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SIG - FINAL REPORT

Special Interest Group on Controlled Substances Management

NOVEMBER 2024

Photo: NVZA

Table of Contents

The work of this Special Interest Group (SIG) was financially supported by BD.

Foreword from EAHP President Nenad Miljković

Controlled substances management is of high importance for patient care and safety. Moreover, it is crucial for identifying misuse and diversion throughout the medication management system, from prescription to administration or destruction of controlled substances. Managing controlled substances is a complex and time-consuming process. Challenges with management of controlled substances in a hospital setting, including the pharmacy and wards, are based on time-intensive mandatory record keeping processes and physical reconciliation of stock, frequently hindered by inadequate storage facilities' capacity.

Hospital pharmacists across Europe, currently mostly work with disconnected and manual based systems when managing controlled substances. Even when digitised, prescribing and administration processes often rely on human intervention to manage elements of the dispensing process which plays a central role in medication management.

This Special Interest Group (SIG) on controlled substances management was set to determine the current practice in Europe and to identify existing challenges in managing controlled substances in healthcare settings. Furthermore, the SIG aimed at describing available and emerging technologies used to manage controlled substances as well as the regulatory landscape and barriers surrounding the implementation of the aforementioned technologies.

I would like to take this opportunity and to thank all members of the SIG, including everyone who participated in the Survey launched earlier this year. This report describes the complex landscape around controlled substances management in Europe, emphasising the need for improvement and advancement in everyday practice of hospital pharmacists.

Nenad Miljković
President of the European Association of Hospital Pharmacists

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Background

Managing controlled substances (CS) is a complex and time-consuming process. Within this report, CS are regarded as substances and medicines that are subject to high levels of regulation due to government decisions (scheduled substances); in general, these substances bear a high addictive and/or abuse potential (NHS, n.d.). The management of CS in a hospital, including the pharmacy, wards, and departments, comprises of mandatory record-keeping processes, and physical reconciliation of stock, which can be hampered by inadequate storage facilities as well as limited capacity.

There are limited viable solutions with the potential to increase the efficiency of medicine logistics, reduce staff workload whilst improving dispensing safety and documentation processes. In addition, the legal framework in some European countries does not yet allow the use of this type of technology for the storage and digital documentation of controlled substances.

To gain a greater understanding of CS management landscape in Europe, specifically regarding the current challenges around the implementation of existing and emerging technologies to manage CS as well as any regulatory requirements and barriers to use of these technologies, the European Association of Hospital Pharmacists (EAHP) established this Special Interest Group (SIG) on CS Management.

The purpose of this group was to develop recommendations to improve CS management processes across European hospitals. The work of the SIG was supported by an educational grant provided by BD.

European Statements of Hospital Pharmacy

In 2014, EAHP adopted the European Statements of Hospital Pharmacy. These statements express commonly agreed objectives which every European health system should strive for in the delivery of hospital pharmacy services.

CS management is linked to several European Statements of Hospital Pharmacy cited verbatim below:

Statement 1.1 "*The overarching goal of the hospital pharmacy service is to optimise patient outcomes through working collaboratively within multidisciplinary teams in order to achieve the responsible use of medicines across all settings."*

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Statement 1.7 *"Hospital pharmacists must be involved in the design, specification of parameters and evaluation of ICT within the medicines processes. This will ensure that pharmacy services are integrated within the general Information and Communication Technology (ICT) framework of the hospital including electronic health (eHealth) and mobile health (mHealth) procedures."*

Statement 2.6 *"Hospital pharmacies should have responsibility for all medicines logistics in hospitals. This includes proper storage, preparation, dispensing, distribution, and disposal conditions for all medicines, including investigational medicines."*

Statement 2.7 "*Hospital pharmacists should be involved in the development of policies regarding the use of medicines brought into the hospital by patients*."

Statement 4.2 "*All prescriptions should be reviewed and validated as soon as possible by a hospital pharmacist. Whenever the clinical situation allows, this review should take place before the supply and administration of medicines."*

Statement 4.4 "*All the medicines used by patients should be entered on the patient's medical record and reconciled by the hospital pharmacist on admission. Hospital pharmacists should assess the appropriateness of all patients' medicines, including herbal and dietary supplements."*

Statement 5.2 *"Hospital pharmacists should ensure the development of appropriate quality assurance strategies for medicines use processes to detect errors and identify priorities for improvement."*

Statement 5.6 "*Hospital pharmacists should identify high-risk medicines and ensure appropriate procedures are implemented in procurement, prescribing, preparing, dispensing, administration and monitoring processes to minimise risk."*

Statement 5.7 *"Hospital pharmacists should ensure that the medicines administration process is designed such that transcription steps between the original prescription and the medicines administration record are eliminated."*

Statement 5.11 *"Hospital pharmacists should support and implement systems that allow traceability of all medicines dispensed by the pharmacy."*

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Part 1 Survey Report

Survey design

The SIG conducted a Survey to evaluate the current situation in Europe around the existing challenges in managing CS. The Survey had a total of 13 questions and was only available in English.

Respondents profile

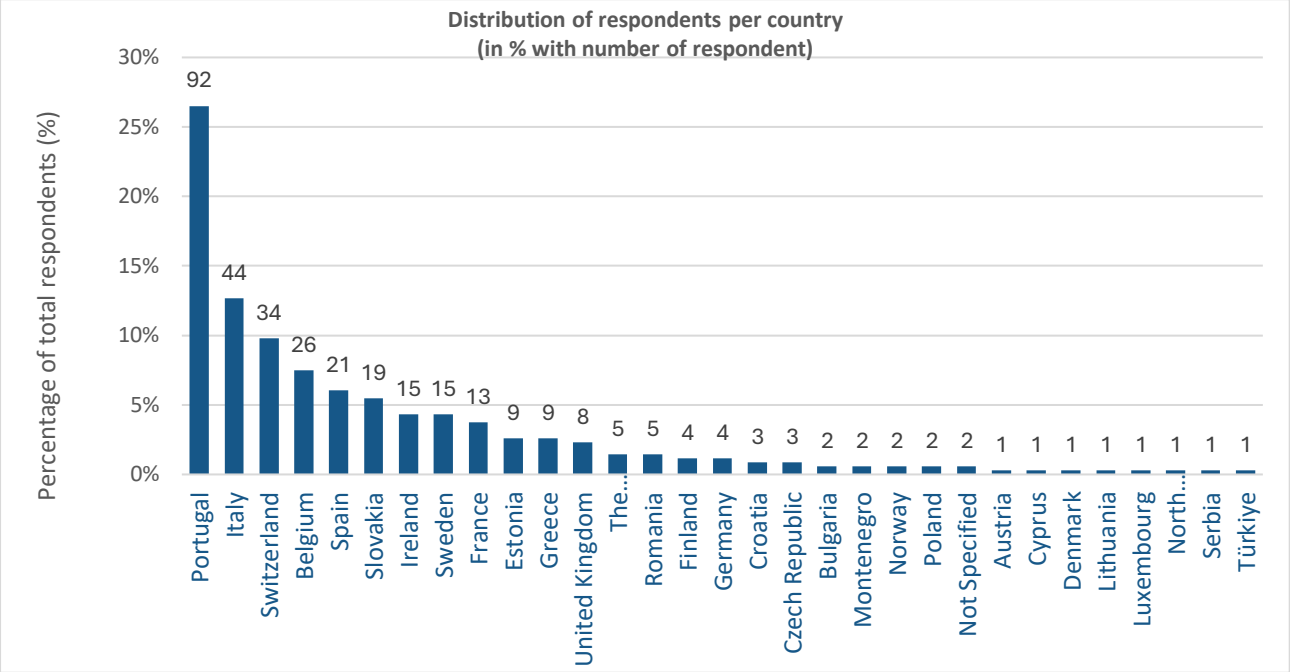

Figure 1: Percentages of total respondents (n=347) per country, answers to Question 1 "Please specify in which country your hospital is based."

The Survey was carried out among individual pharmacists from EAHP's member countries via EAHP's 36 national associations. In addition, it was available on the EAHP website, promoted via social media and poster presentations during the 27th EAHP Congress. The Survey was conducted from March 12th to April 30th, 2024. In total, there were 347 respondents from 31 countries.

Due to the low number of responses from some EAHP member countries, the results of this SIG should rather be perceived as a limited overview of the current CS management landscape in Europe and cannot serve as a mean to draw any general conclusions on CS management in the European context.

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The number of beds served by the respondents' hospitals indicates the size of the hospital. Most respondents offer their services to either 251 to 500 (29%, n=101) or 501 to 1000 beds (30%, n=110). See Figure 2 for more detail.

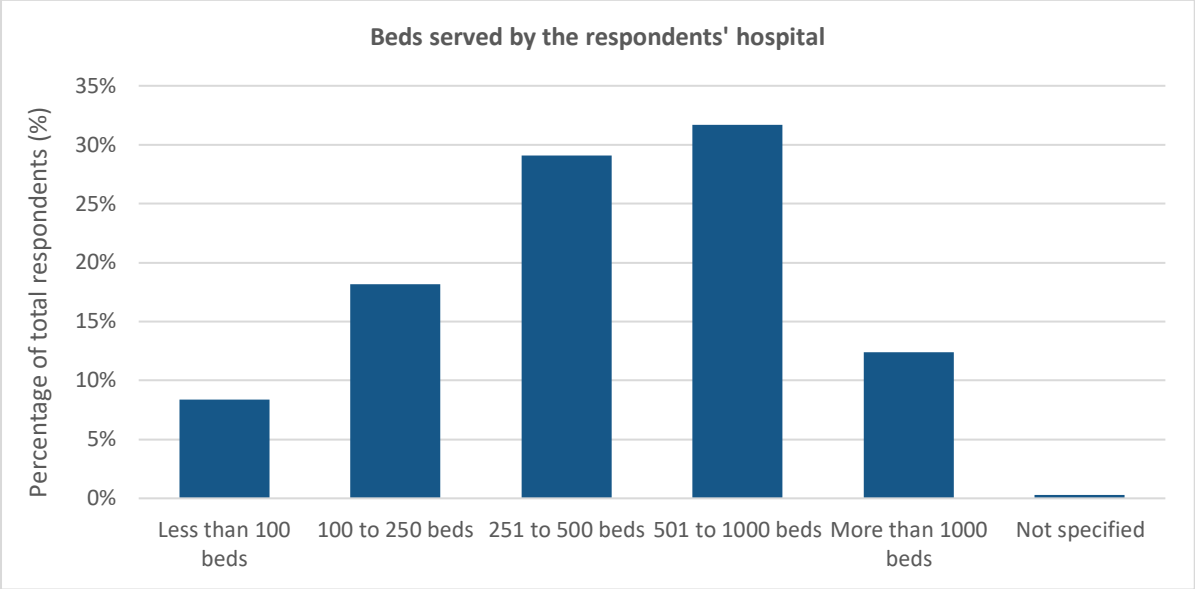

Figure 2: Percentages of total respondents (n=347) answers to Question 2 "How many hospital beds are served by your hospital pharmacy?"

Overall satisfaction with existing controlled substances management processes

Figure 3 shows that 48% (n=169) of respondents are either completely or somewhat satisfied with their existing CS management processes while 20% (n=87) are neither satisfied nor dissatisfied and 30% (n=107) are either somewhat or completely dissatisfied with their current arrangements for CS management.

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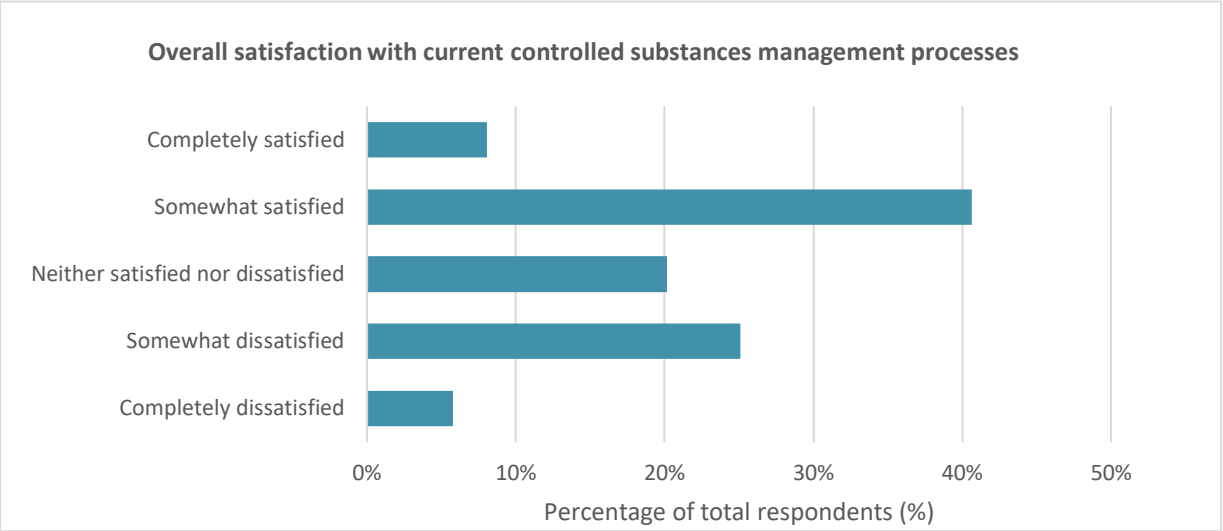

Figure 3: Percentages of total respondents (n=347) answers to Question 3 "To which extent are you satisfied with the current controlled substances management processes in your hospital/institution?"

Automation in existing controlled substances management processes

Most respondents indicated that their existing CS management employed a combination of digital and paper processes (see Table 1) in almost all of the processes described in the survey. Respondents (n=347) were more likely to use paper tools for documentation of destruction process of unused CS (39% n=134 vs. 8% n=27); documentation on ward registries (38% n=133 vs. 5% n=19); the CS register (26% n=90 vs. 20% n=70); audit (26% n=90 vs. 10% n=35); record keeping (20% n=69 vs. 12% n=41); dispensing and distribution to the ward (18% n=64 vs. 14% n=48) and validation and documentation in hospital pharmacy (18% n=82 vs. 16% n=57).

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	Only digitally *In percentages of total respondents (%)*	**Only on paper** *In percentages of total respondents (%)*	**Combination of both** *In percentages of total respondents (%)*	**N/A** *In percentages of total respondents (%)*
Ordering process for the pharmacy	36% (n=124/347)	15% (n=52/347)	48% (n=168/347)	1% (n=3/347)
Ordering process for the ward	28% (n=96/347)	25% (n=88/347)	44% (n=154/347)	3% (n=9/347)
Prescription process	27% (n=93/347)	13% (n=46/347)	59% (n=204/347)	1% (n=4/347)
Documentation of administration to patient	21% (n=73/347)	18% (n=64/347)	59% (n=203/347)	2% (n=7/347)
The controlled substances registry-file	20% (n=70/347)	26% (n=90/347)	50% (n=172/347)	4% (n=15/347)
Registration	18% (n=63/347)	16% (n=54/347)	53% (n=184/347)	13% (n=46/347)
Validation and documentation within the hospital pharmacy	16% (n=57/347)	18% (n=62/347)	62% (n=216/347)	3% (n=12/347)
Dispensing processes and distribution to the ward	14% (n=48/347)	18% (n= 64/347)	66% (n=230/347)	1% (n=5/347)
Record Keeping	12% (n=41/347)	20% (n=69/347)	65% (n=227/347)	3% (n=10/347)
Auditing	10% (n=35/347)	26% (n=90/347)	53% (n=185/347)	11% (n=37/347)
Documentation of the destruction process of unused controlled substances	8% (n=27/347)	39% (n=134/347)	49% (n=171/347)	4% (n=15/347)
Documentation on ward (ward-registry)	5% (n=19/347)	38% (n=133/347)	53% (n=184/347)	3% (n=11/347)

Table 1: Percentages of total respondents (n=347) answers to Question 4 "For the following processes, all linked with controlled substances management, specify if they are carried out digitally, on paper or both?"

When comparing these results with the level of satisfaction with the overall process, there is a positive correlation between respondents who only use digital tools for each process and respondents who are either somewhat satisfied or completely satisfied with the whole process, but the correlation is very weak.

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	Correlation coefficient with respondent who answered either somewhat satisfied or completely satisfied
Prescription process	0.1394
Validation and documentation within the hospital pharmacy	0.1593
The controlled substances registry-file	0.0849
Dispensing processes and distribution to the ward	0.1106
Documentation on ward (ward-registry)	0.0696
Documentation of administration to patient	0.1902
Ordering process for the pharmacy	0.1156
Ordering process for the ward	0.1192
Auditing	0.1714
Record Keeping	0.072
Registration	0.0795
Documentation of the destruction process of unused controlled substances	0.1044

Table 2: Correlation coefficient between respondents who only use digital tools for each process as answered to Question 4 and if they responded somewhat satisfied or completely satisfied in Question 3.

Greatest challenges in managing controlled substances

In Figure 4, 48% (n=168) of respondents indicated that their greatest challenge in relation to CS management was the registration process. Administration to the patient (42% n=147) and dispensing (41% n=143) were also highlighted as key problems. 25% of respondents (n=89) stated that storage was their greatest issue and a further 16% (n=55) reported that it was acquisition. 25% (n=90) of respondents indicated that their greatest challenge was either not listed or other.

Among 16% (n=56) of the Survey respondent other issues which posed a challenge were listed, including limited access to effective digital tools in their hospitals which led to issues such as limited interoperability between the different software, duplication of tasks, or inconsistency in receiving electronic prescription over paper.

Another often-mentioned problem, in the section “other”, was the destruction and return of unused medicines from the wards, as well as the management of residual substances (half ampoules for example). Moreover, problems with hospital wards themselves were mentioned often as the most challenging, this included stock management and expiry date control, documentation on dispensing at wards, borrowing between wards and the control of

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the wards. Additional issues related to prescribing, lack of audits, difficulties with registration processes for authorities, diversions, lack of human resources and medicine shortages.

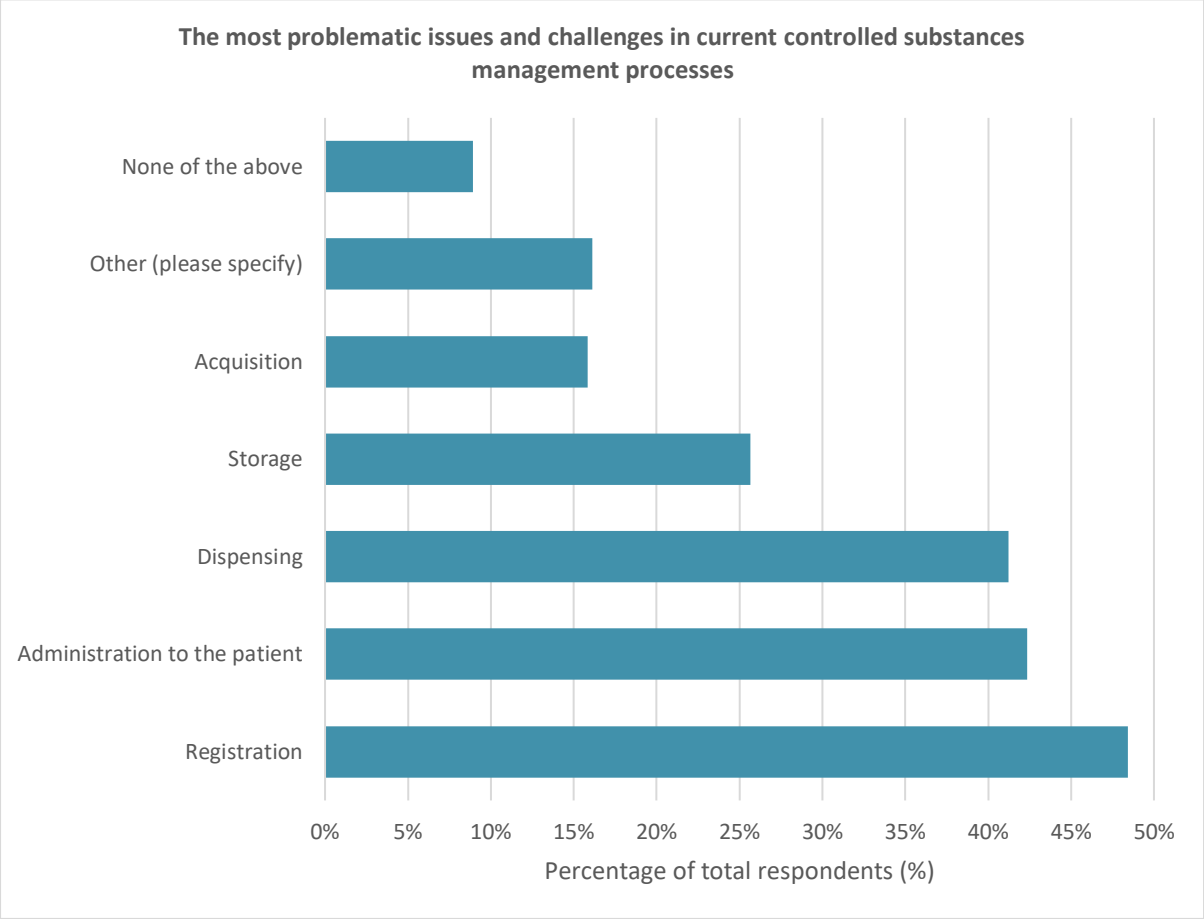

Figure 4: Percentages of total respondents (n=347) answers to Question 5 "Where do you see the most problematic issues and challenges in your current controlled substances management processes of your hospital/institution? Multiple options could be selected.

Obstacles to overcoming challenges

The survey also explored respondents' views on the existing obstacles to their ability to overcome the identified challenges in CS management. In Figure 5, 26% (n=47) of respondents believed that their greatest challenge was the fact that the CS management was a priority for the pharmacy team, but not for the hospital management. Furthermore, 23% (n=72) of respondents would like to address these challenges but do not have capacity to do so, with 8% (n=27) not having the capability to do so, while 22% (n=69) do not have the legislative authority to address their challenges.

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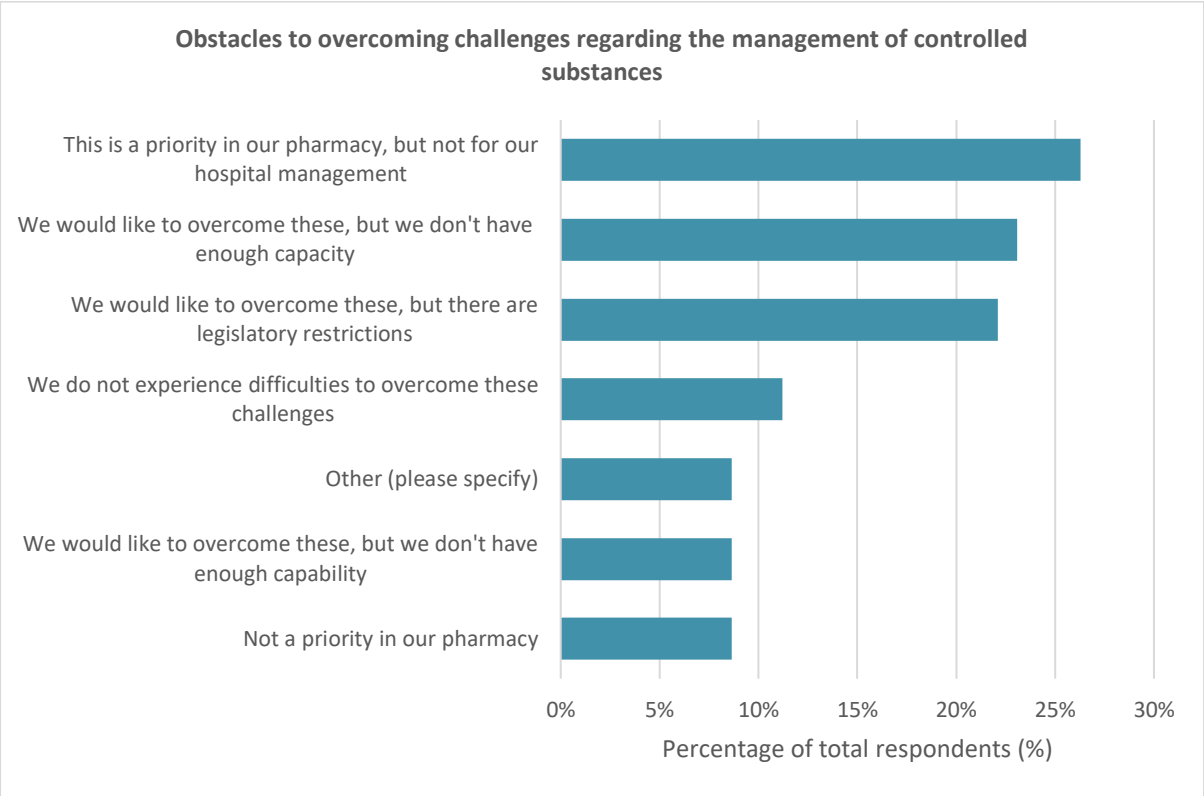

Figure 5: Percentages of total respondents (n=312) answers to Question 7 "Why do you find it difficult to overcome these challenges regarding the management of controlled substances in your institution?" *35 respondents skipped this question.*

In the section "Other" the following reasons were mentioned: lack of budget and financial resources, technical implementation issues, lack of the right tools and software and the number of controlled substances. Moreover, it was mentioned in this section that even though the management of CS is a priority for hospital pharmacists, it remains a challenge for nurses and doctors, either due to their limited understanding of the requirements for controlled substances as it is not a priority for them, or limited capacities on the ward to implement these requirements.

Current practices and procedures – Technological systems

Survey respondents indicated an almost even number of those currently using information technology systems or working on their development for the management of CS, 52% (n=212) compared to those who were not aquatinted with using such systems 48% (n=116). Among those respondents who have information technology systems in place or have them in the development phase, 18% (n=61) use a unit dose medicine distribution system, 16% (n=55) use automated dispensing cabinets and 11% (n=39) use both.

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In addition, 17% (n=57) of respondents selected "other" which includes the following technology systems being mentioned within the free text segment: dispensing robots, card readers, barcode scanners and a range of other systems. Other practices listed included the generation of official papers and control sheets by digital orders, which document dispensing to patients whilst simultaneously confirming dispensing to the patient on the electronic prescribing system.

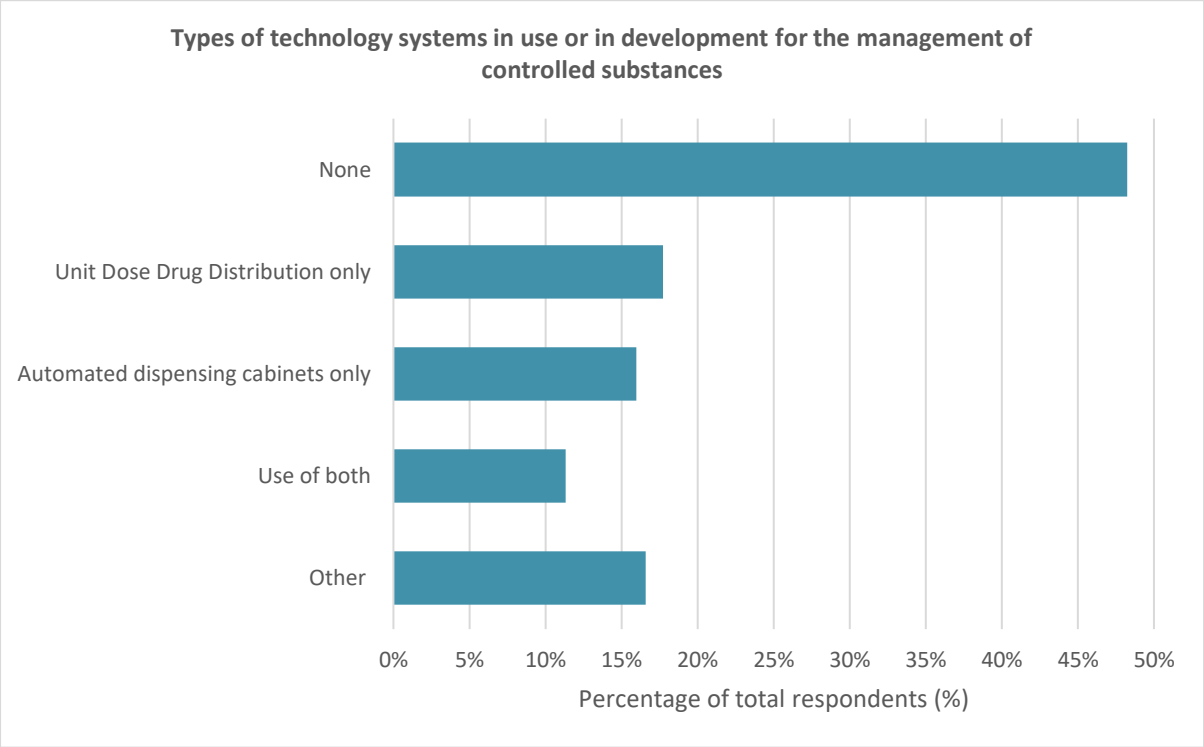

Figure 6: Percentages of total respondents (n=344) answers to Question 8 "What kind of technology systems does your hospital use or are in development for the management of controlled substances? Multiple options are possible." *3 respondents skipped this question*

Current practices and procedures – Diversion Prevention Programme

Only 17% (n=58) of respondents have a CS diversion prevention programme established in their hospital compared to 27% (n=94) of respondents who did not know about the Diversion Prevention Programmes (DPP) and 36% (n=124) did know about it and are not intending to introduce it.

This indicates room for improvement in the implementation and awareness of DPP.

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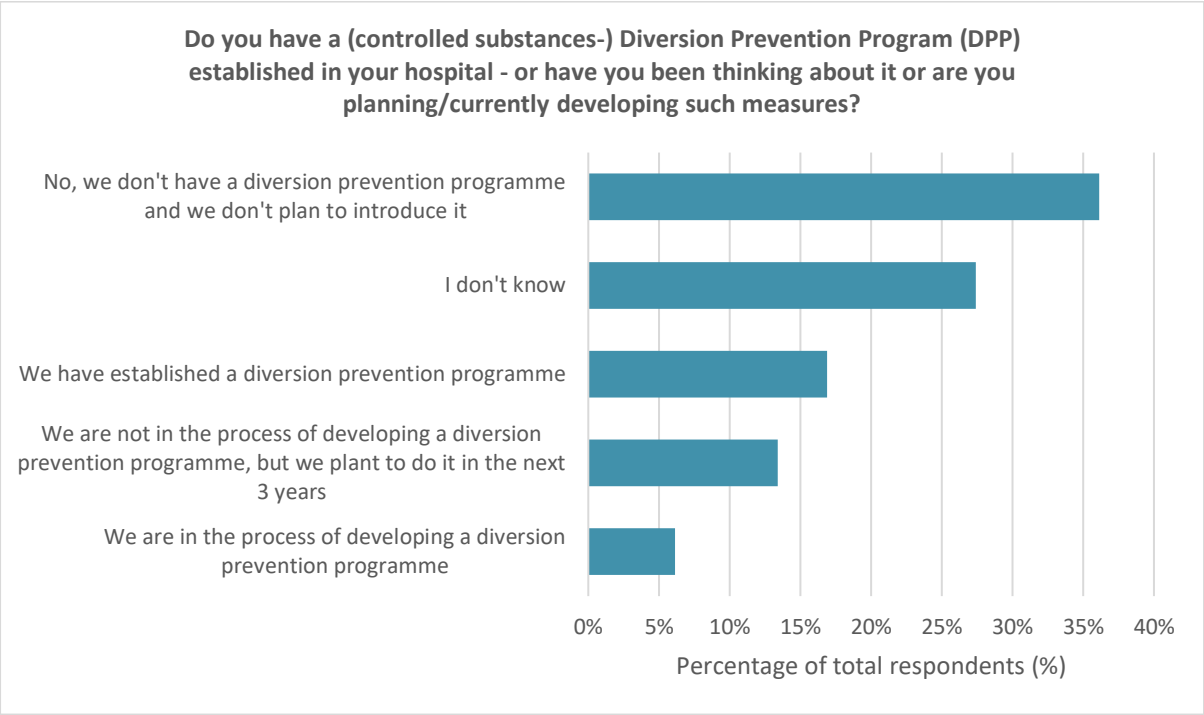

Figure 7: Percentages of total respondents (n=343) answers to Question 9 "Do you have a (controlled substances-) Diversion Prevention Program (DPP) established in your hospital - or have you been thinking about it or are you planning/currently developing such measures?" *4 respondents skipped this question.*

42% (n=56) of respondents who had a DPP planned or established indicated that it contained a definition of the CS policy, 41% (n=55) also had audit plans and 40% (n=54) had an executive DPP committee or team. Respondents were less likely to have CS software (28% n=37) and technology (29% n=38).

Many of the participants who selected "Other" (n=8/16) did not know what the programme contained. However, one respondent answered in this section that the audit of CS is included in the audit of the management process of all medicinal products. Another replied that their diversion prevention programmes included the monthly analysis of unusual consumption or loss institution wide.

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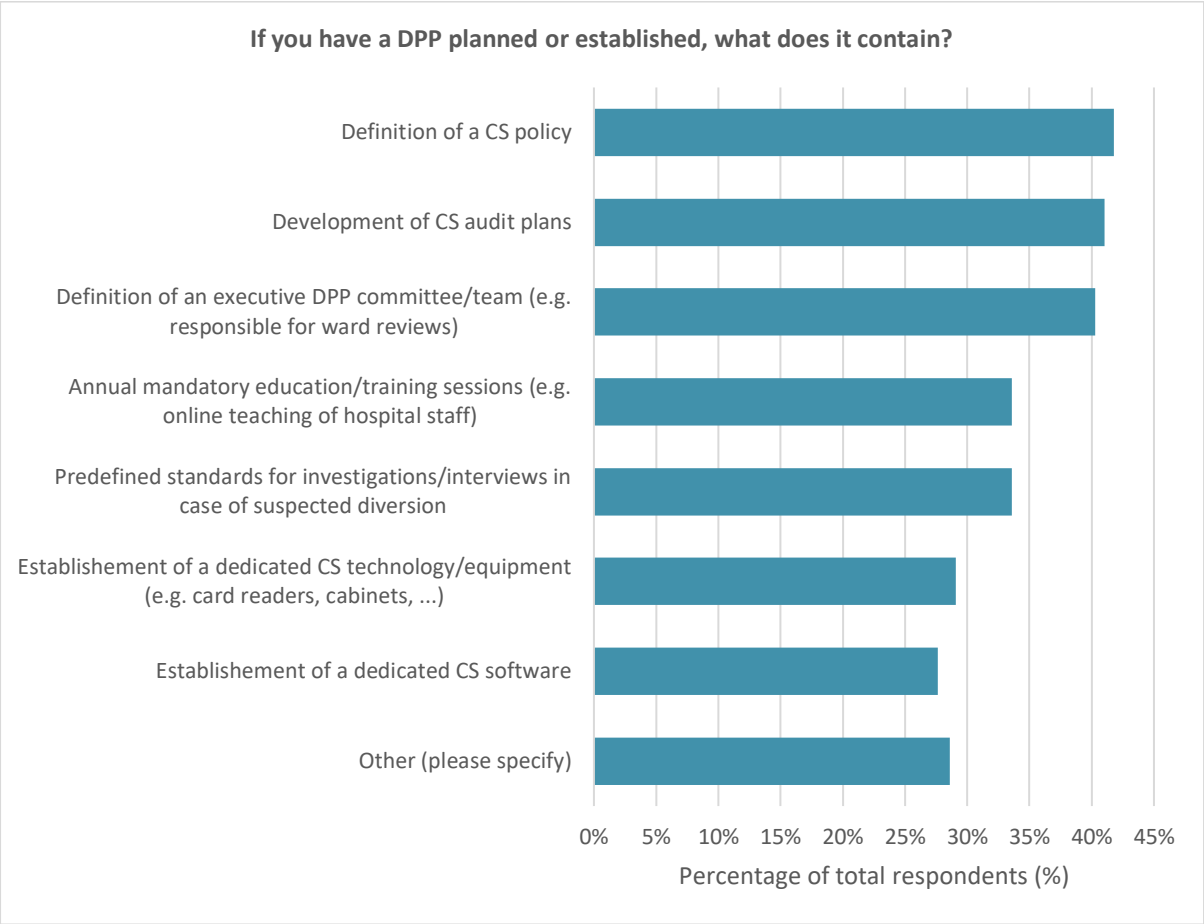

Figure 8: Percentages of total respondents (n=134) answers to Question 9 "If you have a DPP planned or established, what does it contain? Multiple options are possible."

Current practices and procedures – Incident Management

As outlined in Figure 9, there is a great variety in the way of reporting incidents. Most incidents are reported on paper (37%, n=128), or electronically and anonymously (34%, n=116). Reporting on the phone or in person (29% n=99) was used equally whilst a further 14% (n=49) of hospitals do not have any formal procedures to report incidents.

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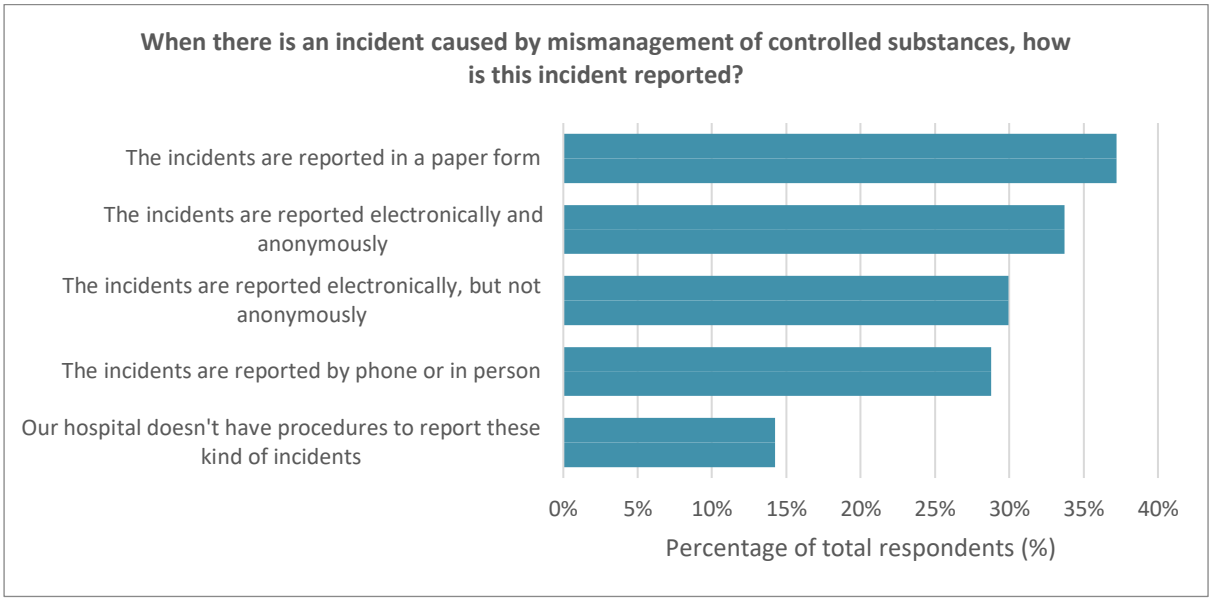

Figure 9: Percentages of total respondents (n=344) answers to Question 11 "When there is an incident caused by mismanagement of controlled substances, how is this incident reported? Multiple options are possible." *3 respondents skipped this question.*

This survey also explored what happened after an incident was reported (Figure 10). In most respondents' hospitals (80%, n=251) the hospital pharmacy team was responsible for the investigation. The investigation is taken over by relevant authorities in only 25% (n=77) of respondents' hospitals.

In the section "Other" (10%, n=31) it was mentioned that investigations are done by hospital pharmacists together with the board or management of the hospital. In addition, it was also mentioned that investigations are done together with a multidisciplinary quality team, a risk management team, or a patient safety group of the hospital. Depending on the nature of the case, the relevant ward, authorities, or other external teams are also involved.

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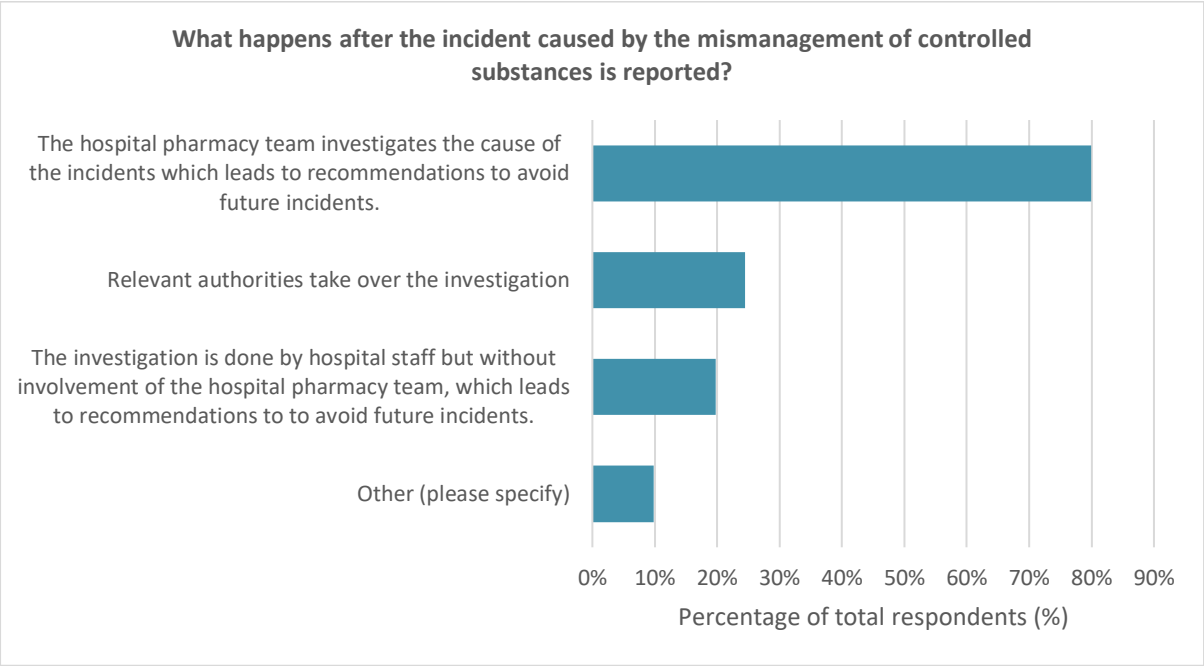

Figure 10: Percentages of total respondents (n=314) answers to Question 11 "What happens after the incident caused by the mismanagement of controlled substances is reported? Multiple options are possible." *33 respondents skipped this question.*

Current practices and procedures – Transportation

As seen in Figure 11, in most of the hospitals, CS are collected by a designated person within the hospital (45%, n=156) and within closed and sealed boxes in separate boxes (39%, n=134). Only 5% (n=17) use electronic tracking systems and only 1% (n=4) have fully automated transport while 13% (n=45) do not have procedures for transporting CS within the hospital.

Respondents also included some means of transportation in the section "Other". For example, the use of CS forms was mentioned as a way to document the transportation of CS. It was also reported that the exchange between wards in case of shortages, even if rare, should be documented in paper logs. Other hospitals commented that the collection and transportation of CS are done in person by authorised ward staff (head nurses) or by pharmacy staff. Furthermore, sealed plastic bags were mentioned to be used instead of boxes.

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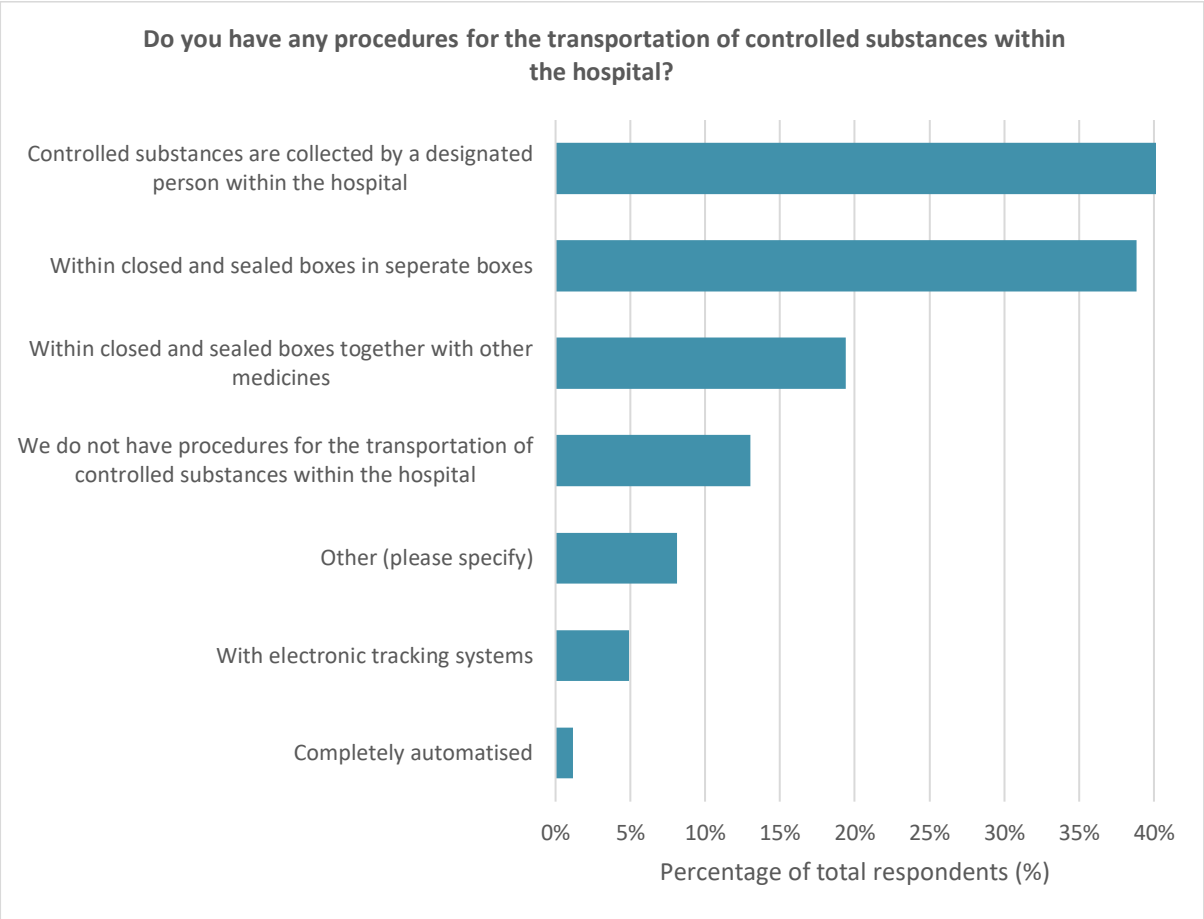

Figure 11: Percentages of total respondents (n=345) answers to Question 13 "Do you have any procedures for the transportation of controlled substances within the hospital? Please click on the most appropriate transportation system your hospital uses, multiple options are possible." *2 respondents skipped this question.*

Conclusions from the survey

The SIG conducted this survey to evaluate the existing processes in use for the management of CS across Europe as well as to collect opinions of EAHP member countries to understand the current challenges in this area.

The SIG want to highlight that although the results partially show the current situation across Europe, the results must be caveated, and cannot be taken as a wholesale representation of the management of CS in Europe due to the limited number of responses.

A total of 347 hospital pharmacists from 31 countries participated. The results outlined that 49% (n=169) were either completely or somewhat satisfied with their current arrangements,

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although only 8% were completely satisfied (n=28), leaving room for improvement for many respondents across Europe.

Across all processes, 55% (n=190) of respondents use a combination of both digital and paper tools. This is due to various reasons including legislations requiring the use of paper or manual processes and preventing digitalisation, which in some cases leads to duplication in the registration processes. Some respondents highlighted challenges in the implementation or difficulty to implement digital registries within their existing IT systems. The most common automated processes within CS management are ordering processes for the pharmacy and ward (36% (n=124) and 28% (n=96) respectively) and prescription process (27% n=96). The least automated processes identified by respondents are the documentation of destruction and the documentation on the ward.

Registration (48% n=63), administration (42% n=147) and dispensing (41% n=143) presented the greatest challenges to respondents in the management of CS. In terms of registration and the limited digitalisation of the dispensing process, the most frequently mentioned issue was a workforce shortage. Additionally, a high workload due to extensive documentation was cited as a significant problem. In the administration process, ensuring the traceability of CS was highlighted as the main issue, both with the return of unused medicines as well as tracking and verifying the administration itself (bedside scanning/documentation). According to the respondents, this lack of traceability makes it challenging to distinguish between units which have been omitted from documentation in error with potential stolen units. When only dispensing parts of a medicine (for example half an ampoule), automatic dispensing systems regularly leave residual CS unrecorded and therefore untraceable. The most reported obstacles identified by respondents to overcoming these challenges in controlled substances management, were minimal support from the hospital management as well as workforce shortages.

Only 17% (n=58) of respondents have a CS diversion prevention programme (DPP) established in their hospital, which indicates room for improvement in the implementation and awareness of DPPs. Of the respondents who did have a DPP, this programme was reported to contain a definition of a CS policy (42%, n=56), audit plans (41%, n=55) and an executive DPP committee (40%, n=54)).

According to the respondents, 48% (n=166) do not have technology systems for managing CS, suggesting an opportunity for automation. Moreover, only 5% (n=17) of respondents are using electronic tracking systems for transporting CS, and only 1% (n=4) have fully automated

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transport. In most hospitals, CS are collected by a designated person within the hospital (45%, n=156) and within closed and sealed boxes in separate boxes (39%, n=134).

The survey responses also revealed a great variety in the method in which incidents are reported. However, after an incident was reported in most respondents' hospitals (80%, n=251), the hospital pharmacy team was responsible for its investigation.

Part 2: Literature review

The SIG conducted a literature review to gain a deeper understanding of the current practices and challenges in the management of CS. The SIG report represents a limited review due to the lack of articles published on this matter, the conclusions are then also limited and should be taken as such.

The diversion of CS in hospitals remains an important and pressing issue that can occur at any stage in the use of medication process, posing significant risks to patient safety and public health (Fan et al., 2019; Martin et al., 2013). To mitigate this risk, there is an ongoing need for immediate and effective action. However, such measures are often hindered by various factors such as limited access to resources (a common barrier for new measures) or effective training for all involved in the process. Pharmacists, through their position, often have a central role in mitigating the misuse or abuse of CS. By actively engaging in the management of these substances and supporting addiction, pharmacists can significantly contribute to improving patient outcomes (Homsted et al, 2017; Fleming et al, 2014).

To address the ongoing risks associated with CS diversion, several sets of recommendations have been developed promoting safe and robust practices within pharmacies. Notably, the British National Institute for Health Care Excellence (NICE) have developed a comprehensive set of guidelines that cover key aspects of CS management, including governance, monitoring, prescribing, administration, and handling of CSs (NICE, 2016). Similarly, the American Society of Health-System Pharmacists (ASHP) have created a detailed roadmap to help institutions design and implement CS diversion prevention programs. This roadmap emphasises accountability and effective processes at three critical levels: core administrative elements, system-level controls, and individual-level controls (Clark et al., 2022).

Such guidelines provide a useful baseline for more targeted measures towards hospital pharmacists. However, not all recommendations apply to all hospitals, due to the variation in needs as well as access to resources which impact the implementation of such improvement measures (McClure et al., 2011; Videau et al. 2019). To facilitate the uptake of new practices

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and recommendations, it is crucial to understand the needs within hospital pharmacies and ensure that recommendations are realistic and can be implemented within the day-to-day activities of hospital pharmacists. Tools such as compliance frameworks offer an improved method of assessing individual hospital's-controlled substance circuit and can then support the most effective method of implementing improvements (Videau et al. 2019).

One critical aspect of reducing diversion risk is the ability to maintain accurate traceability of CS throughout their movement within the healthcare setting. Digital tools offer a promising avenue for achieving this, enabling practitioners to streamline processes and enhance accuracy. Automated dispensing cabinets (ADCs), for instance, are increasingly used to monitor controlled medication by recording all transactions, thereby improving transparency and accountability (Zheng et al., 2021; Shah et al., 2019; Lichtner, 2023). However, these technologies are not without limitations and potential loopholes, which must be carefully considered (Fan, 2019). ADCs should be integrated into the broader management framework with ongoing evaluation to identify and address any gaps or weaknesses in the system. Reconciliation discrepancies between the pharmacy and anaesthesia departments, for example, can often arise due to user errors, underscoring the need for vigilance (Wong et al., 2023).

Nonetheless, there is a possibility of the adaptability of digital tools which could provide more opportunities for continuous improvement than manual alternatives. This should be further explored in future studies. For example, advances in software have enhanced the reconciliation process, making it more accurate and reliable while helping practitioners meet the stringent scrutiny required by regulations (Epstein et al., 2016; Shah et al., 2019). It is important to recognise that technology alone cannot prevent deviations or mistakes. A multifaceted approach that includes adequate resource allocation for the implementation, evaluation, and potential redesign of systems and associated processes is essential for these tools to be fully effective (Zheng et al., 2021).

Another recurring theme in the literature is the critical importance of education and training for all stakeholders involved in the CS management process. Structured and comprehensive training can enhance awareness of diversion risks and improve vigilance throughout the medication use process. Training can include details of new physical or digital tools which could support staff in the re-engineering of CS management in their processes. (Wong et al., 2023; NICE, 2016). Continuous education is key to ensuring that all personnel are equipped with the knowledge and skills necessary to uphold the highest standards of controlled substances management.

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Therefore, effective management of CS in healthcare settings is crucial for ensuring patient safety and preventing diversion. The literature emphasises the importance of comprehensive guidelines, such as those from NICE and ASHP, which offer valuable frameworks for safe medication practices. However, the implementation of these guidelines is often challenged by varying institutional needs and resource constraints, highlighting the need for tailored approaches. Additionally, hospital pharmacists play a key role in preventing misuse and supporting addiction treatment, further underscoring the importance of their involvement in this process.

Technological advancements have shown potential in improving the traceability and accountability of CS. Yet, these tools could be part of a broader strategy that includes ongoing evaluation and continuous improvement to address limitations and ensure effectiveness.

The literature also emphasises the critical need for education and training of all stakeholders involved in the medication use process, as these are essential for maintaining vigilance and fostering a culture of safety within healthcare institutions.

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Part 3: Mapping European controlled substances management regulatory environment

Alongside the survey targeted at individual hospital pharmacists and the literature review, the SIG conducted a country mapping process, in order to comprehensively analyse the regulatory environment governing CS management across European countries. The goal of the mapping was to assess the similarities and differences in national legislation in relation to the processes for acquisition, registration, dispensing, storage, and electronic registry of CS within hospital settings. The SIG members completed process, and the results are presented in Table 3. The mapping aimed to gain a better understanding of the extent of digitalisation in each responding country and to identify associated barriers or challenges. In total, information from 16 European countries was collated, providing an opportunity to compare their respective national legislations and practices (Table 3).

Country	Main legislation	Complementary legislations
Austria	Suchtmittelgesetz	Suchtgiftverordnung Psychotropenverordnung
Belgium	K.B. 06/09/2017	Annexes I, II and III concern substances that are internationally targeted Annexes IV and V (BGL (gamma-butyrolactone) and 1,4-BD are nationally targeted
France	Order of 12 March 2013 on substances, preparations, medicines classified as narcotics or subject to the regulation of narcotics in health facilities.	
Germany	Betäubungsmittelgesetz	BtM-Verschreibungsverordnung - Directive on Prescription of CS BtM-Binnenhandels-verordnung - Directives for Trading Matters with CS
Greece	Δ Νόμος 1729/ΦΕΚ 144/7-8-1987	ΠΔ148/ΦΕΚ 191(10-08-2007) Νόμος 4139/ΦΕΚ 74/20-03-2013)

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Hungary	43/2005 Ministry of Health Decree	66/2012 Government Decree
Italy	Decreto Ministeriale 20 Aprile 1976	Decreto-legge 20 marzo 2014 DECRETO 11 maggio 2010 DECRETO 18 dicembre 2006 DECRETO 3 agosto 2001 Decreto 15 Febbraio 1996 Decreto del Presidente della Repubblica 309 9 Ottobre 1990
Luxembourg	Loi du 19 février 1973 concernant la vente de substances médicamenteuses et la lutte contre la toxicomanie	
Malta	Medicine Act	
The Netherlands	Opium law 2023	
Portugal	Decreto-Lei n.º 15/93 (22 January 1993)	Decreto Regulamentar n.º 61/94, 12 October 1994 (regulates Decreto-Lei n.º 15/93) Portaria n.º 981/98 (8 June 1998)
Serbia	Law on Psychoactive Controlled Substances 2010	
Slovakia	Act. No. 139/1998 Coll. On narcotic and psychotropic substances	Act. No 362/2011 Coll. On Medicines and Medical Device
Spain	Ley 17/1967, about narcotics drugs	RD 1675/2012, regulation of prescriptions and special requirements for the prescription and dispensing of narcotics drugs for human and veterinary use
Sweden	SFS 1992:860 (Law on controlled substances)	LVFS 2012:8 (Hospital pharmacy services) SFS 2009:366 (Law on trade with medicinal products) LVFS 2011:9 (Regulation on control measures)

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		LVFS: 2011:10 (List of controlled substances) HSLF-FS 2017:37 (Regulation on the prescribing and handling of drugs in healthcare) LVFS 2010:4 (Regulation on extemporaneous preparation)
Great Britain	Controlled Drugs (Supervision of management and use) Regulations 2013	The Controlled Drugs (Supervision of Management and Use) (Amendment) Regulations 2020

Table 3: List of legislations outlines by respondents of the country mapping questionnaire.

The mapping process enabled collation of legislative requirements in 16 European countries, facilitating a point prevalence report of practice in this area in 2024. **Due to the limited number of responses, it cannot be inferred as a representative example covering all the different legislative requirements for the management of CS across all European countries. The mapping analysis only represent the countries listed above.**

Current practices and procedures – Acquisition of controlled substances in the hospital setting

Three methods of acquisition of CS were observed in the countries listed, with some having more specific rules depending on the substance. Firstly, for most countries, the process to acquire CS is similar to the process of acquiring other medicinal substances; hospital pharmacists can order CS directly from specific marketing authorisation holders and receive them at the hospital pharmacy. For the United Kingdom, this is done only by organisations assigned the status of designated body under the legislation and only by a specifically appointed Controlled Drugs Accountable Officer who, among other tasks, must establish a secure and safe management and use of CS.

Secondly, some countries have greater oversight by requiring an approval by the Health Ministry or National Health Authority prior to ordering CS from wholesale distributors. For example, in Greece, where the CS are divided into four categories, hospital pharmacists must apply to the Ministry of Health before purchasing any substance included a list with CS with some potential of abuse such as certain anabolic steroids. There is a different list with less

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strong CS where the hospital pharmacists may directly order from the marketing authorisation holder. While the process can be judged to be more secure on a national level, it can cause a delay for hospital pharmacists due to recurring backlogs and long waiting time between the application and reception of the controlled substance.

Thirdly, some smaller countries have a more centralised system from which hospital pharmacists will directly order through. Serbia and Malta have a system where CS in hospitals are obtained either through public tender or a central medicinal repository which procure national health medicine. Staff shortages indirectly impact access for example in Malta, where requests only can be done by pharmacists responsible for CS who are only available at certain times. In Portugal, similar to the Greek process, there are different acquisition processes for substances depending on their potential risks. In addition, Portugal uses a centralised procurement system to buy some substances thus using a combination of all three methods.

Similar to other substances	Application to authority	Centralised procurement
Austria	Belgium	Serbia
France	Luxembourg	Malta
Slovakia	Spain	Portugal (partial)
Greece (partial)	Greece (partial)	
Germany	Portugal (partial)	
Italy		
Portugal (partial)		
Slovakia		
Sweden		
The Netherlands		
United Kingdom		

Table 4: The general process of acquisition of controlled substances for each respondent country.

Current practices and procedures – Registration of controlled substances in the hospital setting

In all surveyed countries, it is a regulatory requirement for hospital pharmacists to maintain comprehensive documentation for the registration and tracking of CS. This documentation is essential for monitoring and managing any movement of these substances, and typically includes at minimum the following data points, with some varying specificities between countries:

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Product information	Tracking information
• Product name • Quantity • Purpose of use • Current stock	• Date • Person responsible for any change • Order form / document number • Import/export license number when relevant • Prescriber and number of prescriptions

This record-keeping plays a crucial role in ensuring that CS are managed securely and used appropriately within hospitals. It allows for an accountable and transparent chain of use from procurement through to dispensation, essential for compliance and patient safety.

In addition to these requirements, there are specific National mandates that regulate how often these records must be reported to health authorities to ensure that CS are handled responsibly and reduce the risk of misuse. In Portugal, hospitals are required to submit a report every three months and a summary annual report detailing their handling of medicines containing CS. These reports are important for Health Ministries to oversee and ensure that CS are securely managed and correctly used in the medical contexts.

The transition towards using digital tools remains uneven across countries. While some have adopted digital registry systems to streamline processes, many continue to rely on manual, paper-based methods. This variance stems from multiple reasons, as there is no requirement to use digital tools for hospital pharmacists, there are also less incentives to invest in digital infrastructure or to integrate them within the existing hospital systems. The use of digital tools thus often remains voluntary and leads to varying levels of digitalisation between countries and hospitals.

The SIG members believe that the use of paper recording can increase the workload for hospital pharmacists and heighten the risks of errors, such as missing information or difficulties in interpreting handwritten entries.

Digital traceability system	Possibility for both	Physical traceability system
Greece	Sweden	Austria
Slovakia	The Netherlands	Belgium
	Italy	Germany
	Portugal	Luxembourg

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	France	Serbia
		United Kingdom

Table 5: The general use of digital tools for the registration process in each respondent country.

Current practices and procedures – Dispensing controlled substances in the hospital setting

Dispensing CS in hospital settings is primarily done based on prescriptions issued by prescribers, whether in paper or electronic format. These prescriptions must contain a certain minimum of information, including the patient's name, prescribed dose, active pharmaceutical ingredient, pharmaceutical formulation, and the quantity requested. Dispensing must then follow standards set by the regulators and the hospital pharmacists or suppliers must confirm the identity of the person before providing the CS. It is often the responsibility of the hospital pharmacists to provide information and advice required to the person receiving the controlled substance, for example on the use of the product, anticipated action, side-effect, duration of use as well as the disposal. Alongside the registration of the substance, hospital pharmacists must record any transfer of the substances including recording the dispensing of products.

A notable challenge commonly highlighted was the dispensing process, due to the inconsistent level of digitalisation across hospitals. While prescriptions by prescribers may require electronic submission, the dispensing process and its subsequent documentation are frequently carried out manually. This often led to additional workload for hospital pharmacists and can pose additional risks such as the traceability gaps in substance management when the documents are in different formats and under different systems.

Current practices and procedures – Storage of controlled substances

Across the 16 countries surveyed, storage protocols for CS varied but largely revolved around the requirements for secure and locked storage areas. These storage areas encompass rooms, cabinets, or safes. Notably, Slovakia stands out for mandating only narcotic substances to be locked in a safe, while other CS adhere to standard storage practices of other medicines. Some countries impose additional security measures. Belgium and Greece require regular security checks, while Germany mandates an approval from the Controlled Substance High Authority for the room plans intended for storage before its utilisation.

The SIG points out again that this report only includes the experiences and guidelines of some of the EAHP member countries.

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Current practices and procedures – Digitalisation of registry

Digitalisation of registries for CS in hospital settings varies significantly among countries surveyed, remaining voluntary and subject to the accessibility of digital tools. Although some countries are moving forwards in the adoption of digital registry systems, disparities continue to exist between hospitals also within the same country.

In France, for instance, a Drug Traceability Software is available in some hospitals to ensure the traceability of specific CS enhancing transparency and accountability in their movement. Similarly, in Germany, hospitals have the option to implement electronic file systems upon approval by authorities, providing a digital platform for managing controlled substances records. In Slovakia, controlled substances movements are recorded via the hospital information systems, although interoperability issues have been reported, often leading to increased workloads for pharmacists. Despite these challenges, efforts to digitise registries in these countries demonstrate a commitment to continuous improvement of the controlled substances management practices.

In many other countries, digitalisation of registries remains limited, with reliance on different IT systems across hospitals. Portugal, for example, highlights the availability of digital registry software available but predominantly accessible to only community pharmacists. Addressing these disparities will be key to increasing the uptake of digital registries throughout Europe and requiring a concerted effort to enhance digital infrastructure and promote interoperability among hospital IT systems. Investing in standardised digital registry platforms and ensuring widespread access to digital tools for hospital pharmacists can streamline controlled substances management, reduce the workload, improve traceability, and enhance regulatory compliance.

Summary of legislations

The SIG conducted the country mapping to better understand the legislative framework, the processes and respective challenges when working with CS in the hospital setting throughout Europe. Overall, the SIG gathered information from 16 EAHP member countries revealing significant diversity in the management of CS across European hospitals. The overall challenge remains around the limited and varied levels of digitalisation leading to an increased administrative workload for hospital pharmacists to remain compliant with legislations. Therefore, there exists opportunities in enhancing digital infrastructure and improving the management of CS across Europe.

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As outlined by the survey, the registration of CS remains complex in hospital settings with high amount of detailed documentation to be manually completed by hospital pharmacists for the registration and tracking. This documentation must be accurately maintained regarding any movement of the CS to ensure their secure and appropriate management. There are limited incentives for digitalisation in these areas, particularly as it is not a legislative requirement thus resources are often used elsewhere. Where digital tools exist, interoperability with existing hospital system is not always ensured, which can lead to complex processes that may then also affect traceability.

The survey revealed the CS management issues related to limited human resources, especially in the processes of dispensing and storage as this is an area not directly mentioned in the mapping, but it is closely related. Legislation requires hospitals to use clear processes assigning personnel responsible for CS which can be a challenge in smaller hospitals.

The mapping outlined the need for the regulatory frameworks to evolve to better accommodate digital advancements and workforce in the management of CS. Policies should promote interoperability between electronic prescription systems and pharmacy databases, ensuring seamless transmission of prescription data without the need to use both paper and electronic format while maintaining necessary security and privacy standards. Training programs and resources should be made available to hospital staff to foster digital literacy and facilitate the transition to electronic workflows effectively.

Part 4: Conclusion and recommendations

The SIG considered the advancements in technologies with potential to improve the traceability and accountability in the management of CS across Europe. Progress is often hindered by the need for increased awareness and training for all stakeholders involved in the process, as well as the limitations of existing digital and physical infrastructure in hospitals, which may struggle to accommodate new technologies, including the lack of interoperability between systems. Limited incentives to transition towards digital or automated technologies coupled with outdated national legislation often requiring processes to be done manually is hindering progress in many countries. The SIG members developed a set of 19 recommendations to improve the management of CS within European hospitals targeting all stakeholders involved in the process including hospital pharmacists, hospital management, healthcare professionals, and decision makers.

The SIG recommendations are suggestions made solely by the SIG members, based on the limited scope of the SIG research that has been carried out.

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General recommendations

1. Hospital managements and hospital pharmacists should promote communication in their organisation to raise awareness on CS and DPP for all stakeholders within their hospitals involved such as on medication diversion risks, recognising signs of diversion, and promoting a culture of reporting and accountability.
2. The SIG encourages EAHP to provide continuous support to the member countries where needed when developing national programs or resources on the management and tracking of CS.
3. The SIG underlines that health systems should acknowledge the need for recognising operational and/or investment priorities that may enhance digitalisation and automatisation and by that increase the quality and safety of CS management.
4. The SIG believes that EAHP should provide training programmes for completion within hospitals for all stakeholders directly involved in the process of CS management to practice.
5. The SIG believes that EAHP and national associations of hospital pharmacists should advocate for the development of harmonised legislation, guiding principles, and recommendations that could enable the digitalisation and automatisation of management of CS when applicable, to allow for real-time and accurate stock and demand visibility.
6. Promote the development and enforcement of standard protocols for data formats, communication, and integration between digital reporting and automation systems to ensure interoperability between all systems.

Recommendations for the selection & procurement of controlled substances

7. Promote the use of digital inventory management allowing for specified limitations applied to different ward categories enabling better monitoring and customisation of the stocks of controlled substances based on the patient treatment needed.
8. Promote the use of software to request the acquisition of controlled substances from the supplier based on pre-determined stock levels and provide automatic electronic feedback about its reception.

Recommendations for the storage of controlled substances

9. CS management can benefit from the storage in a place that is only accessible by using personal access measures, non-transferable identification card surveillance, or

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other biometric verification measures throughout the hospital to ensure restricted access and better understanding of possible discrepancies.

10. Promote the use of transportation containers between the ward and pharmaceutical services that are traceable where authorised personnel must be present at the point of reception and sign the receipt of controlled substances.

Recommendations for the prescribing & administration of controlled substances

11. Promote the use of electronic prescribing with integrated limitations such as restrictions per areas and protocols approved by hospital formulary authority or similar internal authorities.
12. Ensure the interoperability of the IT system to incorporate electronic prescription module allowing for traceability (closed loop of the medication management) from prescribing, storage, dispensing, and administration to the right patient and immediate return of possible medication leftovers to pharmaceutical services.

Recommendations for the preparation & dispensing of controlled substances

13. Promote the use of a digital CS register that supports full electronic documentation of controlled substances transactions and the recording of a witness where required during the workflow.
14. For centralised preparation of CS in the aseptic pharmacy unit recommend the implementation of standard quality measures with the possible use of compounding technologies to support accurate compounding and an audit trail that facilitates tracking and monitoring of medication compounding activities.

Recommendations for the disposal & waste management of controlled substances

15. Provide secure bins and integrate disposal in the electronic CS registry to ensure accountability.
16. Ensure that waste can be recorded and stored securely until disposal or destruction with the use of appropriate measures.
17. Ensure the use of digital CS register that permits recording of part vials used and subsequent waste.

Recommendations for the record keeping & reporting of controlled substances

18. Promote the use and monitoring of electronic record keeping for all medicines, and especially for CS. This enables the use of a digital log of all transactions, including

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medication dispensed, accessed, or returned facilitating prompt responses to any discrepancies.

19. Provide CS management software with auditing, monitoring, and real-time alerting capabilities including generating reports as well as notifying owners of the access to their electronic health records.

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Annex I: SIG Membership

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Adriana Durkanska	SIG member	Slovakia
Chahal Mantej	SIG member	United Kingdom
Emmanuela Pella	SIG member	Italy
Eleni Rinaki	SIG member	Greece
Florence Heylen	SIG member	Belgium
Tiago Costa	SIG member	Portugal
Erica Magni	SIG member	Italy
Evelyn Donohoe	SIG member (EHMA representative)	United Kingdom
Amaya Delgado Latorre	SIG member	Spain
Laura Nijstad	SIG member	The Netherlands
Laure Deville	SIG member	France
Dipak Duggal	BD representative	United Kingdom
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SIG - FINAL REPORT

Special Interest Group on Controlled Substances Management

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