Observatory on current biosafety practice in European Oncology

FEBRUARY 2019

European Biosafety Network

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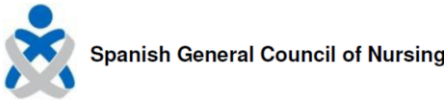
Introduction

About the European Biosafety Network (EBN)

The EBN was established in 2009 by founding partners the Spanish General Council of Nursing and the British public services union UNISON. It was established to help support the effective implementation of the Directive on preventing sharps injuries in the hospital and healthcare sector 2010/32/EU and to prevent and protect healthcare workers from occupational exposure to hazardous drugs, including cytotoxic drugs, by amending the Carcinogens and Mutagens Directive 2004/37/EC. The Network is an inclusive organisation made up of national and European professional institutions, representative associations, unions and other interested parties committed to biological and occupational safety in healthcare throughout the European Union.



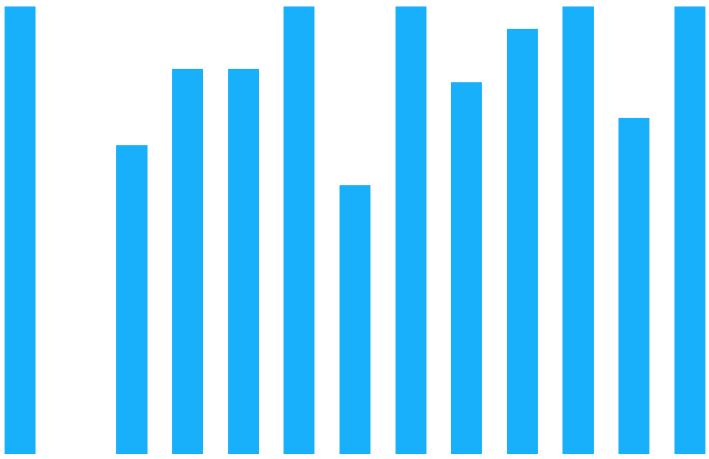
Purpose of the report

The EBN has been campaigning for proper protection for healthcare workers involved in the preparation, administration and disposal of hazardous drugs across the European Union. There is increasingly conclusive and mounting evidence of the risks to those healthcare workers from long term exposure to hazardous substances. As part of this effort, the EBN Observatory is has collected data from 14 European Union member states, engaging directly with healthcare workers to collect real world evidence on current practice and the extent of protection in place, to demonstrate the need for improved protection. These data support the efforts being taken at a European Union and national level to introduce legislative provisions to protect those healthcare workers, better informing policymakers and social partners on the failures of current practice and the need for proper interventions in pharmacy and in hospitals, to ensure that healthcare workers are properly protected as they perform their duties for patients.

Survey methodology

An online questionnaire addressing key aspects of awareness, training and implementation of hazardous drugs protocol was published by the EBN for the attention of hospital pharmacies and oncology outpatient units.

Data collection for the Observatory was outsourced to Ipsos MORI, and started in September 2018. The collection of evidence was completed in December of the same year. The dataset is comprised of the submissions of **147 heads of pharmacy** and **142 oncology outpatient unit supervisors/managers**, drawn from 14 countries from across the EU. A breakdown of these interviews is given on the next page. As this survey sampled a largely self-selecting group, the reality of awareness and compliance may be worse than the headline survey results.



Reading the data

The sample size varies between countries. This is important to bear in mind when interpreting the data quoted and displayed in graphs. For example, the result that all of the pharmacies in France, with a sample size of 23, carried out a simple safety measure may be highly reassuring, whereas the same may not be true for, say, Latvia, with a sample size of 1. Given this, it may often be more illuminating to observe the EU-wide figure.

Interviews breakdown

Europe	**•289 Interviews** •147 heads of pharmacy •142 oncology outpatient unit managers/supervisors
Sweden	**•7 Interviews** •4 heads of pharmacy •3 oncology outpatient unit managers/supervisors
Estonia	**•2 Interviews** •1 head of pharmacy •1 oncology outpatient unit manager/supervisor
Latvia	**•2 Interviews** •1 head of pharmacy •1 oncology outpatient unit manager/supervisor
Poland	**•27 Interviews** •13 heads of pharmacy •14 oncology outpatient unit managers/supervisors
Germany	**•58 Interviews** •29 heads of pharmacy •29 oncology outpatient unit managers/supervisors
Italy	**•42 Interviews** •21 heads of pharmacy •21 oncology outpatient unit managers/supervisors
Denmark	**•4 Interviews** •2 heads of pharmacy •2 oncology outpatient unit managers/supervisors
Netherlands	**•9 Interviews** •5 heads of pharmacy •4 oncology outpatient unit managers/supervisors
Belgium	**•12 Interviews** •6 heads of pharmacy •6 oncology outpatient unit managers/supervisors
France	**•46 Interviews** •23 heads of pharmacy •23 oncology outpatient unit managers/supervisors
UK	**•37 Interviews** •20 heads of pharmacy •17 oncology outpatient unit managers/supervisors
Ireland	**• 4 Interviews** •3 heads of pharmacy •1 oncology outpatient unit manager/supervisor
Spain	**•32 Interviews** •16 heads of pharmacy •16 oncology outpatient unit managers/supervisors
Portugal	**•7 Interviews** •3 heads of pharmacy •4 oncology outpatient unit managers/supervisors

Recommendations

Hospital pharmacies

- **Increase the use of risk assessments** as a key proactive exposure prevention measure (currently employed by only **84%** of hospital pharmacies)

- **Promote the active recording of incidents involving hazardous drugs** to avoid issues being ignored

- **Ensure that decontamination protocols are in place in all pharmacies -** a measure that **11%** of hospital pharmacies still lack

- **Increase levels of training for patients and caregivers,** which are currently falling a long way behind the levels of training offered to staff and are a high exposure risk

- **Increase medical surveillance**, particularly in Western European countries. Regular medical testing, for example, is only carried out regularly in **62%** of the pharmacies, falling to 20% in the UK, 30% in France, for example

- **Ensure that hazardous drugs are universally prepared in hospital pharmacies** rather than in wards - currently **21%** of preparation is carried out outside the pharmacy area

- **Ensure that closed systems drug transfer devices (CSTDs) are the primary device used in the preparation of hazardous drugs** to protect worker and patient safety

- **Ensure that sterile rooms used in the preparation of hazardous drugs are equipped with either a Biological Safety Cabinet (BSC) or an Aseptic Isolator (AI) - 9%** of pharmacies revealed that this was not the case, with low results especially in Eastern Europe. Further, the use of CSTDs should be required as recommended by the World Health Organisation

- **Regular monitoring of surface contamination should be universal, more frequent and more comprehensive** - this is currently only carried out in **55%** of hospital pharmacies, and where it is carried out it is often infrequent and superficial

- **Formalise a European list of hazardous drugs –** currently the National Institute for Occupational Safety and Health (NIOSH) list is used but this is based on non-European criteria and is insensitive to the particulars of the European oncology environment

- To achieve these recommendations, **hazardous drugs should be included in the Carcinogens and Mutagens Directive EU 2004/37, combined with mandatory European guidelines and a European list of hazardous drugs**

Oncology outpatient units

- **Increase the use of risk assessments** as a key proactive exposure prevention measure (currently employed by **90%** of oncology outpatient units)
- **Promote the active recording of incidents involving hazardous drugs** to avoid issues being ignored
- **Ensure that preparation of hazardous drugs and spiking of medication bags is carried out in the hospital pharmacy** - currently only **86%** of the preparation and **61%** of the spiking of medical bags occurs in pharmacies, meaning that many workers in wards are exposed to the risk of spillages and leakages
- **Eliminate the use of outdated administration systems** and **promote the use of systems offering full protection, such as CSTDs**
- **Increase the use of all forms of personal protective equipment (PPE) where appropriate -** this is critical to worker safety, but most measures fail to be employed by approximately **25%** of units
- **Increase levels of training for patients and caregivers,** which are currently falling a long way behind the levels of training offered to healthcare staff but who are also at high exposure risk
- **Increase regular medical testing,** particularly in Western European countries - it is only carried out regularly in **58%** of the units, falling to 33% in Ireland, 35% in France, for example
- **Regular monitoring of surface contamination should be universal, more frequent and more comprehensive** - this is currently only carried out in **55%** of oncology outpatient units
- **Ensure a universal protocol for the cleaning of administration areas -** currently this only exists in **82%** of units and is essential for the maintenance of a safe environment for staff and patients
- To achieve these recommendations, **hazardous drugs should be included in the Carcinogens and Mutagens Directive EU 2004/37, combined with mandatory European guidelines and a European list of hazardous drugs**

Findings for Hospital Pharmacies

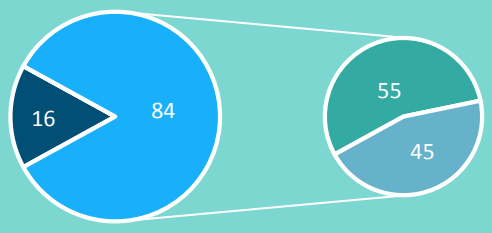
General procedures with hazardous drugs

Although 84% of the hospital pharmacies in Europe had an official list of hazardous drugs, the list was only updated and reviewed at least annually 55% of the time (Figure 1.1). Further, only 56% of the pharmacies had a procedure for evaluating new drugs for hazardous properties. This suggests that the practical application of the lists was often limited.

All of the pharmacies surveyed had a protocol for emergencies and exceptional situations (e.g. breakage or leakage of vials, aerosol or liquid spills etc.), suggesting a strong response to pharmacy accidents. However, the proportion of pharmacies that carried out risk assessments for their staff members that handled hazardous drugs was significantly lower (84%) (Figure 1.2), suggesting that the approach taken by many hospital pharmacies is reactive rather than proactive, and that preventative work is limited.

Further concerns were raised when assessing the recording of incidents involving hazardous drugs, with no incident logs in 21% of the pharmacies (Figure 1.2), suggesting that incidents are often unreported and that figures cited in other studies may underestimate the number of incidents with hazardous drugs. This figure may actually over-represent the recording of incidents, as it refers simply to there being a log in place but ignores its usage.

Figure 1.1



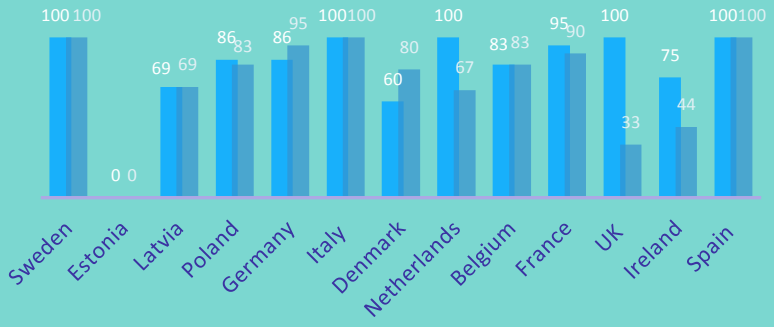
- Had no list of hazardous drugs
- Had a list (regularly updated)
- Had a list (not regularly updated)

84% of hospital pharmacies had a list of hazardous drugs used in the pharmacy

But only 55% of these were updated at least annually, suggesting low usage

Despite some countries showing a high proportion of the pharmacies with risk assessments and incident logs in place, this was often not the case - notably in Ireland, the UK, Latvia and Denmark

Figure 1.2



- Had a risk assessment policy
- Had a log for recording incidents

Cleaning protocol and procedure

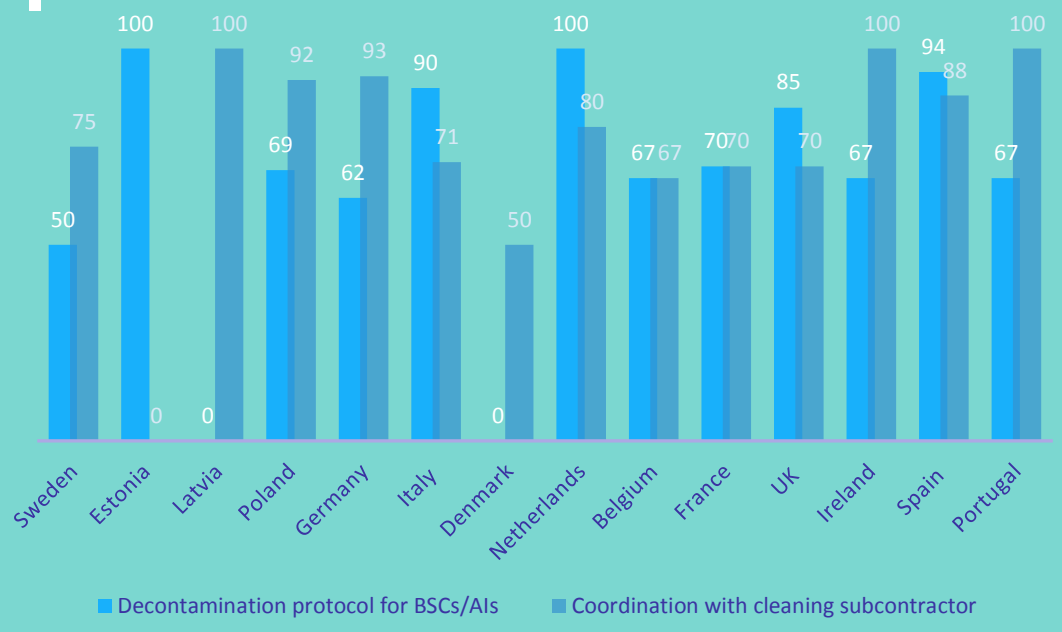
97% of hospital pharmacies reported that there was a procedure in place to specify the use of personal protective equipment (PPE) in cleaning processes, which, although not universal, suggests that hospital pharmacies are working to protect their cleaning staff from exposure to hazardous drugs.

However, the cleaning protocols were often not as thorough as the seriousness of the hazards requires. For example, only 76% of the pharmacies had a decontamination protocol for BSCs and AIs, which is an essential process in worker safety and limiting product contamination (Figure 1.3).

Further, in cases where the cleaning and waste management was outsourced to a subcontractor, only 80% of hospital pharmacies coordinated with that company over policies and protocol (Figure 1.3). This is a concerning trend as it suggests either an ambivalence on behalf of some hospital pharmacies or a willingness to transfer responsibilities onto the subcontractor, and could endanger staff from both the pharmacy and the subcontractor.

Figure 1.3 shows a breakdown by country of the proportions of hospital pharmacies with cleaning protocol in two example areas: the decontamination of BSCs/AIs, and the protocol when outsourcing cleaning duties to subcontractors. The proportion of hospital pharmacies with protocol in these areas varied highly between the countries, and often showed little consistency within countries

Figure 1.3



Training protocol and procedure

The availability of training information was generally high for staff, but lower for non-staff such as patients and carers. This is critical as it risks exposure to patients, who are often most vulnerable due to their existing conditions and low immunity, and also to those such as family members who lack background knowledge of the dangers of hazardous drugs. For example, whilst 79% of the pharmacies had training plans available for new staff, only 51% of the pharmacies had information available to patients and caregivers (Figure 1.4).

New staff were assessed on their uptake of this information in 74% of the pharmacies. Further, it was clear that availability of material often failed to translate into concrete training, with only 67% of the pharmacies carrying out annual training on hazardous drugs, suggesting that expertise in these area will often grow outdated or be forgotten (Figure 1.5).

Figure 1.4

In most countries surveyed, the training of staff exceeded that given to patients and carers, particularly in Italy, Denmark and Portugal

Figure 1.5

Figure 1.5 demonstrates that even where training material was available to staff, this often failed to give rise to periodic training or evaluation of the effectiveness of the training

Medical testing

Medical testing is a crucial tool that hospital pharmacies can employ not only to monitor the health of their workers and treat exposure quickly, but to ensure that the protocols they have in place are effective in preventing exposure. To this end, we would expect to see high levels of regular medical testing on those workers who deal with hazardous drugs.

However, only 62% of the hospital pharmacies surveyed conducted regular medical testing on their healthcare workers (Figure 1.6). This figure was highly variable across Europe, and curiously was particularly low in wealthier countries such as the UK, France, Sweden and the Netherlands.

Figure 1.6

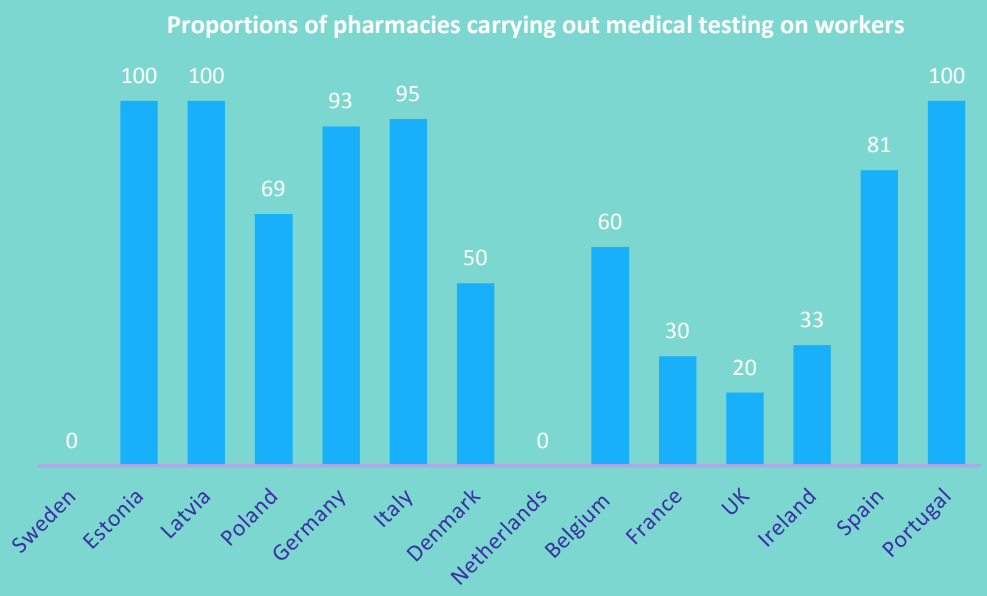


Figure 1.6 offers a breakdown of the rates of medical testing in the countries surveyed. Wealthier, more developed northern and western European nations tended to perform worse in this field

Repackaging, Counting, Crushing, Splitting and Non-Sterile Production

In the handling of hazardous drugs, be it in the repackaging, counting, crushing, splitting or non-sterile production, there is a danger to both the worker actively handling the drug and to the patient, who risks exposure through contamination of any medication they may be administered. However, there was often a lack of protocol in this area.

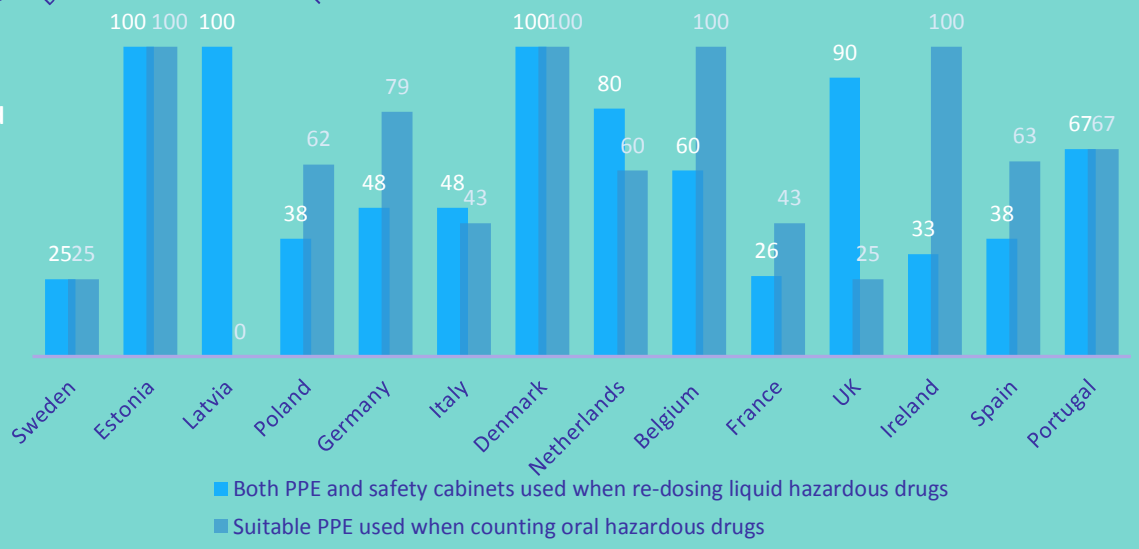
For example, only 58% of the pharmacies made a written policy available to staff on the protocol of working in this area (Figure 1.7). And in terms of practical safety measures, these were often poorly applied, with only 65% of the pharmacies reporting that suitable PPE was used when counting oral forms of hazardous drugs, and only 60% of the pharmacies employing both PPE and biological or chemical safety cabinets for the re-dosing of liquid hazardous drugs (Figure 1.8). These are basic measures of worker safety that are often failing to be used to protect staff.

Figure 1.7

Figure 1.7 outlines the proportion of hospital pharmacies that made protocol regarding repackaging, counting, crushing, splitting and non-sterile production of hazardous drugs available to their staff

Figure 1.8

Figure 1.8 shows the often limited uptake of crucial safety measures such as PPE and safety cabinets, particularly and perhaps surprisingly in Italy, France and Sweden



Sterile Compounding and Aseptic Production

Preparation areas

It is crucial to limiting exposure to hazardous drugs that sterile compounding and aseptic production occur in the pharmacy department rather than in the wards. If carried out in the wards, where the equipment to limit the threat of the hazardous drugs is often lacking, nurses and patients will be vulnerable to exposure. Hence there is a target set that all of the sterile compounding and aseptic production of hazardous drugs occur in the pharmacy department. However, only 79% of sterile compounding and aseptic production across Europe was carried out in the pharmacy department, with this figure particularly low in Latvia (0%), Poland (32%), Netherlands (61%) and Spain (63%) (Figure 1.9). The prevalence of this issue will be further demonstrated below upon investigation of handling activities in the oncology outpatient units themselves.

Figure 1.9

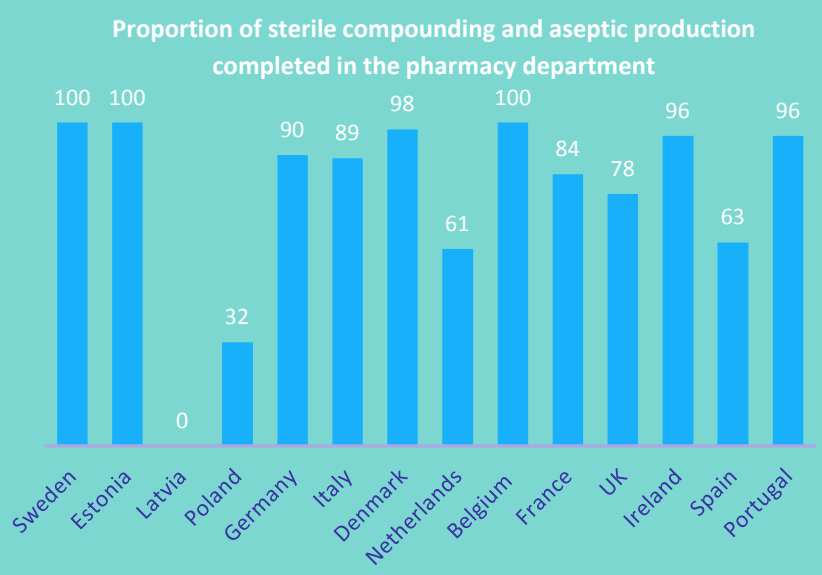
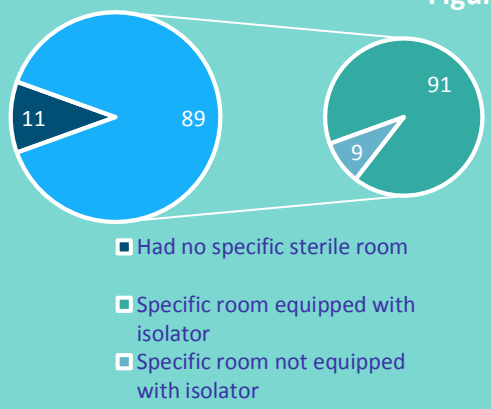


Figure 1.10



11% of hospital pharmacies lacked a specific sterile room for the preparation of hazardous drugs

9% of these production areas were equipped with neither a BSC nor an AI

A major advantage of the preparation of hazardous drugs in pharmacy departments is that the pharmacies should have specific sterile rooms for the preparation of hazardous drugs that are equipped with either Biological Safety Cabinets (BSCs) or Aseptic Isolators (AIs). Despite this often being the case, in 11% of the pharmacies there were no such rooms. Further, 9% of these rooms were equipped with neither BSCs nor AIs (Figure 1.10), fundamentally undermining the efficacy of the rooms. This was particularly acute in poorer countries such as Poland, where many of the surveyed pharmacies had neither BSCs nor AIs. This situation makes critical the use of CSTDs as recommended by the World Health Organisation.

The ages of the BSCs and AIs used in the sterile preparation rooms varied widely from country to country, and this variation is outlined below (Figures 1.11, 1.12). BSCs tended to be marginally older, with an average age of 10.2 years compared to the 9.4 years of the AIs.

While there is no set lifetime for the BSCs or AIs, they are more likely to grow faulty with age. Further, in the cases of this equipment, it will not always be clear that there has been a fault, meaning that faulty equipment could continue to be used, endangering pharmacists. Only the use of a supplemental device such as a CSTD would adequately protect workers in this scenario. There is also an issue of contamination build-up in older machines, especially when contamination monitoring is lacking (see page 18)

Figure 1.11

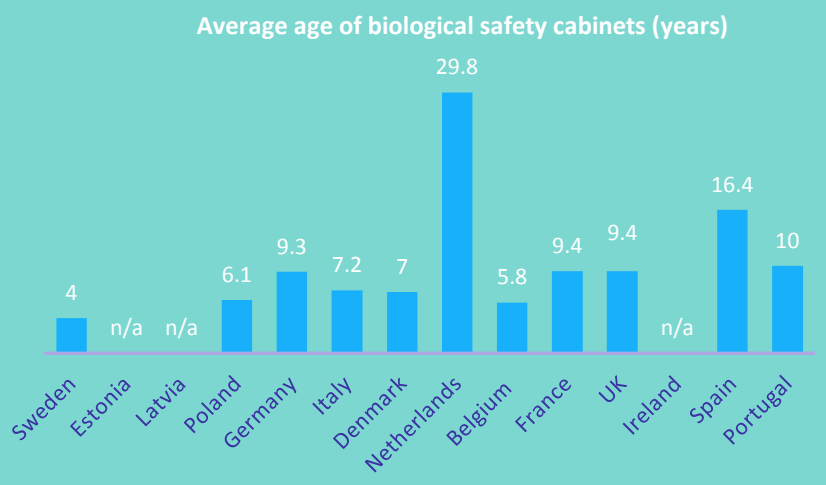


Figure 1.11 shows the disparity between the average ages of BSCs in each country. The cabinets were particularly old in the Netherlands and in Spain

Figure 1.12

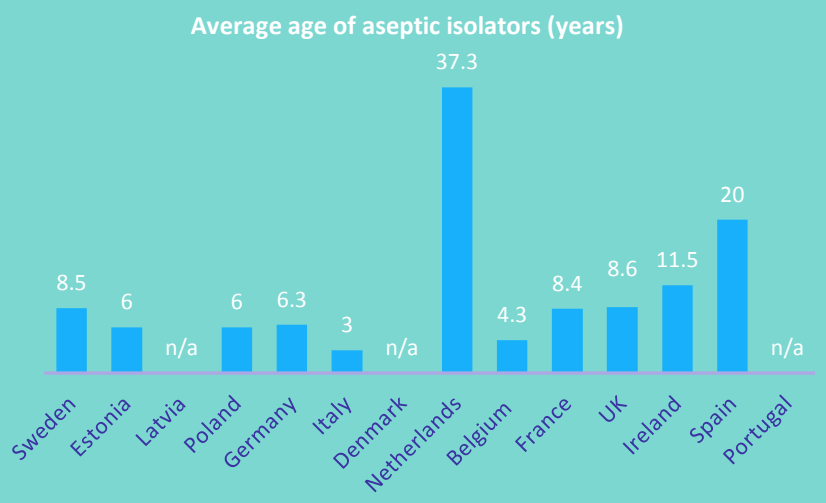


Figure 1.12 shows the variation between the average ages of AIs in each country. As was the case for the BSCs, the isolators were substantially older in Spain and especially in the Netherlands

Medical devices

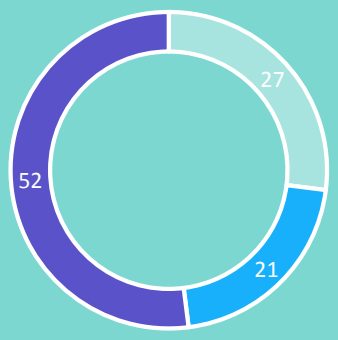
In the preparation of hazardous drugs, there are three main devices in use across Europe. These are syringes and needles, spikes, and CSTDs. The former pose the greatest risk of leakage, spills and contamination and are widely regarded as outdated technology. Spikes offer greater protection than syringes and needles, but still carry a high risk of aerosol and liquid spills. CSTDs are regarded as the "gold standard" in exposure prevention, and as such offer the greatest protection to those involved in the preparation of hazardous drugs.

However, uptake of the more advanced devices has been limited. The majority of parenteral hazardous drugs, for example, are still prepared using spikes, and 27% using syringes and needles. Only 21% of preparations are carried out using CSTDs, meaning that only a very small minority of workers are receiving adequate protection (Figure 1.13). For the preparation of BCG, uptake of advanced devices was better, but still widely underperforming. 42% of pharmacies were still using syringes and needles, 27% spikes, and 38% CSTDs.

A further example is the accessing of multi-dose vials. In this case, only 19% of pharmacies employed CSTDs, with 47% using spikes, 9% syringes and needles, and 33% using tamper seals. In this case, further issues are caused as CSTDs are the only system that prevents micro ingress, as they close the vials hermetically. Micro ingress risks patient safety, and is especially concerning with oncology patients who will often have suppressed immunity and will be particularly vulnerable to exposure. These data are displayed in Figures 1.14 – 1.16.

Figure 1.13

Percentage of preparations of parenteral hazardous drugs conducted by each medical system



Syringes and needles CSTDs Spikes

Figure 1.13 represents the proportion of preparations carried out using each system, rather than the proportion of hospital pharmacies where each system is in use, as below. It demonstrates the prevalence of unsafe methods - in almost 80% of preparations of parenteral hazardous drugs, hospital staff are under protected against exposure

The charts below show the proportion of hospital pharmacies using CSTDs, spikes, and syringes and needles in both the preparation of BCG and the accessing of multi-dose vials

Figure 1.14

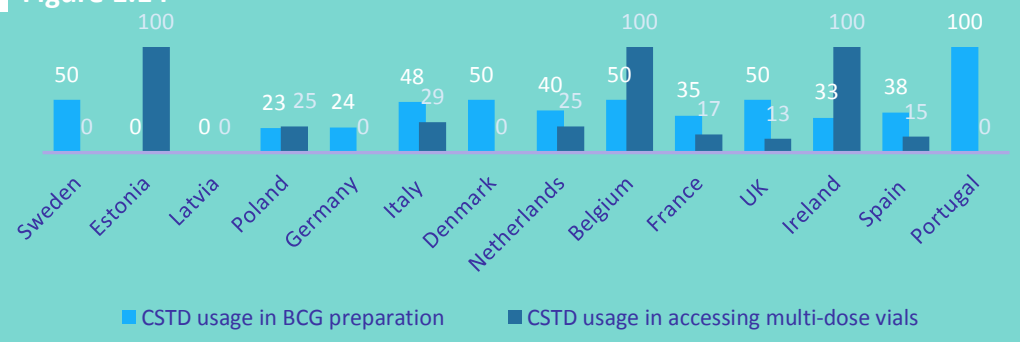
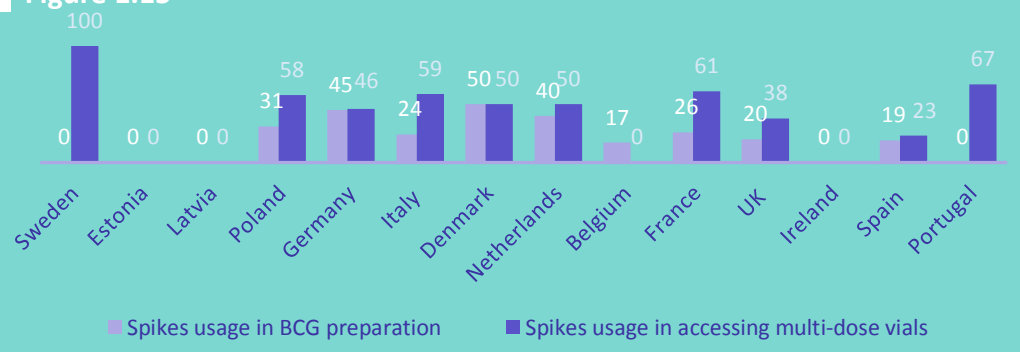


Figure 1.14 shows that general uptake of CSTDs has been limited, and that in many countries CSTDs are used for some purposes but not others. In Portugal, for example, CSTDs are used in 100% of pharmacies for the preparation of BCG, but in none for accessing multi-dose vials. Uptake was particularly weak in Eastern Europe

Figure 1.15



In Figure 1.15 we can see that some countries (Ireland, Estonia, and Latvia) neglect to use spikes entirely. However, in most Western European countries around half of the pharmacies reported that spikes were in use in these two processes

Figure 1.16

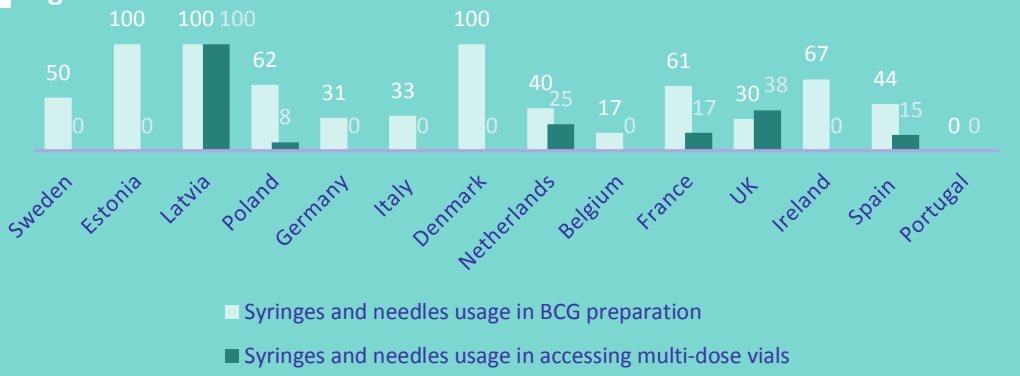
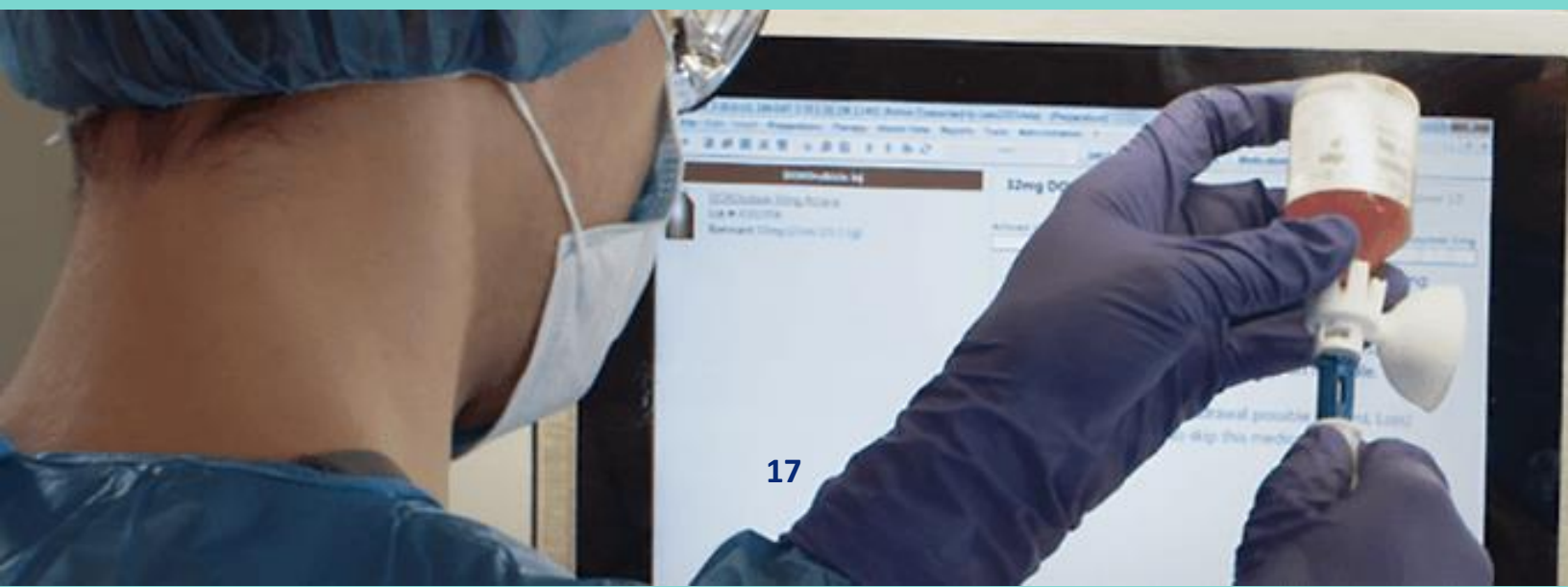


Figure 1.16 outlines the widespread maintained use of syringes and needles, particularly in the preparation of BCG in Eastern Europe. However, progress has been made in the eradication of this system for accessing multi-dose vials



Contamination monitoring

Regular monitoring is a critical element in ensuring internal policies and controls are effective in preventing exposure to healthcare workers. However, only 55% of the hospital pharmacies reported that they performed regular monitoring of hazardous drugs surface contamination in the work areas. The level of monitoring varied widely by country (Figure 1.17), and was notably low in Belgium (17%) and Portugal (25%). These results are disappointing, with recent advances in technology allowing rapid testing of surface contamination, perhaps a barrier to more frequent monitoring has been removed.

Further, where monitoring was regular it was often infrequent, with most hospital pharmacies carrying out monitoring doing so annually or less frequently (Figure 1.18). And often the most widely-used and highest-risk hazardous drugs failed to be tested for in the regular monitoring of surface contamination, with 23% of those surveyed were testing for none of the hazardous drugs listed in the questionnaire (Figure 1.19). This suggests that even where it is frequent, monitoring in its current format is often ineffective as a tool to combat exposure to hazardous drugs.

Figure 1.17

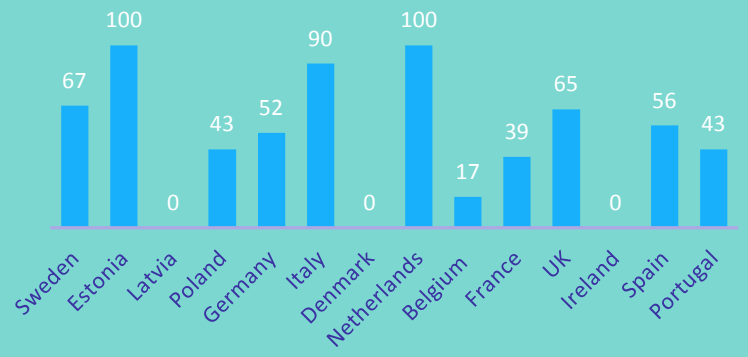


Figure 1.17 shows the proportion of pharmacies carrying regular surface contamination monitoring, with highly variable results by country

Figure 1.18 shows the frequency of the monitoring, with the majority being carried out annually

Figure 1.19 shows the drugs that are tested for in the monitoring

Figure 1.18

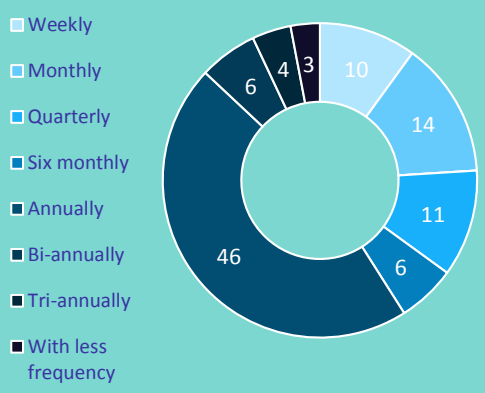
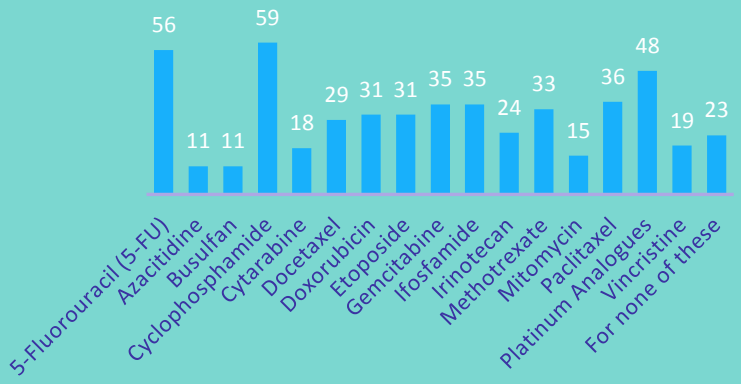


Figure 1.19



Reception, Unpacking, Relabelling, Storage and Transportation

Only 60% of reception areas in the hospital pharmacies had a list of hazardous drugs that could distinguish them from other medicines, suggesting that hazardous properties will often go unidentified and their dangers unchecked.

Storage facilities at pharmacies often lacked equipment and protocol. For example, only 68% of hospital pharmacies reported that there was sufficient ventilation in storage areas (Figure 1.20), suggesting that minor breakages, spills etc. may cause sustained airborne contamination. Further, the majority of hospital pharmacies were failing to provide documentary proof that the hazardous drugs vials were clean on the outside and free from contamination (Figure 1.21).

Figure 1.20 **Proportions of pharmacy reception areas that had a list of hazardous drugs to distinguish them from other medicines**

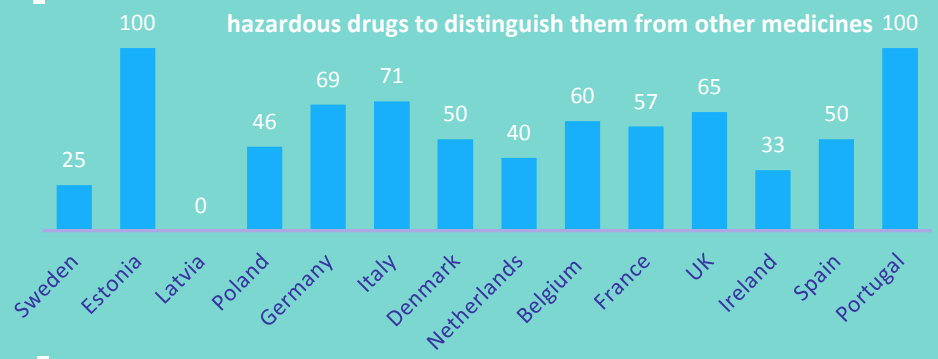
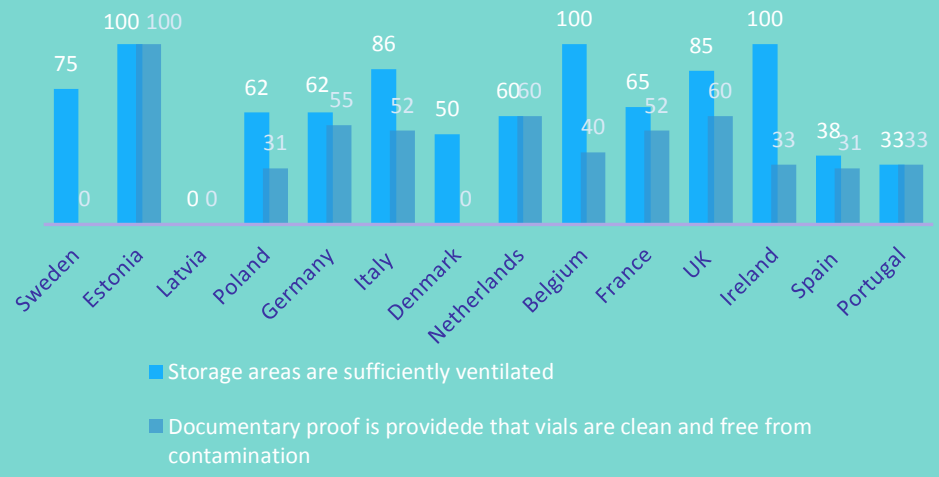


Figure 1.20 shows that often hospital pharmacy reception areas lack record of hazardous drugs, and are thus unable to distinguish them from other medicines

Figure 1.21



In figure 1.21, results are displayed for two examples of storage protocol. "Sufficiently ventilated" is defined as giving it least 12 changes/hour with neutral or negative pressure

Findings for Oncology Outpatient Units

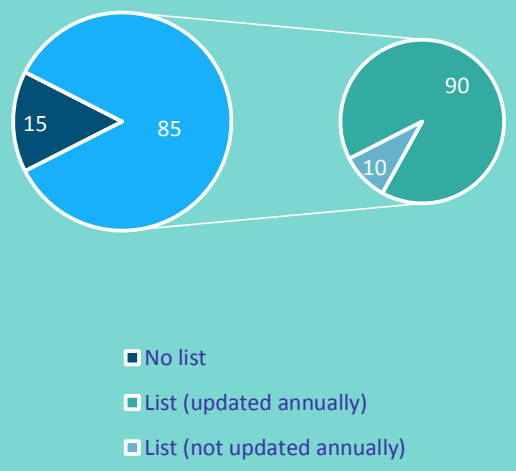
General procedures with hazardous drugs

85% of the oncology units surveyed had a list of hazardous drugs in place, and significantly, in 90% of cases this list was updated at least annually, suggesting that it was often in use (Figure 2.1).

Whilst all hospital pharmacies had put protocols in place for emergency situations, 3% of oncology outpatient units failed to do so, which although low, is higher than would be expected or desired. Many more failed to carry out risk assessments for staff handling hazardous drugs, although to a lesser extent than hospital pharmacies, but again showing that exposure prevention is often reactive rather than proactive (Figure 2.2).

Concerns outlined above over the recording of incidents with hazardous drugs can be echoed here, with 11% of the units failing to have a log available which although lower than the same figure for hospital pharmacies, still represents a widespread failing from the units (Figure 2.2).

Figure 2.1

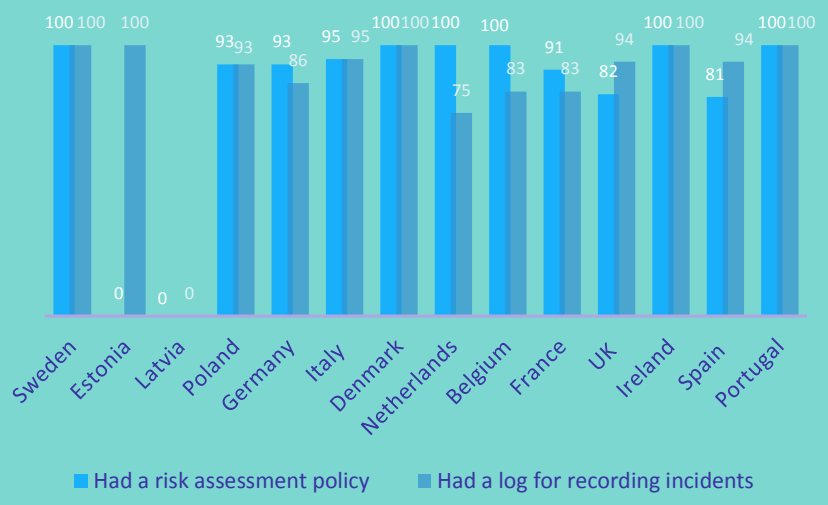


85% **of oncology outpatient units had a list of hazardous drugs used in the unit**

90% **of these were updated at least annually**

Despite some countries showing a high proportion of the pharmacies with risk assessments and incidents logs in place, this was sometimes not the case - notably in Latvia and Estonia

Figure 2.2



Administration

Handling areas

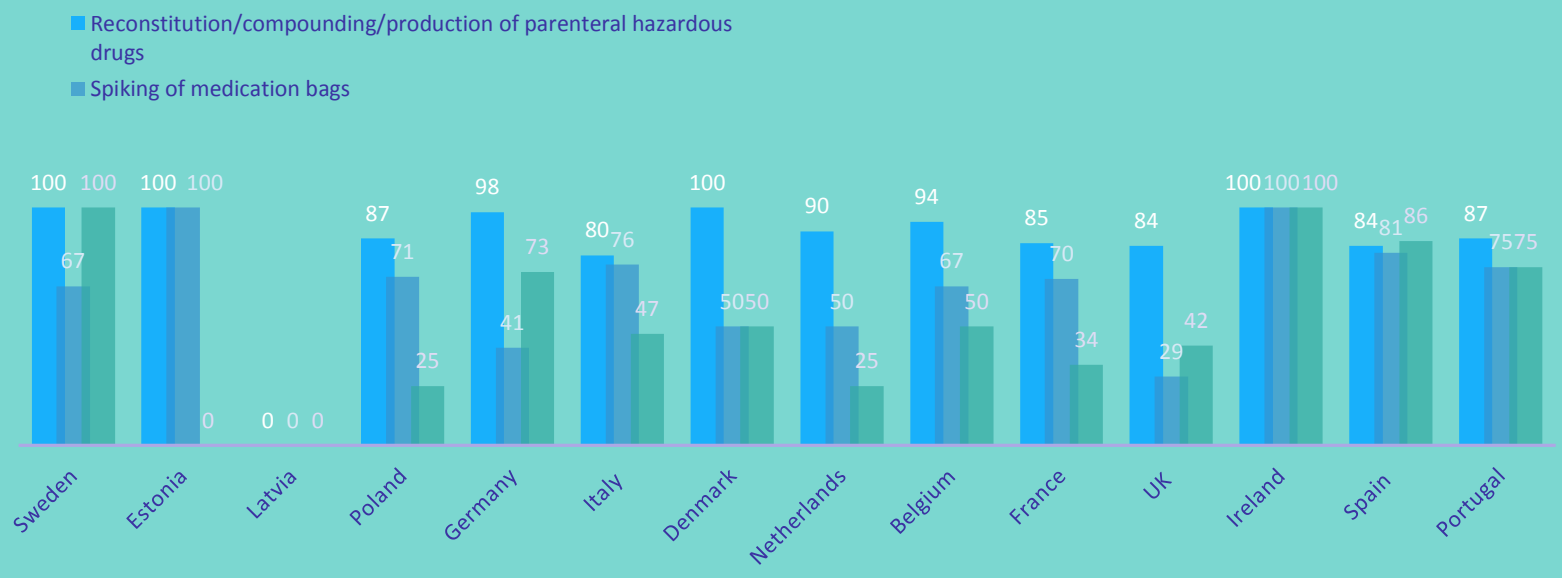
Across Europe, processes involving hazardous drugs that should be carried out in the pharmacy department, to protect nurses and patients from exposure, are often being carried out in the wards.

The vast majority (86%) of reconstitution, compounding and production of parenteral hazardous drugs was carried out in the pharmacy departments, but there is still room for improvement, especially in Italy (80%) and Spain (84%). 39% of the units reported that the spiking of medication bags occurred in the wards, and 47% reported that the crushing, grinding or splitting of solid oral hazardous drugs also occurred in the wards (Figure 2.3).

This is often a legislative issue rather than the fault of the individual units. In the UK, for example, the proportion of medication bags of parenteral hazardous drugs spiked in the wards is 71%, as spiking in the pharmacies is prohibited - despite it being safer practice. This increases the risk of exposure not only to workers, but also to the patients, carers and accompanying family members in the wards.

Figure 2.3

The proportion of various processes involving hazardous drugs carried out in the pharmacy



39% **of oncology outpatient units reported that the spiking of medication bags occurred in the wards**

47% **of the crushing, grinding and splitting of solid oral hazardous drugs occurred in the wards**

Systems

Outdated technology and administration practices were still common amongst the respondents. The practices of “un-spiking” drug containers and disconnecting with open systems are highly unsafe administration practices, but were being used in 40% and 53% of units respectively. CSTDs, however, were only being used in the minority of the units (41%) (Figure 2.4). The use of outdated technology in the units increases the risk of exposure to both staff and patients through an increase in leaks and spills.

Figure 2.4 **The proportions of oncology outpatient units using various medical practices/systems in the administration of hazardous drugs**

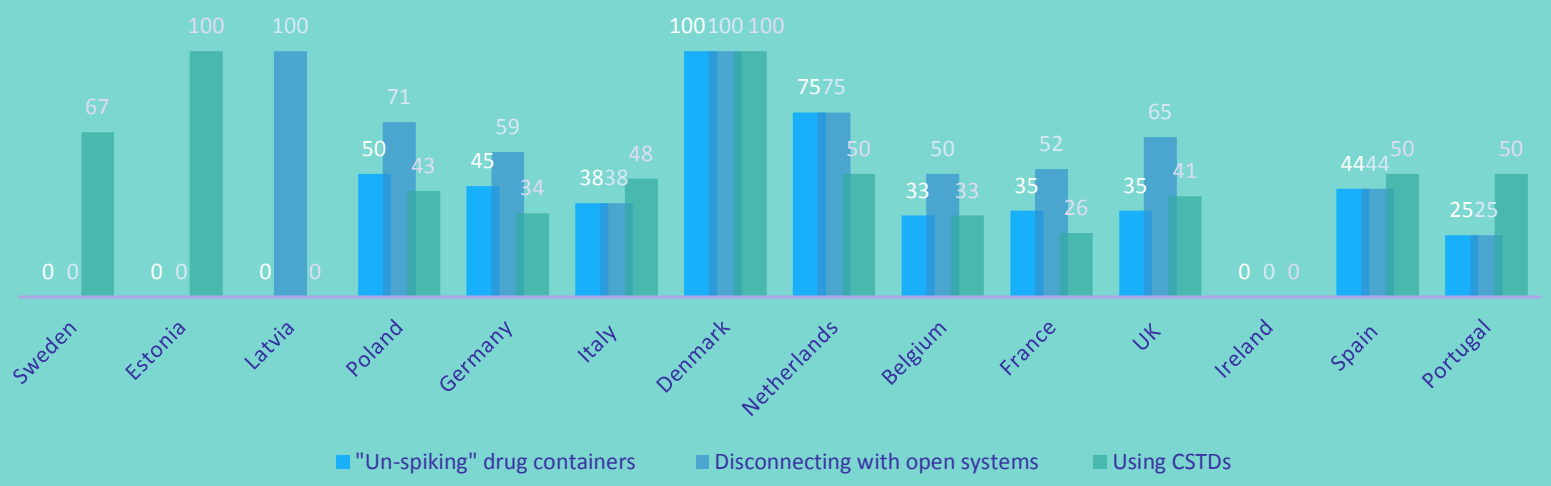


Figure 2.4 displays the proportions of oncology outpatient units using the unsafe practices of “un-spiking” drug containers and disconnecting with open systems, compared to the safe practice of using CSTDs. The majority of countries surveyed used two or more of these practices. Further, many individual units were using multiple methods, such as Denmark, in which all units surveyed were using all three methods

PPE

Especially where administration systems are outdated, PPE is essential to protect against worker exposure to hazardous drugs, and offers protection especially in emergency situations (from breakages, spills etc.) However, there were many cases where even the most basic forms of PPE were not used when required, with only 49% of units using double gloves, 77% employing gowns, 72% using eye protection when needed, and 75% respiratory protection when needed (Figure 2.5). And in 2% of oncology outpatient units, neither single nor double gloves were used.

Figure 2.5

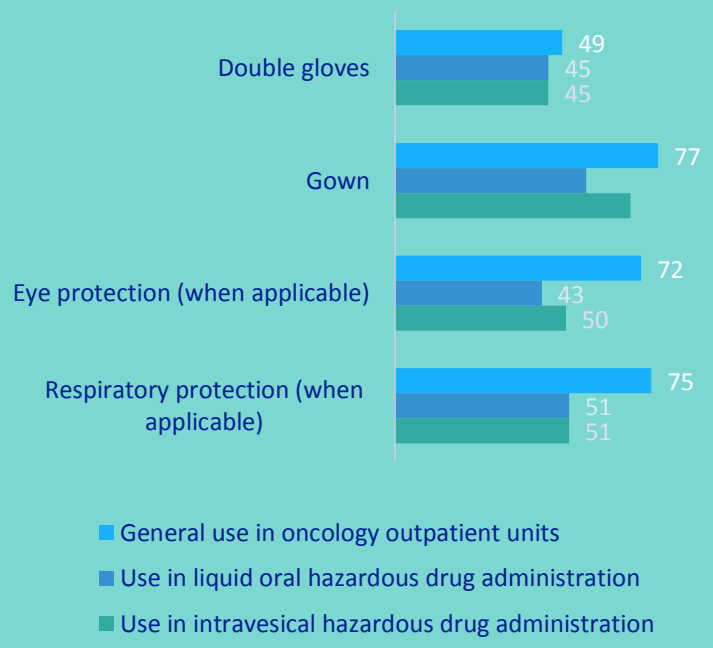


Figure 2.5 shows the use of PPE in general usage, intravesical and liquid oral hazardous drug administration. The figures for eye and respiratory protection apply to only those units in which the protection is required. The use of double gloves was particularly low

Contamination monitoring

Levels of monitoring in the oncology outpatient units were as low as for hospital pharmacies, with only 55% of the units reporting performing regular monitoring for surface contamination. Levels again varied widely by country, and were especially low in Latvia, Belgium (0%), Poland (23%), Sweden and Spain (25%) (Figure 2.6). Particularly in the wards, where risk of surface contamination is high and patients are vulnerable to exposure, monitoring is crucial, yet critically underused.

The frequency of the monitoring was higher than for hospital pharmacies, with the majority of the monitoring was carried out less than monthly (Figure 2.7). As was the case for pharmacies, many units failed to test for the highest-risk and most widely-used hazardous drugs (Figure 2.8).

These results are disappointing, with recent advances in technology allowing rapid testing of surface contamination, perhaps a barrier to more frequent monitoring has been removed.

Figure 2.6

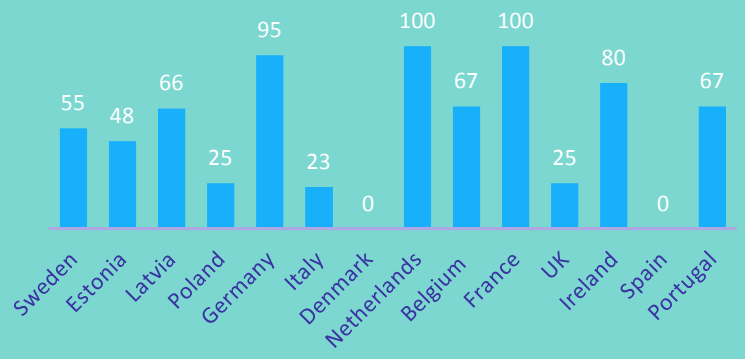


Figure 2.6 shows the proportion of units carrying regular surface contamination monitoring, with highly variable results by country

Figure 2.7 shows the frequency of the monitoring, with the majority being carried out annually

Figure 2.8 shows the drugs that are tested for in the monitoring

Figure 2.7

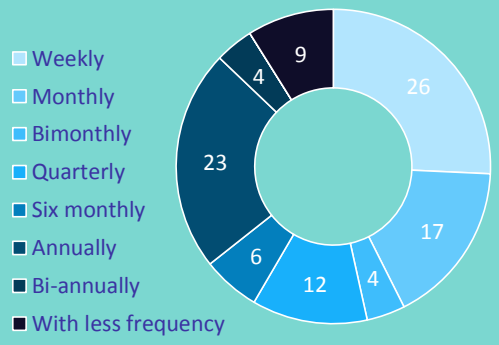
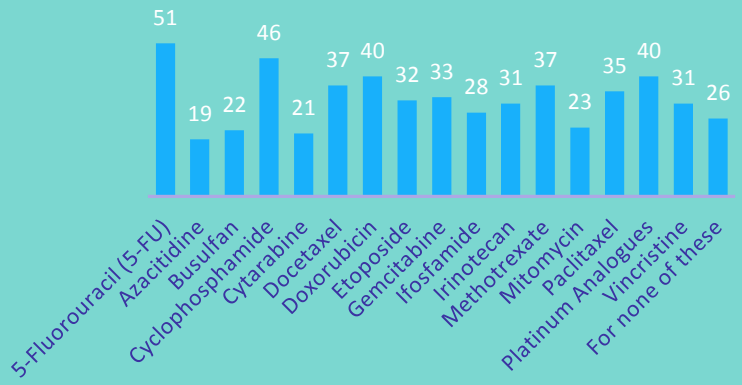


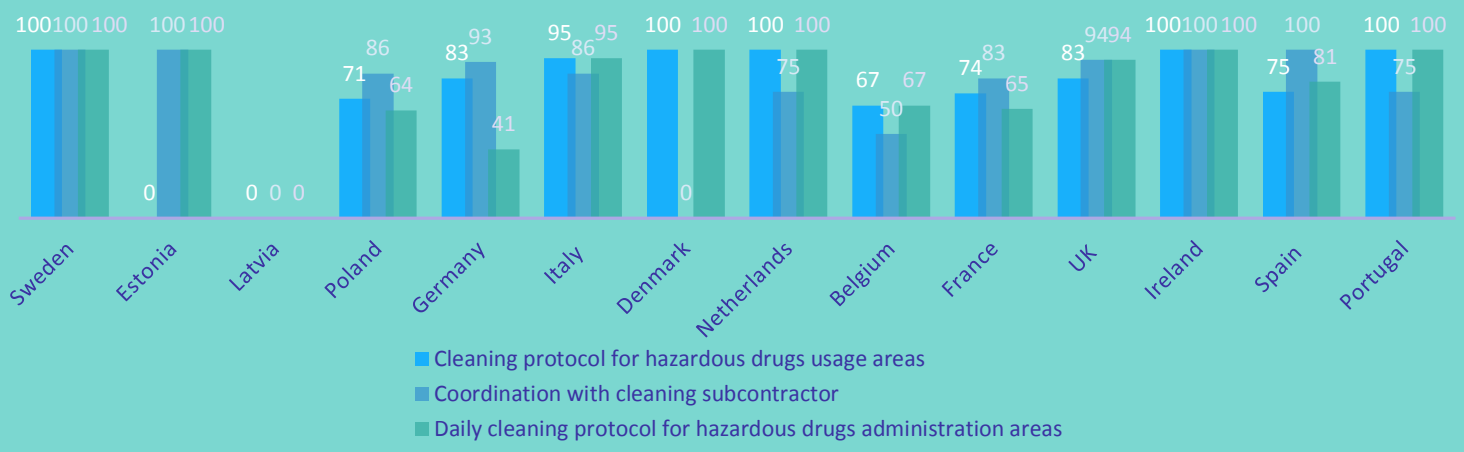
Figure 2.8



Cleaning

The proportion of oncology outpatient units with written protocols in place (82%) for cleaning shows a clear deficit in an area essential to contamination and exposure prevention. To reinforce this, 24% of the units failed to have a daily cleaning protocol, suggesting that cleaning may be infrequent and fail to sufficiently protect against contamination and exposure, with spills, leakages etc. causing long-term dangers to workers, patients and caregivers. Again, in situations where cleaning was outsourced to a subcontractor, there were many cases of the respondents admitting that they failed to coordinate with cleaning and waste management companies over policies and protocol.

Figure 2.9



There was a large variety in all areas of cleaning protocol, but there tended to be consistency within countries. Belgium and France were particularly lacking in their cleaning protocol

Training

As was the case with hospital pharmacies, the training protocol available to non-staff such as patients and caregivers (51%) was lacking compared to that available to staff (77%) (Figure 2.10). The deficit of training material in both categories is especially concerning in the wards, where patients are often at their weakest and most vulnerable to exposure. Further, only 68% had a training plan that must be carried out at least annually, and only 64% conducted an initial assessment on the training given (Figure 2.11), suggesting that although the information is available to a relatively wide section of the relevant individuals, it is often not implemented and maintained.

Figure 2.10

Figure 2.10 displays the proportions of oncology outpatient units making available training for both staff and non-staff

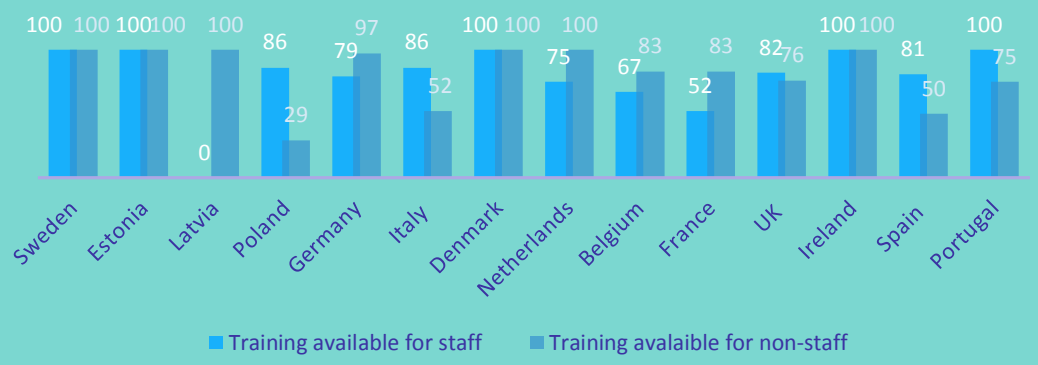


Figure 2.11

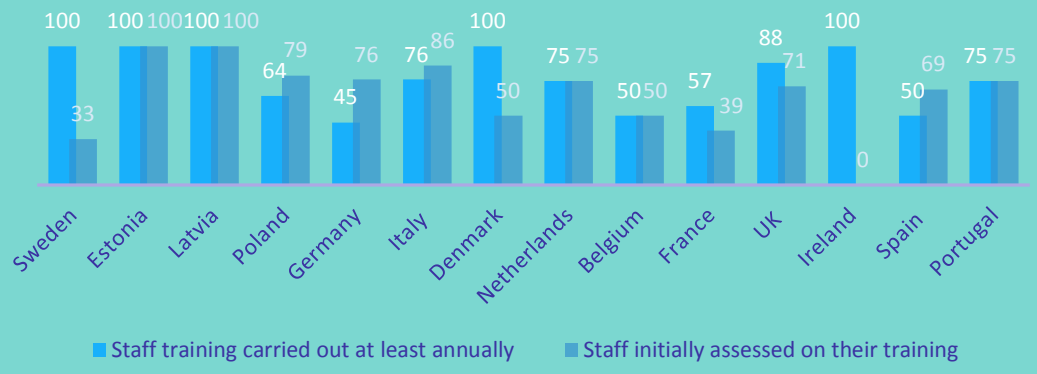


Figure 2.11 displays the proportions of the units carrying out periodic training at least annually and initial assessments on their uptake of any training received

Medical testing

Regular medical testing was carried out on workers on their exposure to hazardous drugs with highly variable results by country. The figure was lower than expected across Europe (58%), suggesting that worker exposure to hazardous drugs will often go undetected. On aggregate, the oncology outpatient units performed worse here than hospital pharmacies, although several wealthier countries (UK, France, Germany) registered improvements.

Figure 2.12

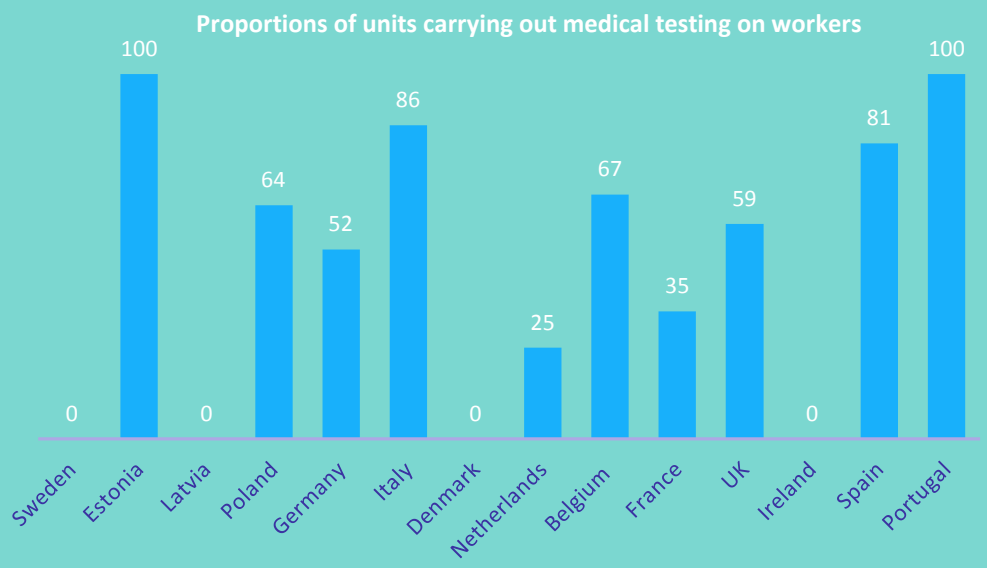


Figure 2.12 offers a breakdown of the rates of medical testing in the countries surveyed. Wealthier, more developed northern and western European nations tended to perform worse in this field, as was the case for hospital pharmacies

Glossary

AI (Aseptic Isolator)
Medical device that creates a sterile environment for the processing of pharmaceutical products

BCG (Bacillus Calmette–Guérin)
A vaccine used in cancer immunotherapy to stimulate immune systems, especially in cases of bladder cancer

BSC (Biological Safety Cabinet)
Enclosed, ventilated laboratory workspace for safely working with materials contaminated with (or potentially contaminated with) pathogens

CSTD (Closed System Drug Transfer Device)
Drug transfer device that mechanically prohibits the transfer of environmental contaminants into a system and the escape of hazardous drug or vapour concentrations outside the system

Cytotoxic
Toxic to living cells. Cytotoxic drugs are commonly used in oncology due to their ability to target living cancer cells, but carry the potential to damage normal tissue

Hospital pharmacy
Area in hospital for the handling, sorting, storage and processing of medications for hospital patients

Micro ingress
Microbial contamination of drugs containers (e.g. vials) from outside sources that is often caused through poor aseptic technique or the use of outdated medical devices

Oncology outpatient unit
Treatment and administration area for cancer patients

Parenteral
Administered or occurring elsewhere in the body than the mouth and alimentary canal

Spike
Drugs transfer device designed to improve on the use of syringes and needles but which carries a risk of aerosol and liquid spills

Syringe and needle
Traditional drug transfer device that fails to protect against spills, leakages etc.

European Biosafety Network

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