportionate or prolonged disruption of emotional and family life.

It is against this background that the survey questions were designed to explore current practice for supporting HID staff.

14.2 Data from the surveys (aggregate and punctual data)

General item: 15. HCWs' safety – administrative issues

Topic 15.a) Presence of service(s) for HCWs' safety

The isolation facility has services/responsible persons for the management of HCWs'safety (Deriving from: Checklist III, question A.1.a)

Strength score: A

Evaluation score:

- A: Services/responsible persons for the management of HCWs' safety are available on 24-h basis
- B: Services/responsible persons for the management of HCWs' safety are available, but not on 24-h basis
- C: Services/responsible persons for the management of HCWs' safety are not available

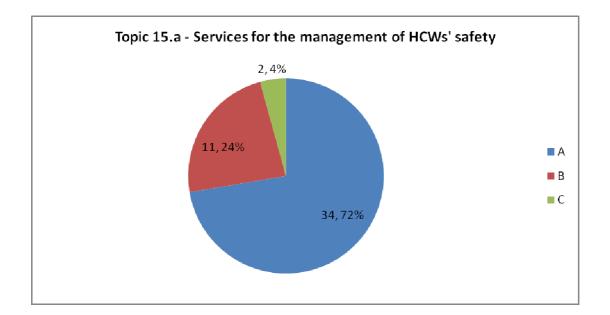


Figure 14.1 – Availability of services for the management of HCWs safety (valid answers: 47)

The results demonstrate a commitment to HCW safety in the majority of the units. While a 24/7 Occupational Health service may not be required, an alternative such as a senior doctor on duty, should be available to provide an interim, immediate response to an urgent situation, such as a needle-stick exposure, or an exposure due to the failure of PPE or a decontamination procedure.

Topic 15.b) Availability of protocols for accidents

The isolation facility has protocols for the accidents involving HCWs (Deriving from: Checklist II questions B.3.e, E.3.e; Checklist III question A.1.b)

Strength score: A

Evaluation score:

- A: Protocols for the accidents involving HCWs are available for 5-7 of explored items
- B: Protocols for the accidents involving HCWs are available for 3-4 of explored items
- C: Protocols for the accidents involving HCWs are available for 2 or less of explored items

Explored items were: availability of protocols for the management of (i) biological accidents, (ii) chemical accidents, (iii) mechanical accidents, (iv) HCWs physical accident (e.g. HCWs fall), (v) fire in the facility, (vi) PPE damage or leakage, (vii) accidents during patient's transport.

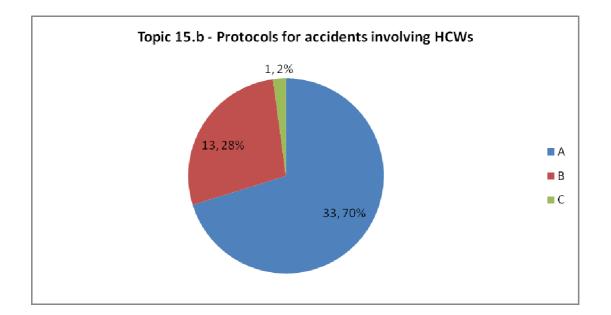


Figure 14.2 – Availability of protocols for the management of accidents involving HCWs (valid answers: 47)

Most of surveyed facilities (45, 98%) report to have at least protocols for the management of 3 among explored items. The commitment to HCW safety is supported by the existence of protocols to facilitate the best management of an accident. As recommendation, a risk register appropriate to the facility should be maintained. Clear, risk management protocols should be available for predictable incidents or situations, such as biological accidents, chemical accidents, fire, flood, systems or structure failure (consider ventilation, electricity, information systems, medical services such as vacuum, gases), transport accident, personnel illness/injury while using PPE

Topic 15.c) Special insurance/compensation

The isolation facility has a special insurance or some form of special compensation to HCWs working in the facility (Deriving from: Checklist III, questions A.2.f, A.2.g)

Strength score: B

Evaluation score:

- A: Both special insurance and some form of special compensation are planned in the facility
- B: Special insurance OR some form of special compensation are planned in the facility

C: Special insurance and some form of special compensation are not planned in the facility

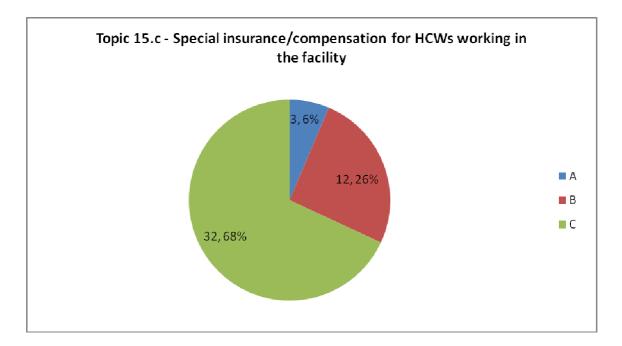


Figure 14.3 – Presence of special insurance/compensation for HCWs working in the isolation facility (valid answers: 47)

Only few facilities offer both special compensation and insurance for their staff. Among the facilities classified as B, special compensation is planned in 8 facilities, special insurance in 4. Although this requirement was considered to be highly desirable, at first appearance it seems to be not widely available. Some facilities offer a salary incentive or extra days' holiday to reward workers who provide services to the isolation room(s). This should be part of the shift plan developed for the isolation facility. In some cases, the national health and safety legislation (not only for healthcare workers) makes provision for compensation if injury occurs as a result of an employee's work (see: http://ec.europa.eu/social/main.jsp?langId=en&catId=656). However, there is no consistency in the route by which insurance or compensation may be available, or the scale of compensation involved, in individual countries.

Workers should be made aware that they are entitled to professional insurance, injury/accident insurance and compensation for damage to health provided in line with European and national legislation on occupational health and safety.

General item: 16. HCWs' safety – psychological issues

Topic 16.a: Evaluation and assessment of HCWs' "perception" of safety

The isolation facility has procedures for the assessment of fears and concerns of HCWs, and for the assessment of safety climate and culture of the unit (Deriving from: Checklist III, questions A.2.a, A.2.b, A.2.d)

Strength score: C

Evaluation score:

- A: Procedures available for 2-3 explored items, with appropriate methods (personal interview and/or questionnaire)
- B: Procedures available for 1 explored item, with appropriate methods (personal interview and/or questionnaire) OR procedures available for 2-3 explored items, with no completely appropriate methods (group discussion)
- C: Procedures available for 1 explored item, with no completely appropriate methods (group discussion) OR no procedures at all.

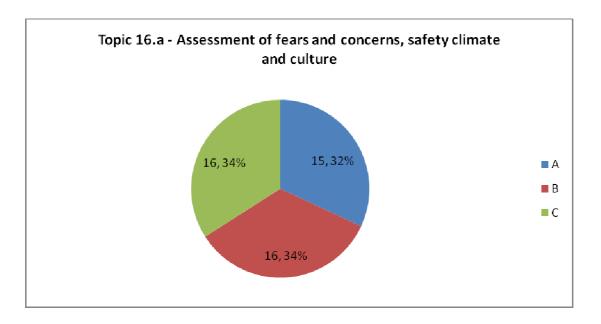


Figure 14.4 – Evaluation of HCWs' perception of safety (valid answers: 47)

These split results are of no surprise. As professionals, HCWs should be appropriately chosen, trained and supported to ensure that they are able to do the job without the risk of

psychological harm to themselves. Therefore, additional procedures may not be in place. This does not mean that there is not a need; there are published reports of HCWs verbalising their fears and concerns on the topics of HIV and VHF transmission.

Recommendations on this point include:

Exploring HCWs concerns and opinions should be part of:

- Assessment at pre-employment workup-in combination with other occupational health reviews (Strength A)
- Review of HCW opinion and effectiveness of risk management during the work of the unit (Strength A)
- Debriefs; at the time of the event, to allow for immediate feedback and improvement and afterwards.

This criterion is considered to be a key part of occupational health administration, which is strength A.

An occupation health administration includes:

- trained staff to run the service
- Pre-employment Screening, to ensure we match the job to the person and to ensure that any adjustments or adaptations can be made before the candidate starts work or as soon as possible there after.
- Health Screening to advise both Managers and employees about fitness for work.
- Specific Health Surveillance programmes where appropriate, e.g. Respiratory and Skin surveillance, Immunisations.
- Health Education and promotion.
- Advice on Sickness Absence management and return to work programmes
- Advice on health aspects of Health & Safety legislation and general Occupational Health issues

Topic 16.b: Selection of HCWs considering psychological attitude also

The isolation facility has planned to select the HCWs also on the basis of a psychological attitude (Deriving from: Checklist III, question A.3.a)

Strength score: C

Evaluation score:

- A: Procedures for the selection of HCWs on the basis of a psychological attitude are available
- B: Option not present
- C: Procedures for the selection of HCWs on the basis of a psychological attitude are not available

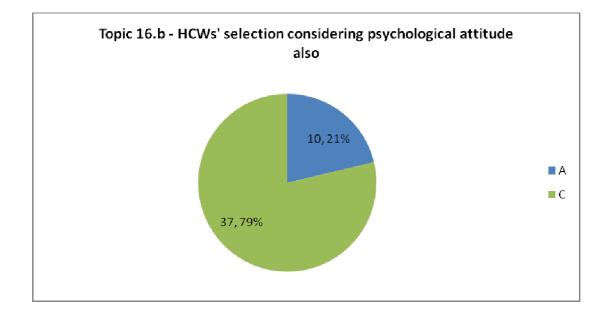


Figure 14.5 – Criteria for HCWs selection considering psychological attitude (valid answers: 47)

This item is not considered in the 79% of surveyed facilities. Staff for isolation facilities are usually selected from among existing staff in a hospital, so that their occupational health history and psychological attributes are usually known and can be considered in references and citations held by current employers. Many such staff are volunteers with an interest in carrying out work in the isolation facilities (though this does not exclude the possibility of psychological vulnerability). More study should be performed to evaluate if this is an area which needs and could be improved upon.

Topic 16.c: Psychological support service

The isolation facility has the opportunity to provide psychological assistance to HCWs, before, during and after an event (Deriving from: Checklist III, questions B.1.c, B.1.d)

Strength score: C

Evaluation score:

- A: Psychological support is available both for the staff and for the external consultants
- B: Psychological support is available for the staff but not for the external consultants
- C: Psychological support is not available

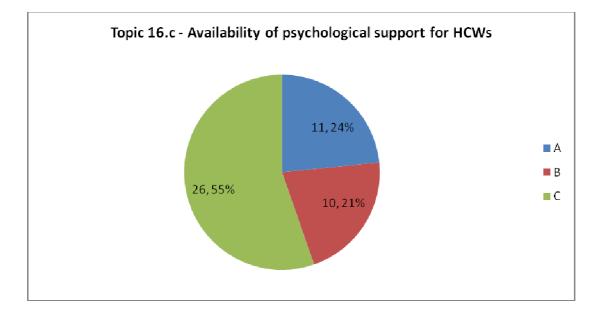


Figure 14.6 – Availability of psychological support for HCWs working in isolation facilities (valid answers: 47)

Specific support for staff who have suffered psychological stress or illness during a demanding deployment in the isolation facilities is completely available in only 11 facilities in 5 countries. However, peer support and general occupational health support are more readily available, as evidenced in the evaluation results for requirements 15a and 15b. Provision for requirement 16c is probably better than appears to be the case simply from the evaluation of requirement 16 alone. This may indicate that psychological support is one aspect of employee health and safety which should receive specific consideration in planning to provide HLIU services.

As a minimal requirement, HCWs and others in the facility must have access to psychological support appropriate to their particular concern and situation. This may be informal, in the form of group discussion, sympathetic debriefing, or time off for rest and recuperation. However, formal professional support services must be available for those Unit staff who continue to require support when they have not derived adequate benefit from less formal facilities.

General item: 17. HCWs' safety - medical issues

Topic 17.a: Evaluation of HCWs' health status

The isolation facility has procedures for the monitoring of health status of HCWs working in the facility before, during and after an event (Deriving from: Checklist III, questions A.3.b, B.1.a)

Strength score: B

Evaluation score:

- A: Procedures for the initial evaluation <u>and</u> routine monitoring of health status of HCWs working in the facility are available
- B: Procedures for the initial evaluation <u>or</u> routine monitoring of health status of HCWs working in the facility are available
- C: Procedures for the initial evaluation and routine monitoring of health status of HCWs working in the facility are not available

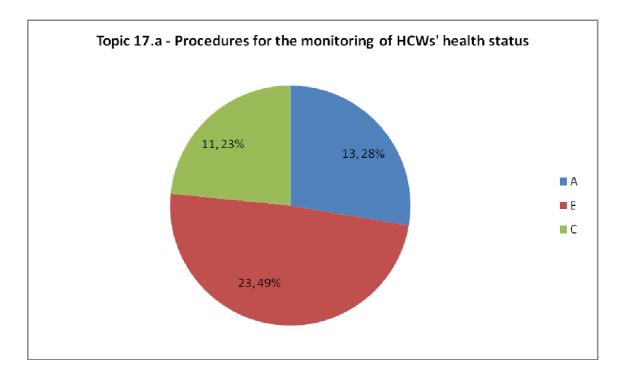


Figure 14.7 – Availability of procedures for the monitoring of HCWs' health status (valid answers: 47)

The health status is initially evaluated and continuously monitored in 13 facilities. In 8 facilities, only initial evaluation of health status is performed, in 15 only routine monitoring is performed. This may be because the isolation facilities will not be operational all the time and that the staff are usually drawn from a cadre of already employed staff.

The strength scores of A and B for the requirements under this heading of HCW health status show that most experts and isolation facilities providers consider them to be key to the safety of personnel, and also to the safety and reputation of the facility itself. Medical safety procedures will be part of the necessary risk management programme for most facilities, and risks of accidents, exposure to pathogens and other adverse events should be included in the operational risk register for the unit.

As recommendations, the suitability of workers to continue their work for the isolation centre should be reviewed on a regular, for instance an annual basis and after any significant sickness absence. During periods when the Unit is in operation, and for as safety period afterwards (e.g. the incubation period of the infection concerned), HCWs should check their health (by taking their temperature) if they have any feverish symptoms and report by telephone or other message system to the responsible occupational health person or equivalent. If this is reliably done, other, regular health surveillance, for instance daily temperature surveillance, of workers is not necessary.

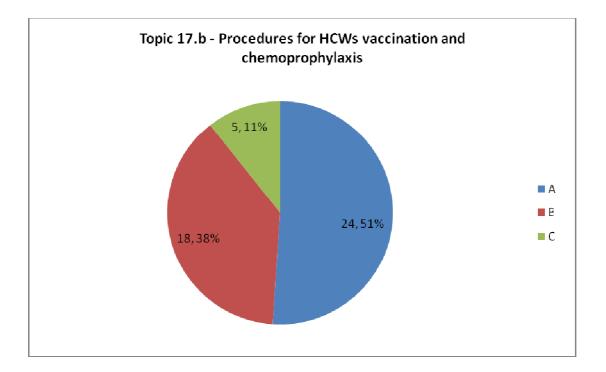
Topic 17.b: Policies for vaccination and chemoprophylaxis

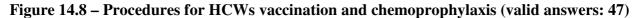
The isolation facility has procedures for the administration of vaccine and chemo-prophylaxis to HCWs (Deriving from: Checklist III, questions B.2.a, B.2.b)

Strength score: B

Evaluation score:

- A: Procedures for the administration of vaccine <u>and</u> chemo-prophylaxis are available
- B: Procedures for the administration of vaccine <u>or</u> chemo-prophylaxis are available
- C: Procedures for the administration of vaccine and chemo-prophylaxis are not available





These procedures are both available in the 51% of surveyed facilities. In 15 facilities, only protocols for chemoprophylaxis are available, in 3 facilities only vaccination policies are available.

The low number of vaccination policies may be due to the fact that occupational health or equivalent services should be providing the appropriate vaccination requirements. However, if additional staffing was required due to a patient being in the unit for a prolonged period this is a health issue which may be forgotten due to lack of time to vaccinate rapidly-deployed staff members and allow for protection. Additionally, many of the diseases which could be cared for in an isolation facility do not have a vaccine to prevent or modify infection.

Post exposure prophylaxis is more likely to be practiced than chemoprophylaxis, as witnessed in the results of 17c.

According to the EuroNHID panel, there is no requirement for routine programmes for special vaccination (exceeding national standards for HCWs) for all clinical HCWs in a isolation centre. Special vaccination programmes, for instance for pandemic influenza or another severe emerging health threat will be nationally prioritised, and the national plan should be followed. There is no general recommendation for pre-exposure or continuing prophylaxis with antibiotic or antiviral medicines.

Topic 17.c: procedures for the post-exposure management

The isolation facility has procedures for the post-exposure management of HCWs (Deriving from: Checklist III, questions B.2.c, B.2.e)

Strength score: A

Evaluation score:

- A: Procedures for post-exposure management <u>and</u> for the administration of vaccine and drugs are available
- B: Procedures for post-exposure management <u>OR</u> for the administration of vaccine and drugs are available
- C: Procedures for post-exposure management and for administration of vaccine and drugs are not available

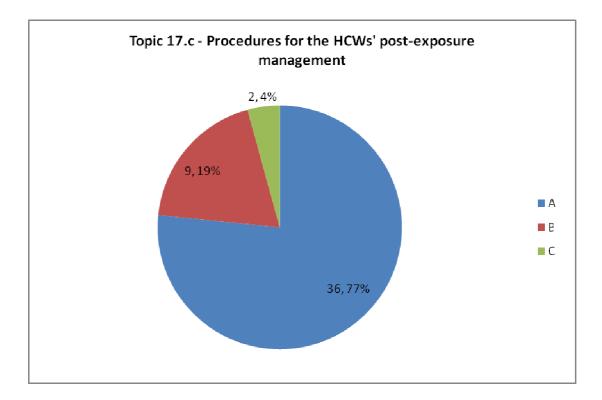


Figure 14.9 – Procedures for the HCWs' post exposure management (valid answers: 47)

Post-exposure management of HCWs is given a high priority in all countries, being fully or mostly provided. The vast majority of surveyed centres report to have procedures for HCWs' post exposure management. In 2 facilities, only procedures for the post-exposure surveillance are available, in 7 facilities only procedures for the post-exposure administration of vaccine and chemoprophylaxis are available.

Decisions about vaccination should be based on the local and national situation, the disease of concern and the contingency at the time. Post-exposure antibiotic prophylaxis, for instance using ciprofloxacin or doxycycline, should be used as recommended in Bichat and WHO guidelines. Post-exposure prophylaxis or treatment with antiviral medicines is available, and should be used, based on risk assessment of the severity of exposure, for instance ribavirin for Lassa and CCHF (preferably intravenously for symptomatic individuals).

Topic 17.d: inclusion of external consultants and HCWs' family members in safety procedures

Medical procedures also consider external consultants and HCWs' family members (Deriving from: Checklist III, questions B.2.d, B.2.f)

Strength score: B

Evaluation score:

- A: Medical procedures consider both external consultants and HCWs' family members
- B: Medical procedures consider external consultants <u>OR</u> HCWs' family members
- C: Medical procedures do not consider external consultants and HCWs' family members

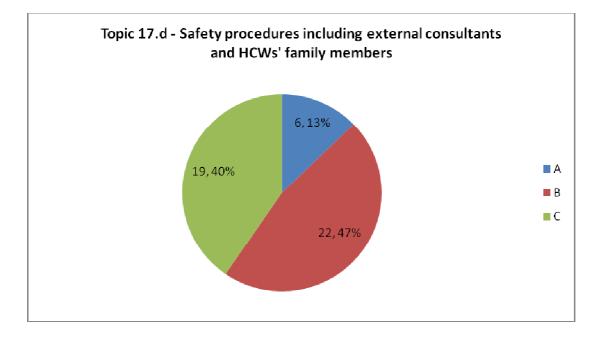
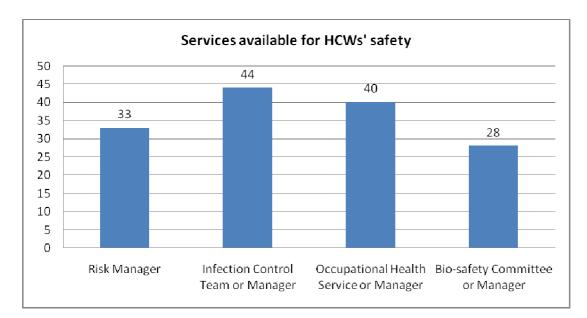


Figure 14.10 – Procedures including external consultants and HCWs' family members (valid answers: 47)

Very few isolation facilities include in their safety procedures both external consultants and family members of HCWs. These results may reflect that 1) the support from external consultants is rarely required or indeed it simply has not been considered amongst the other priorities, 2) that the risks to household members is deemed to be low.

Decisions and actions about the management of exposed persons who are not members of the HLIU staff should be coordinated with national health protection requirements, including the duties to report exposures or events to health protection authorities, and to support the activities of the health protection authorities. Where post-exposure management depends on an urgent decision and this is taken within the HLIU, the action must be reported to the health protection authorities

without delay. External consultants who work as temporary staff members of the Unit should be included in staff arrangements (and should be included in all occupational health arrangements).



Data from Checklists: specific evaluation aspects and outcome

Figure 14.11 - Services available for HCW's safety (Deriving from: Checklist III, question A.1.a, valid answers: 47)

The leads on HCW safety from the data are Infection control, an occupational health service or manager. This is probably a reflection of national infrastructures for the care of HCWs in that some countries infection control will lead on such issues as opposed to an occupational health service. Risk is likely to be considered in this infrastructure despite the lack of an official being allocated as a risk manager.

Table 10 - Awareness to the "perception" of safety by HCWs in the isolation facilities, and evaluation of safety culture					
	Assessment of HCWs' fears and concerns		Assessment of safety climate		Evaluation of safety culture
	With approrpiate	With non-optimal methods	With approrpiate	With non- optimal methods	

	methods		methods		
Number of facilities (%)	13 (27,6)	12 (25,5)	16 (34,1)	4 (8,5)	26 (55,3)

(Deriving from: Checklist III, questions A.2.a, A.2.b, A.2.d, valid answers 45-46 answers)

The data reflects that this is an area that requires further work to understand how big an issue is it and what can be done to address any concerns and fears. In the health care setting safety culture and climate has been studied with regard to the compliance with universal precautions (now standard precautions).

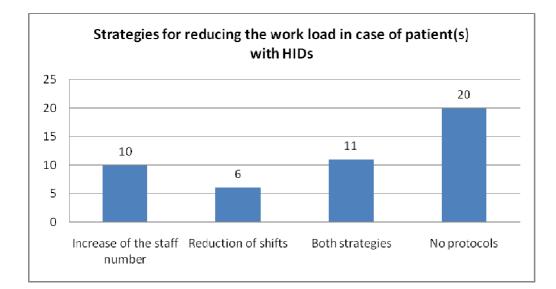


Figure 14.12 - Strategies for the reducing of work load (Deriving from: Checklist III, questions B.1.b, valid answers: 47)

The data demonstrates a significant proportion have no surge plan to cope with an excessive workload. Many countries health care systems including intensive care units have felt the strain of H1N1 (2009) and will as a result have a clearer idea of what needs to be in place to cope with a sudden demand in workload over a period of time.

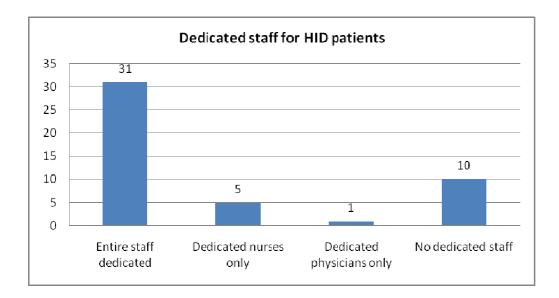


Figure 14.13 - Availability of dedicated staff in case of HID patient(s) (Deriving from: Checklist III, questions B.1.e, valid answers 47)

The data is likely to reflect how often the unit/facility is used. The main concern for the units with no dedicated staff would be one of maintenance, training and familiarity with the unit and procedures.

14.3 Comments and recommendations

HCWs are obviously a resource worth protecting. All must be done that can be to ensure that they remain safe while caring for a patient with a highly infectious disease. Preceding chapters have dealt with the infra-structural, infection control and many of the administrative issues. Chapter 14 has focussed on some of the more qualitative issues, which need further study outside of this project.

HCW fears and concerns:

HCWs are naturally altruistic and will put their patients' welfare first. In the interviews carried out by Hewlett and Hewlett at Ebola outbreaks in central Africa, what emerged repeatedly is that despite the profound fear, lack of resources with which to protect themselves and stigmatisation suffered at work and home, many nurses were clearly committed to their profession [69].

But caring for a patient with a highly infectious disease will challenge this instinct and duty of care, as the HCW must ensure their own safety prior to proceeding. There are some similarities in the ethos for Basic and Advanced Life Support. There are various publications regarding HCWs concerns for their family contracting the illness in relation to outbreaks e.g. SARS, Smallpox. Understanding HCWs behaviour when they are tasked with caring for a patient with a dangerous pathogen infection is an area which is not fully understood. But HCWs fears and perceptions are expected to have an influence [70].

The introduction of this manual cites references from the SARS experience. The fact that 21% of SARS-CoV probable cases were HCWs is a staggering figure that should never be repeated. Learning from our own or others experience is essential to ensure that we change what has to be changed to ensure the safety of our health system and all of those who work in it. It was clear during the SARS epidemic that it was not only medical and nursing staff who were are risk of infection [71,72].

Caputo et al (2006) [73] interviewed 33 healthcare workers who had intubated SARS patients. They asked the healthcare workers for their recommendations on how a response could be improved – they had perceived that their experiences were ineffectively integrated into risk management protocols; they had limited opportunities to inform policy makers about appropriate protocols and/or refine treatment guidelines. One of the recommendations cited is the need to foster two-way communication (in other words, healthcare workers' concerns need to be heard).

Lau et al [74,75] highlighted in a case control study with regard to the risk of HCWs to SARS infection the following three points; perceived inadequacy of personal protection equipment supplies, infection control training <2 hours, and inconsistent use of personal protection equipment when in contact with SARS patients were significant independent risk factors for SARS infection.

Chapter 15 will address some of the training requirements which will help to ensure the HCWs' safety.

Medical issues

The 12th Session on the Joint International Labour Organization/WHO Committee on Occupational Health of 5-7April 1995 adopted a new definition of occupational health, which should aim at the promotion and maintenance of the highest degree of physical, mental and social well-being of workers in all occupations with the following three objectives:

- The maintenance and promotion of workers' health and working capacity;
- The improvement of working conditions and the working environment to become conducive to safety and health;

• The development of work organisation and working cultures that should reflect essential value systems adopted by the undertaking concerned, and include effective managerial systems, personnel policy, principles for participation, and voluntary quality-related management practices to improve occupational safety and health.

Some institutions may not have occupational health but many of the issues will be covered by e.g. infection control teams. The main point is that the HCWs health is protected and maintained in relation to their working environment. There are aspects of pre- employment, employment and post exposure care that need to be considered, planned for and responded to. The potential psychological concern and impact of such a job has been highlighted throughout this chapter. To fulfil this need, at a minimum, a senior member of the team should do 'hot debriefs' (listen and speak with the team as they care for the patient/s) Ideally, also the culture and procedures of the unit should include a more formal assessment and support system for the HCWs involved in such activities.

Administrative issues

Administrative structures and policies need to be in place to support the medical issues in prevention and control of infection and to acknowledge or address any mental, physical or social issues. This is particularly important if we expect the HCWs to function well in such an environment for potentially weeks at a time [76]. Training helps to support these and will be addressed in Chapter 15.

Risk management; assessment and mitigation should be part of the integral functioning of such a unit. A senior member of the team should lead on this and ensure that it is regularly reviewed and kept up to date, reflecting any lessons learned and actions taken.

EuroNHID recommendations:

Optimal requirements:

- A commitment from senior management that HCW safety is paramount;
- All that needs to be done to implement that commitment is performed including adequate building infrastructure;
- The HCW should work in a safe environment with adequate resources; people and equipment;

- Risk assessments and procedures should be in place to prevent exposure and to manage any exposures that occur despite precautions;
- HCWs should be aware of what will be offered to them in the form of insurance and/or compensation;
- HCWs' opinions, fears and concerns should be listened to and answered;
- Adequate debriefing and other psychological support should be available;
- Adequate resources including personnel should be in place to monitor and advise on the day to day health of the HCW e.g. vaccination policy;
- Adequate resources including experienced personnel should be in place to advise on the management of an exposure;
- All members of the team should be considered including cleaners, workmen and external staff;
- Adequate training must be given to ensure safe practice.

Minimal requirements: not included for this point, because, according to the EuroNHID panel, only optimal requirements should be applied for HCWs safety issues.

14.4 Brief conclusive remarks

The global healthcare workforce is struggling to deal with the day-to-day threats and pressures on it. Therefore, we have to do all we can to prepare, in advance of any case or cases of a highly infectious disease, the system and the HCWs who will work within that system to ensure their safety, which in turn allows them to care for the patient /s.

Chapter 15 – Health Care Worker Training

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15.1 Introduction

Specific training is required for workers to gain the knowledge and skills required to work in a HLIU. Appropriate training also provides confidence in the unit, its procedures and the safety of staff who work in the specialist environment. Experience of teamwork in emergency situations clearly demonstrates that experienced specialists do not work safely and effectively in teams without specific training Without refreshment of training, skills and knowledge are gradually degraded by an increasing tendency to make omissions, and by slow alteration in procedure through a process of custom and practice [77-80]

Personnel knowledge and skills.

All staff must be aware of the nature of the infections which will be managed in the unit, the routes of transmission and how nosocomial amplification may occur, what to do in an emergency and the safety measures which operate to protect the staff, visitors and other patients from exposure to infection. The whole range of professional groups require the knowledge and skills appropriate to their duties. This may include staff from other healthcare-providing services, such as ambulance personnel who may occasionally need to enter and perform duties in the unit.

Well-designed training programmes can provide excellent levels of knowledge and skill. However, where update and refreshment training is not provided, skills tend to degrade and knowledge to be forgotten over a period of two or three years. As well as this, trained teams disperse because of retirements or relocation of personnel. Additionally, the training programmes must be implementable and applicable to the resources available. This is particularly pertinent if one is training workers from another country, where the trainer may not be fully aware of the resource limitations or other barriers to implementation.

Skills, once acquired, are easily maintained by relatively infrequent exercises and drills, which can sometimes be conducted in the classroom-but it is important that these take place. Another way of maintaining-and improving skills is to involve all staff in audit and review

activities, particularly after the admission and care of a patient, so that all staff have a good understanding and 'ownership' of safety and excellence in the isolation facility [81,82].

15.2 Data from the surveys (aggregate and punctual data)

General item: 18. HCW training

Topic 18.a) Training requirements for working in isolation facilities

The isolation facility has a "training requirement" to be completed before working in the facility (Deriving from: Checklist III, question C.1.a)

Strength score: A

Evaluation score:

- A: The facility has an international or a national-validated training requirement to be completed before working
- B: The facility has an internal training requirement to be completed before working
- C: The facility does not have a training requirement to be completed before working

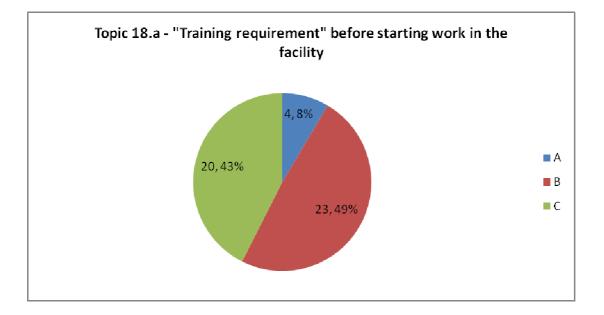


Figure 15.1 – Availability of a "training requirements" to be completed before work in the isolation facility (valid answers: 47)

According to the checklist results, in 43% of surveyed facilities no basic training is required before being admitted to work into the isolation facility. These results are of some concern as there is a lack of an induction to working in the isolation centres.

According the EuroNHID, core workers who are hospital as well as Unit staff should be trained in isolation facilities' safety features, PPE, decontamination, and the features and protocols of the isolation area before working within. General training should also be offered, including the activities and protocols of other units in Europe. A record should be kept of personnel who have undertaken training, and the dates when they were trained. Surge capacity workers, trained on-site to work in the Unit should receive training in PPE and the layout and key protocols of the unit, before commencing clinical activities. Some of this training will be brief, and carried out within the working Unit.

Topic 18.b) Continuous education programmes while working within isolation facility

The isolation facility has a programme of continuous education for HCWs working in the facility (Deriving from: checklist III, question C.1.b)

Strength score: B

Evaluation score:

- A: A specific continuous education programme exists
- B: Option not present
- C: A specific continuous education programme does not exist

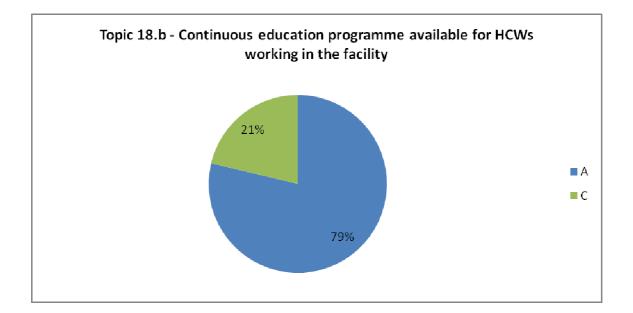


Figure 15.2 – Availability of a continuous education programme for staff working into isolation facilities (valid answers 47)

The majority of the units do have a continuous education programme. However, a significant proportion do not. This might be due to the fact that some are only utilised and available for training activities when they have a patient with a HID in them.

Every facility, whether HLIU, IC or RC, **must** provide continuation training for all professional groups on a periodic basis as a minimum once a year. It is necessary to provide practical training as well as theoretical updates for each staff member, on a rotating basis if necessary. Records must be kept of training attendance and satisfactory performance for staff members. Shared experience with other facilities is considered to be valuable, and should be encouraged as an additional training modality.

Topic 18.c) Organization of and participation to training exercises

The isolation facility conducts training exercises on regular basis (Deriving from: Checklist III, questions C.2.a, C.2.b)

Strength score: C

Evaluation score:

A: The facility participated in a table-top or practical exercise/s, leading it/them

- B: The facility participated in a table-top or practical exercise/s, not leading it/them
- C: The facility did not participate in a table-top or practical exercise

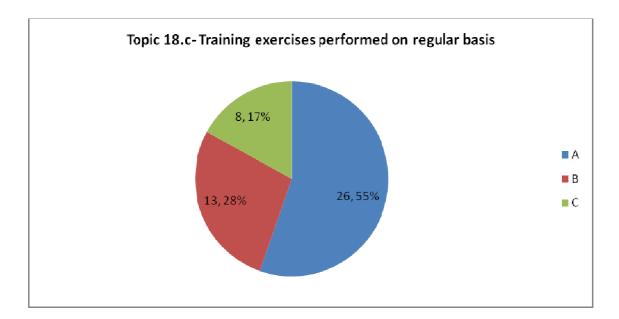


Figure 18.3 – Participation into theoretical and practical exercises (valid answers: 47)

The very high proportion of isolation facilities providing continuing education programmes for their workers indicates the importance which is placed on maintenance of a good level of knowledge and skills.

Despite the lack of induction training, the majority did partake in training exercises on a regular basis, however, a significant proportion of these programmes were not originated by the isolation facility itself (response B). This may be a disadvantage, as not all of such programmes will be appropriate to the needs of the service.

Table 11 - Experiences of isolation facilities in training exercises							
	Organization of	Participation					

Data from	Checklists:	snecific	evaluation	aspects and	outcome.
Data II UII	CIICKIISts.	specific	<i>cvaluation</i>	aspects and	outcome.

Organization of and participation in table-top exercise(s)	Participation only in table- top exercise(s)	Organization of and participation in practical exercise(s)	Participation only in practical exercise(s)	No experience in training exercise(s)
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Number of	23 (48,9)	11 (23,4)	21 (44,7)	12 (25,5)	7 (14,9)
facilities (%)	20 (10,5)	11 (20,1)	21(11,7)	12 (20,0)	, (1,,,)

(Deriving from: Checklist III, questions C.2.a, C.2.b, valid answers: 47)

One suggestion would be that a buddying or pairing arrangement between facilities who do not participate in training with an active unit. This pairing could facilitate training exercises and the development of a programme.

15.3 Comments and recommendations

In the long 'down time' periods between active operations in any unit, staff education is one of the major expenses involved in maintaining the service. In the culture of financial efficiency found in the health services of most countries, securing the funding needed to train staff for rare events is often a severe challenge. Although the requirement for continuous training has been assigned **Strength level B** in the consensus assessment of the important of requirements for isolation facilitiess, actual practice across countries suggests that it may deserve **Strength level A**. An indication that this training is considered essential may aid HLIU directors in accessing appropriate funds for training.

It is interesting to see that, in practice, initial training scores poorly. The provision for initial training could be seen as inadequate, with less than half of all isolation facilities providing it to Evaluation score B. Part of the explanation for this may be the difficulty of providing realistic initial training when the isolation centre is not operating. No new member of staff would be alone in, or responsible for, isolation centre activities as several staff members are necessary to operate an isolation facility and care for a patient. It is not clear from the remarks on the reporting questionnaires, but it may be the case that initial training is performed 'in-service'. This would not be an ideal situation if the unit was operating at a high level of pressure with a very sick patient-but it would ensure sufficient support and mentorship for a new and inexperienced staff member.

Continuation training is reported by a number of units. However, this may not always be designed to include specific issues for HLIU staff-and particularly may not include training on managing emergency events.

EuroNHID recommendations:

Optimal requirements:

- All staff should be adequately trained before working in the isolation facility;
- All staff who work regularly or as surge staff should have ongoing continuous training;
- The training programme should be assessed to ensure that it is having an appropriate impact;
- Buddying or pairing between HLIUs could be considered to help facilitate training.

Minimal requirements: not included for this point, because, according to the EuroNHID panel, only optimal requirements should be applied for HCWs education and training issues.

15.4 Brief conclusive remarks.

There may be an important opportunity for using training capacity across Europe, to maintain and update staff training in a supportive system. Collaboration between units could also ensure that innovations and developments can be rapidly shared.

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