Skåne University Hospital
Department of Research and Education
Regional HTA Unit

Drug Safety - How to Optimally Organise the Storage of Medications in a Ward Setting

[Läkemedelssäkerhet – hur skall läkemedelsförråd på en slutenvårdsavdelning organiseras på ett optimalt sätt?]

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Table of contents

Abstract

Background
Many patients cared for by the Swedish healthcare system are harmed due to drug mix-ups. It is thus pivotal to identify methods that can reduce the risks. One significant contributing factor to drug mix-ups is the way in which medications are stored in the clinical wards.
Aim
The aim of the present study was to identify published methods that reduce the risks for medication errors in a clinical ward setting. Special emphasis was set on human factors associated with how prescribed drugs are picked from the shelf, handled, and dispensed.
Method
The literature searches were performed in the Embase, PubMed, Cochrane Library, and CINAHL databases as well as in a number of other HTA databases. Two librarians conducted the primary literature searches and independently read and sorted the articles before sending selected articles to the project group for assessment. A third information specialist completed the literature searches in the HTA databases and in the biomedical database Embase. The members of the project group read articles independently and consensus was used to decide which articles should be included in the report.
Results
Two studies were identified which reported on the effect of organization of medication storages on rates and types of medication errors. Both studies found medication errors to be common. They also concluded that when drugs where issued and administered at the patient's bedside they were less likely to be omitted and more likely to be given on time.
Conclusion
There is at present insufficient evidence to recommend methods of storage that might decrease medication errors in a ward setting. This calls for further research in the field.

Health Technology Assessment (HTA)

HTA is a systematic evaluation of the available scientific literature concerning the properties, effects, and impacts of health-care technologies. The purpose is to evaluate technologies and methods by focusing on

- the effects in terms of patient benefits and risks
- ethical aspects
- organisational aspects
- costs and cost-effectiveness

To evaluate the level of evidence, the HTA Unit in Region Skåne is using the GRADE system.

	GRADE	
High level of evidence	(⊕⊕⊕⊕)	Further research is very unlikely to change our confidence in the estimate of effect.
Moderate level of evidence	(⊕⊕⊕◯)	Further research is likely to have an important impact on our confidence in the estimate of effect and might change the estimate.
Low level of evidence	(⊕⊕◯◯)	Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate.
Very low level of evidence	(⊕◯◯◯)	Any estimate of effect is very uncertain.

An HTA offers guidance to decision makers in the health-care system. If the level of evidence for a positive effect of a technology is of high or moderate quality, then the technology most probably qualifies for use in routine medical care. If the level of evidence is of low quality, the use of the technology might be motivated provided there is an acceptable balance between benefits and risks, cost-effectiveness, and ethical considerations. Promising technologies with a very low level of evidence motivate further research but should not be used in routine clinical work.

Conclusion

Two studies were identified that examined the effect of medication storage systems on the rate of medication errors and on the type of medication errors. Both studies were of low methodological quality and concluded that:

- Medication errors are common
- Medications are less likely to be omitted and are more likely to be given on time when they are issued and administered at the patient's bedside

No studies were found that examined the effects of drug storage in ATC (Anatomic Therapeutic Chemical classification) order versus alphabetical order. There were neither any studies on the use of high-alert medication lists nor separate storage for look-alike medications.
Currently there are no national Swedish recommendations concerning which drugs are considered to be high-alert medications. There are neither any consensus lists of look-alike nor sound-alike medications.
These shortcomings and knowledge gaps thus highlight the need for further research studies in this field.

Quality of evidence: GRADE (⊕○○○) - very low level of evidence.

Background

Medication errors have been identified as the most common single preventable cause of adverse drug events (1). Errors are the result of complex interactions between human and system factors that go wrong (2). Negligence or failure to follow manuals and protocols and lack of knowledge are commonly identified individual factors preceding such errors. Other known factors are work overload, unclear communication, inadequate access to guidelines, bad routines, inappropriate location, and look-alike medications.

Medication errors can occur at any stage of the medication process, including physician ordering, nurse administration, transcription or dispensing (3). Studies have shown that many errors occur during administration (4-6). Other important error-contributing factors are related to organisation of the medication storage or the presence of sound-alike and look-alike drugs (7-8). The latter include drugs that are quite different but are delivered in similar packaging which thus causes a potential for confusion errors. The Swedish network Collaboration for Safe Health Care has estimated that nearly 6,000 patients are injured in the Swedish health-care system due to drug mix-ups every year (9). Of these, 750 events are considered to be serious or disastrous. It is thus of pivotal importance to find methods that could reduce medication errors through safe systems of organising and storing drugs.

Project organisation

Inquirer

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Project members from the profession

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Clinical question

What can be done to reduce the risk of medication errors in a ward setting when the prescribed medications are picked from the shelf, handled, and dispensed?

Limitations: The clinical question concerns medication errors occurring when nurses pick, handle, and dispense medications to adult patients in a ward excluding direct delivery to the patient.

PICO	
P Patients	Adult patients in a ward setting. ICUs (Intensive Care Units) not included
I Intervention	Medication errors due to human factors associated with mistakes when the prescribed medications are picked from the shelf, handled, and dispensed
C Control/Comparison	Not applicable
O Outcome	Eligible outcome parameters: patient mortality, morbidity, or any reported harm or quality deviation report

Magnitude of the problem

Although the true incidence of medication errors in wards is unknown, a previous review reports a median error rate of 19,6% (IQR/Interquartil Range 8.6-28.3%), (10).

The Swedish network Collaboration for Safe Health Care has estimated that nearly 6,000 patients are injured in the Swedish health-care system due to drug mix-ups every year (9). Of these, 750 events are considered to be serious or disastrous. Almost 200,000 patient ward episodes are yearly recorded at hospitals in Skåne county, which potentially equals 600 medical errors every year.

Medication errors leads to potentially serious adverse effects among patients, lengthen of hospital stay, reduction of patient quality of life all of which increases health-care costs. Errors can also cause psychological trauma for the staff involved.

Literature search and selection

Systematic literature searches were conducted in January and February of 2012 in the Embase, PubMed, Cochrane Library, and CINAHL databases as well as in a number of HTA databases.

On 7 Oct. 2015, four updated literature searches were conducted in Embase (including Medline), and one search in Cochrane Library. Key words and search terms were chosen with the PICO as a starting point. After the removal of duplicates altogether 556 articles were identified eligible for assessment.

Two librarians conducted the primary searches and independently read and selected 249 articles which were sent to the project group for assessment. Another informatics specialist made subsequent literature searches in the HTA databases in May 2012 and in June 2012 in the Embase database. If in doubt as to whether an article should be included, the article was sent to the project group.

The search strategies, limitations, and selection process are reviewed in Appendix 1 and in the flow chart. The number of references and the selection are shown in Appendix 2. The two primary articles are presented in Appendix 3, and the excluded articles are presented in Appendix 4.

Members of the project group read the articles independently and decided in consensus which articles should be included in the analysis.

Results

Two studies reporting on a total of 710 medication error events fulfilled the P and I of the PICO criteria. The publications were observational studies without controls and of poor methodological quality. The primary outcome in both studies was the occurrence of medication error rates and type of errors as an effect of the medication storage system. Both studies concluded that when medications are issued at the patient's bedside they are more likely to be well-timed and less likely to be omitted. No outcome data for mortality, morbidity or other specified adverse events were reported. As a consequence, the study results are presented in a narrative manner omitting statistics. For study details, see Appendix 3.

Conclusion

Medication errors are common and are less likely to occur when using medication trolleys/bedside systems compared to a ward bay.
Quality of evidence: GRADE (⊕○○○) - very low level of evidence

Recommendations from experts and professional organisations

Institute for Safe Medication Practices (ISMP)

1. Establish guidelines for safe storage and handling
   - limit access (eliminate)
   - reduce options (avoid stocking different strengths of the same drug)
   - reduce "look-alike" potential (Tall Man lettering, storage at different locations, bold face lettering)
   - require redundancies (independent double check)
   - educate staff
   - employ technology (bar coding, automated dispensing technology)
   - educate patients
   - monitor patients (implement policies)

2. Focus on high-alert medications (drugs that bear a heightened risk of causing significant patient harm when errors occur), including: insulin, heparin, opioids, concentrated injectable potassium chloride/phosphate, neuromuscular blocking agents, and chemotherapy drugs. http://www.ismp.org/

3. Promote the use of Tall Man lettering names http://www.ismp.org/

The Joint Commission on Accreditation of Healthcare Organizations (JCAHO)

- Maintain awareness of problematic product names and error prevention recommendations provided by the ISMP (Institute for Safe Medication Practices), FDA (Food and Drug Administration), and USP (US Pharmacopeial Convention).
- Develop processes for managing high-alert drugs.
- Identify and, at a minimum, annually review a list of look-alike/sound-alike drugs used in the organisation, and take action to prevent errors involving the interchange of these drugs.

The World Health Organization (WHO)

- Drugs are arranged in alphabetical order of generic names.
- Each dosage form of a drug is arranged in separate and distinct areas.

- Sufficient empty space should demarcate one drug or dosage form from another. http://apps.who.int/medicinedocs/en/d/Js7919e/

Vårdhandboken
Storage is done according to the manufacturer and may be divided into four groups:

- drugs for injection
- other drugs for internal use
- drugs for external use
- drugs requiring refrigeration

Within the groups, the drugs are stored in alphabetical order or in the order of the pharmacological ATC system.
http://www.vardhandboken.se/Texter/Lakemedelshantering/Oversikt/

Statens beredning för medicinsk och social utvärdering (SBU)
No support to suggest that storing drugs in the order of the pharmacological ATC system reduces the risk of medication errors.
http://www.sbu.se/sv/Publicerat/Upplysningstjanst/Ger-lakemedel-sorterade-efter-ATCkod-okad-patientsakerhet/?printall=true

Ongoing research, knowledge gaps and unanswered questions

The Swedish network Collaboration for Safe Health Care
The Swedish network Collaboration for Safe Health Care, in 2010, initiated a project to reduce the risk of medication mix-ups by using safer medication packages. The project is still on-going (July 2015), and a standardised medication packaging has been proposed with the following features:

- a standardised allocation of the information label
- a prominent generic name
- a particular marking for solutions that are to be diluted
- a non-standardised colour for different medicine strengths
- Tall Man lettering[1] for selected medications
- a particular colour for specific “high-alert” drugs
- non-transparent labels

As mentioned, no studies were found that addressed the effect of storage in the ATC order versus alphabetic order, the use of Tall Man Lettering, the use of high-alert medication lists, or the use of separate storage on the medication error rate.

There is currently no Swedish national definition of which drugs are considered to be high-alert medications. There is neither any consensus of look-alike nor sound-alike medications that are candidates for likely being mixed-up. However one Swedish study based on nurses’ views on the likelihood and consequences of mix-up drugs have been published
(11).

[1] **Tall Man lettering** is the practice of writing part of a drug’s name in capital letters to help distinguish sound-alike and look-alike drug names from one another in order to avoid medication errors. In the US, the Food and Drug Administration (FDA) Centre for Drug Evaluation and Research and the Institute for Safe Medication Practice (ISMP) have published a list of look-alike drug names with the recommended Tall Man letters. For more information, see https://www.ismp.org/tools/tallmanletters.pdf.

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Literature searches

Kristina Ellingjord Johansson, Librarian, Skåne University Hospital Library, Region Skåne, Matthias Bank, Medical librarian, Library & ICT, Faculty of Medicine, Lund University and Göran Hollenby, Informatician, HTA unit, Region Skåne conducted the literature searches.

Duplicates were sorted out on 6 Feb. 2012 by KEJ, MB, and GH.
No publication date limits were used for the searches below, apart from search 4 which was limited to 2009–2012.
The updated literature searches were conducted on 7 Oct. 2015.

Appendix 1 – Search strategies

1. Search strategy in Embase (including Medline) - Medication errors and drug storage/storerooms
Result: 60 hits, 2012-01-05
Result: 29 hits, 2015-10-07. Limited to year 2012 to 2015.

'drug storage'/exp AND 'medication error'/exp/mj

2. Search strategy in Embase (incl. Medline) - Medication errors and high-alert medications, Reviews
Result: 7 hits, 2012-01-05
Result: 9 hits, 2015-10-07. Limited to year 2012 to 2015.

('high-alert medications' OR 'high-alert medication' OR 'high-risk medications' OR 'high-risk medication') AND ('medication error'/exp OR 'medication error' OR 'drug administration error' OR 'drug administration errors')

Limited to literature reviews.

3. Search strategy in Embase (incl. Medline) - Medication errors and the 'human factor'
Result: 107 hits, 2012-01-05. Limited to references in English, Danish and Swedish.
Result: 24 hits, 2015-10-07. Limited to year 2012 to 2015.

'nurse'/exp/mj OR 'hospital personnel'/exp/mj AND 'medication error'/exp/mj

4. Search strategy in Embase (incl. Medline) - Medication errors and BCMA/automated dispensing systems. Limited to year 2009 to 2012.
Result: 15 hits, 2012-02-01
Result: 24 hits, 2015-10-07. Limited to year 2012 to 2015.
(BCMA=Bar Code Medication Administration.)

'medication error'/exp and ("bar code assisted medication administration" OR bcma OR "automated dispensing systems")

5. Search strategy in PubMed - Medication errors and bar code-assisted medication
Result: 25 hits, 2012-02-02

("medication errors"[MeSH Terms] OR ("medication"[All Fields] AND "errors"[All Fields]) OR "medication errors"[All Fields]) AND ("automatic data processing"[MeSH Terms] OR ("automatic"[All Fields] AND "data"[All Fields] AND "processing"[All Fields]) OR "automatic data processing"[All Fields] OR ("bar"[All Fields] AND "code"[All Fields]) OR "bar code"[All Fields]) AND assisted[All Fields] AND ("pharmaceutical preparations"[MeSH Terms] OR ("pharmaceutical"[All Fields] AND "preparations"[All Fields]) OR "pharmaceutical preparations"[All Fields] OR "medication"[All Fields])

6. Search strategy in PubMed - Medication errors and drug storage
Result: 102 hits, 2012-02-02

("medication errors"[MeSH Terms] OR ("medication"[All Fields] AND "errors"[All Fields]) OR "medication errors"[All Fields]) AND ("drug storage"[MeSH Terms] OR ("drug"[All Fields] AND "storage"[All Fields]) OR "drug storage"[All Fields])

7. Search strategy in PubMed - Medication errors and high-alert medications
Result: 38 hits, 2012-02-02

("medication errors"[MeSH Terms] OR ("medication"[All Fields] AND "errors"[All Fields]) OR "medication errors"[All Fields]) AND high-alert[All Fields] AND ("pharmaceutical preparations"[MeSH Terms] OR ("pharmaceutical"[All Fields] AND "preparations"[All Fields]) OR "pharmaceutical preparations"[All Fields] OR "medications"[All Fields])

8. Search strategy in PubMed - Medication errors and human factors
Result: 161 hits, 2012-02-02

("medication errors"[MeSH Terms] OR ("medication"[All Fields] AND "errors"[All Fields]) OR "medication errors"[All Fields]) AND ("Hum Factors"[Journal] OR ("human"[All Fields] AND "factors"[All Fields]) OR "human factors"[All Fields])

9. Search strategy in the Cochrane Library - Medication errors and storage
Result: 4 hits, 2012-01-16
Kristina Ellingjord Johansson searched for 'medication errors storage' and this resulted in 4 articles but no reviews.

Result: 5 hits, 2015-10-07. The last reference below (Irwin et al.) is new compared with the search 2012-01-16.

Fisher M, Norris D, Camac K, Hawkshaw B. A comparison of medication errors between two storage sites. 2001.

Dehoff RC, Handberg E, Heissenberg C, Johnson K. Electronic prescribing via the Internet for a coronary artery disease and hypertension megatrial. 2001.

Camac KJ, Fisher MJ, Norris DE. Medication errors: a comparative study of drug storage sites. 1996.

Callaghan J, Story I. The impact of an ACAT clinical/consultant pharmacist on medication use by older people. 1994.

Irwin A, Mearns K, Watson M, Urquhart J. The effect of proximity, Tall Man lettering, and time pressure on accurate visual perception of drug names. 2013.

10. Search in CINAHL – 'Medication errors' AND 'high-alert medications' in the text fields
Result: 30 hits, 2012-02-15

Kristina Ellingjord Johansson searched in the text fields for 'medication errors AND high-alert medications'. This resulted in 30 references to articles, but no relevant hits were retrieved that had not been found in the other databases.

11. Additional searches in Embase (including Medline) – The ATC code order
Result: 25 hits, 2012-06-20. Searches done by Göran Hollenby.

#	Searches	Results
1	'atc':ab,ti OR 'anatomical therapeutic chemical':ab,ti	2,656
2	'drug storage'/exp OR store*:ab,ti OR storage*:ab,ti OR room*:ab,ti OR reservoir*:ab,ti OR repositor*:ab,ti OR depositor*:ab,ti	370,261
3	#1 AND #2	48
4	#3 AND hospital*	30
5	'drug storage'/exp OR 'drug storage'	8,601
6	hospital NEAR/3 storage	207
7	hospital NEAR/3 'store room'	1
8	hospital NEAR/3 reservoir*	852
9	hospital NEAR/3 repositor*	24
10	hospital NEAR/3 depositor*	2

11	#5 OR #6 OR #7 OR #8 OR #9 OR #10	9,671
12	#1 AND #11	0
13	#6 OR #7 OR #8 OR #9 OR #10	1,086
14	#1 AND #13	0
15	#1 AND #5	0
16	#6 OR #7 OR #8 OR #9 OR #10 AND ('drug storage'/exp OR store*:ab,ti OR storage*:ab,ti OR room*:ab,ti OR reservoir*:ab,ti OR repositor*:ab,ti OR depositor*:ab,ti)	288
17	#1 AND #16	0
18	'atc':ab,ti OR 'anatomical therapeutic chemical':ab,ti AND (storage* OR 'store room' OR storeroom)	25

No relevant references were found among the new hits.

12. Searches in HTA databases
Searches were also carried out during May 2012 in a number of HTA databases and on HTA sites, but no relevant hits were found.

13. Number of articles before removal of duplicates
661 (318 from PubMed, 189 from Embase, 86 from Embase (incl. Medline) and 69 additional references from other sources)

14. Number of articles after removal of duplicates and screening by KEJ, MB, and GH
556 (285 from PubMed, 185 from Embase and 86 from Embase including Medline)

15. Number of articles sent to and screened by the project group
249 (77 from PubMed, 86 from Embase and 86 from Embase including Medline)

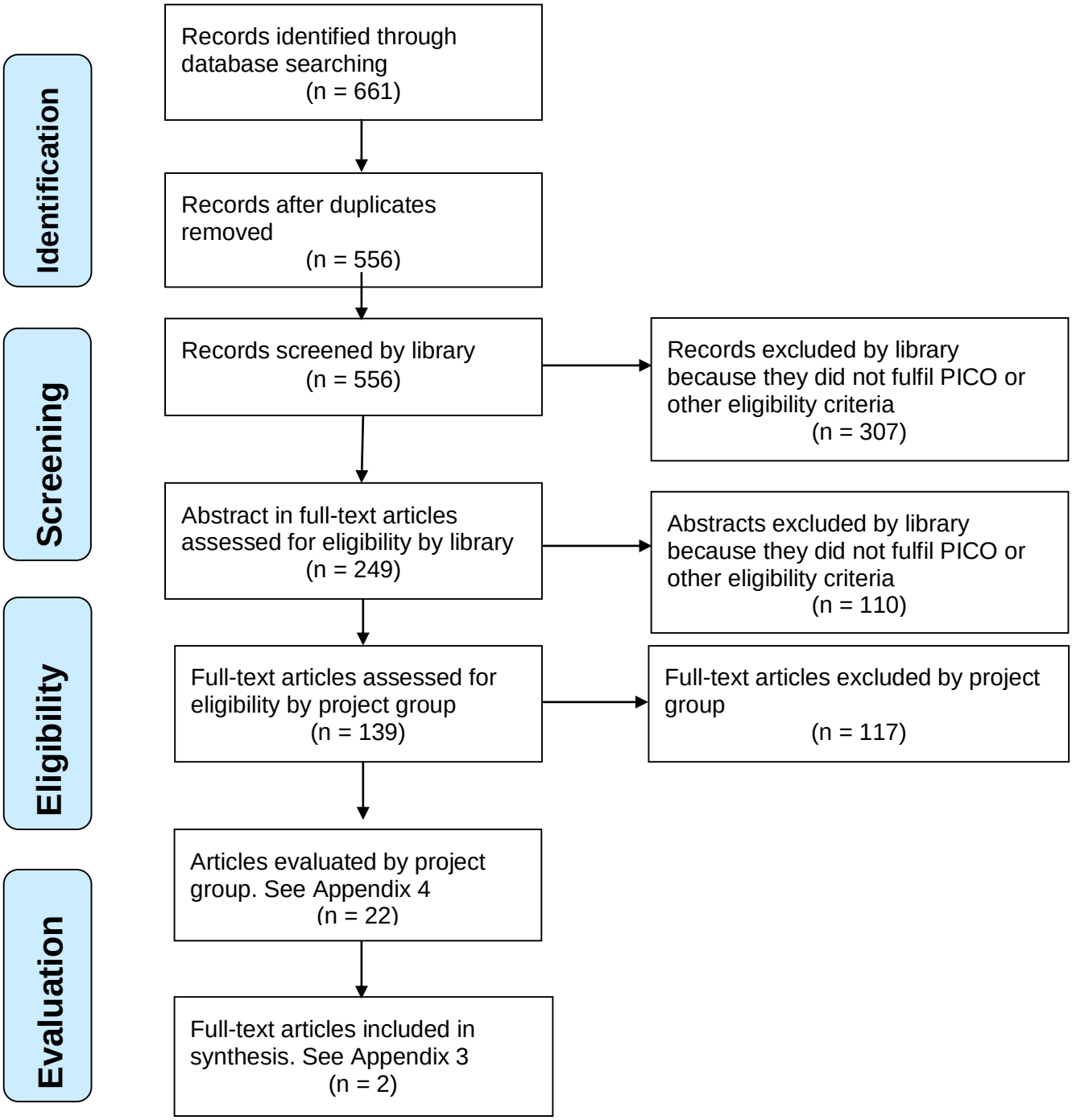
16. Number of articles assessed for eligibility by the project group
139

17. Number of articles evaluated by the project group
22

18. Number of articles nominated for inclusion in the final report
2

Appendix 2 – Selection process – flow chart

Drug safety – how to optimally organise the storage of medications in a ward setting



Appendix 3 – Summary of included studies

Author, (year) country	Study type	Methods	Characteristics of samples	Data analysis	Major findings	Comments
Fisher, M., et al (2001) Australia	Prospective observational	Observation of errors occurring during preparation and administration of medications Storage and issued of medications in a ward bay vs. a medication trolley at the patient's bedside	340 observations for errors in a surgical ward	Descriptive statistics and Chi-square statistics	Observed errors 20 (5.8%) When medication trolley 4 (2.6%) When ward bay 15 (9.2%) Significant more errors when medication from ward bay *($X^2 = 4.47$; $p = 0.034$)* Type of error Medication unavailable 4 Drug omission 4 Wrong time 6 Wrong route 3 Wrong dose/rate 2 Wrong medication 1	Inter observer reliability was 1.0 Observational bias risk Presence of the observer might have positively or negatively influenced the drug administration process Single site study Small sample
Camac, KJ., et al (1996) Australia	Prospective observational	Observation of errors occurring during preparation and administration of medications Storage and issued in a ward bay vs a locked drawer at the patient's bedside	370 observations for errors were observed during five eight-hour shifts in a surgical ward	Descriptive statistics and Chi-square statistics	Observed errors 47 (12.7%). Using bedside system 7 (6.8%), Using the ward bay 39 (16 %). Significantly more errors when medication was issued ward bay *(X2 = 5.67; p = 0.02).* Type of error Drug omission 4 Incorrect calculation 1 Dose/rate error 5 Incorrect time 21 Incorrect frequency 1	Inter observer reliability was consistent Observational bias risk Presence of the observer might have positively or negatively influenced the drug administration process Single site study Small sample Injections excluded from analysis

Appendix 4 – Excluded studies

Author, year	Motivation for exclusion
Prescribe International, 2004	Not relevant, only about the French medication error-reporting program, type of errors, main causes, and contributing factors.
Joint Commission of Accreditation of Healthcare Organization, 2005	Not relevant, only provided requirements for programs to minimize risks for errors.
Benjamin MN, 2003	Not relevant, only patient case studies.
Bergqvist M, 2009	Not relevant, too general of an article.
Bergqvist M, 2010	Not relevant, only a description of medication errors reported to the National Board of Health and Welfare.
Alvarez Diaz AM, 2009	Not relevant, deals only with types of errors, main causes, and contributing factors when introducing new technologies.
Bertsche T, 2008	Not relevant, deals only with strategies for preventing medication handling.
Brady A-M, 2009	Not relevant, deals with individual and system factors that contribute to medication errors in nursing practice, but not storage.
Cohen MR, 1994	Not relevant, only about look-alike names.
Evans J, 2009	Not relevant, deals with prevalence, risk factors, consequences, and strategies for reducing medication errors. Too general.
Hakonsen H, 2010	Not relevant, only deals with generic substitutions.
Hellman R, 2004	Not relevant, only deals with analysis and redesign of systems to develop a “culture of safety”.
Lisby M, 2005	Not relevant, deals only with the prevalence of errors, stages of errors, and type of errors.
Nair, 2010	Not relevant, only about dispensing errors from a pharmacy point of view.
Reeve JF, 2005	Not relevant, only two case reports.
Runy LA, 2004	Not relevant, only considers high-alert medications and case studies.
Schulmeister L, 2006	Not relevant, only considers look-alike and sound-alike oncology medications.
Simmons D, 2009	Not relevant, deals with the environment.
Sundhagen R, 2006	Not relevant, deals only with barcoding.
Arinal MF, 2014	Not relevant, deals with reported medication errors.