The High 5s Project

Implementation Guide

Safe Management of Concentrated Injectable Medicines

Implementation Guide
Safe Management of Concentrated Injectable Medicines Standard Operating Protocol

The Safe Management of Concentrated Injectable Medicines Standard Operating Protocol and the Getting Started Kit was developed under the High5s Project by the United Kingdom, National Patient Safety Agency in 2008 and subsequently tested in 16 hospitals in the Netherlands during the last phase of the High 5s Project from 2013-2015. SOP implementation and data collection was limited and done only by the Netherlands Lead Technical Agency (LTA). The Standard Operating Protocol (SOP) was not implemented by any other participating country LTA. Synthesis and analysis data from the 16 Dutch hospitals was not part of the overall High 5s Steering Group expert consultation and outcomes development. The described guiding principles, strategies, oversight actions, work planning, and all other SOP-implementation-related actions exclusively refer to the experiences presented by the Netherlands LTA.

"The High 5s Project" Attribution Statement

The work of the High 5s Project was carried out by the World Health Organization in 2007 and coordinated globally by the WHO Collaborating Centre for Patient Safety, The Joint Commission in the United States of America, with the participation of the following Lead Technical Agencies including: Australian Commission on Safety and Quality in Health Care, Australia; Canadian Patient Safety Institute, Canada and the Institute for Safe Medication Practices Canada, Canada; National Authority for Health- HAS, France, with CEPPRAL (Coordination pour L' Evaluation des pratiques professionnelles en santé en Rhône-Alpes), France, OMEDIT Aquitaine (Observatoire du Medicament, Dispositifs medicaux et Innovation Therapeutique), France (from 2012- 2015) and EVALOR (EVAluation LORraine), France (from 2009-2011); German Agency for Quality in Medicine, Germany and the German Coalition for Patient Safety, Germany; CBO Dutch Institute for Healthcare Improvement, the Netherlands; Singapore Ministry of Health, Singapore; Trinidad and Tobago Ministry of Health, Trinidad & Tobago; Former National Patient Safety Agency, United Kingdom of Great Britain and Northern Ireland; and the Agency for Healthcare Research and Quality, USA.

The work of the High5s Project has been supported by the Agency for Healthcare Research and Quality, USA, WHO, and the Commonwealth Fund, USA.

Acknowledgements

This Implementation Guide has been adapted from the 'Closing the Gap', National Patient Safety Agency, April 2008 (Author Suzette Woodward) and the 'How to Guide' for Measurement for Improvement, Patient Safety First Campaign for England.[1] Contributions on the finalization of the Implementation Guide and the SOP for the Safe Management of Concentrated Injectable Medicines by Margaret Duguid (Australia) are greatly appreciated and acknowledged.

[1] How to Guide' for Measurement for Improvement, Patient Safety First Campaign for England. www.patientsafetyfirst.nhs.uk/ashx/Asset.ashx?path=/How-to-guides-2008-09-19/External+-+How+to+guide+-+measurement+for+improvement+v1.2.pdf (Accessed 4 June 2015).

TABLE OF CONTENTS

Patient story 1

An ampoule of sodium chloride was selected from the ward medication cupboard to flush a cannula inserted in a patient's hand. The patient quickly became distressed and within minutes stopped breathing. The ampoule thought to be sodium chloride was actually concentrated potassium chloride. The patient could not be resuscitated.
Australian Council for Safety and Quality of Health Care Medication Alert 1 2003

Patient story 2

A massive overdose of heparin was given to three infants, including the twins of actor Dennis Quaid. The newborns' intravenous catheters were flushed with the adult therapeutic dose of heparin (10,000 units/mL) rather than the 10-units/mL solution typically used for infants.

www.medpagetoday.com/Pediatrics/GeneralPediatrics/7469 Accessed 12 May 2015

1. Introduction

This Implementation Guide outlines in what is needed to do to successfully implement the Standard Operating Protocol (SOP) for the Safe Management of Concentrated Injectable Medicines. It is intended to assist front line hospital staff and leaders to achieve a smooth and successful implementation of the SOP and introduce systems for safely managing concentrated injectable medicines. Thereby avoiding those errors associated with the prescribing, preparation, storage, or administration of concentrated injectable medicines that most frequently results in death or serious patient harm.

It provides tools and support for implementing Safe Management of Concentrated Injectable Medicines SOP and evaluating its impact. It should be used in conjunction with the Safe Management of Concentrated Injectable Medicines SOP.

It is well recognised that medication errors constitute one of the highest risks to patient safety. The fourth report from the National Patient Safety Agency's Patient Safety Observatory in England and Wales, states that 60,000 medication incidents were reported to the former NPSA via the National Reporting and Learning System (NRLS) between January 2005 and June 2006. Of the 92 medication incidents reviewed in detail in the report 38 resulted in death.[2] Medicines most frequently associated with severe harm were:

- Anticoagulants;
- Injectable sedatives;
- Opiates;
- Insulin;
- Antibiotics (allergy related);
- Chemotherapy;
- Antipsychotics; and

[2] National Patient Safety Agency.(NPSA) Patient Safety Observatory Report 4. Safety in Doses, July 2007, NPSA, London www.npsa.nhs.uk/patientsafety/medication-zone

- Infusion fluid.

There is worldwide evidence that concentrated injectable medicines have been involved in medication incidents resulting in death or serious harm. Between January 2005 and June 2006 NPSA received around 800 reports a month to its NRLS relating to injectable medicines, representing approximately 24 per cent of the total number of medication incidents. They included 25 incidents of death and 28 of serious harm.[3] In 2002, The Institute of Safe Medication Practice Canada reported six serious incidents involving concentrated potassium chloride, three of which were fatal.[4]

Research evidence indicates that the incidence of errors in prescribing, preparing and administering injectable medicines is higher than for other forms of medicine.[5] [6] In one study, at least one error occurred in 49 per cent of intravenous medicine doses prepared and administered on hospital wards; one per cent were judged to be potentially severe errors; and 29 per cent potentially moderate errors.[5] These errors have frequently been associated with:

- Mis-selection of the wrong product due to look-a-like labeling and packaging, where concentrated injectable medicines are mis-selected for other injectable medicines.
- Incorrect calculation, measurement and dilution errors in dose and rate of administration.

For these reasons, the safe management of concentrated injectable medicines is a key priority in health care. This High 5s CIM SOP seeks to support the improvement of the safe management of high risk concentrated injectable medicines based on Leape's vision on a procedure to make tragic types of errors *im*possible:

> *"The way to prevent tragic deaths from accidental intravenous injection of concentrated KCl is excruciatingly simple—organizations must take it off the floor stock of all units. It is one of the best examples I know of a 'forcing function'—a procedure that makes a certain type of error impossible."*
>
> Lucian L. Leape, MD, Harvard School of Public Health

[3] National Patient Safety Agency.(NPSA) Patient Safety Observatory Report 4. Safety in Doses, July 2007, NPSA, London www.npsa.nhs.uk/patientsafety/medication-zone

[4] ISMP Canada. How to use Failure Modes Effects Analysis to prevent error induced injury with potassium chloride. ISMP Canada Safety Bulletin 2002. Vol 2 issue 5

[5] Taxis K and Barber N. Ethnographic study of incidence and severity of intravenous medicince errors. Br Med J. 2003; 326: 684-687

[6] Cousins DH et al. Medication errors in intravenous medicine preparation and administration: a multicentre audit in the UK, Germany and France. Qual Saf Health Care. 2005; 14: 190-195

2. Overview of the Safe Management of Concentrated Injectable Medicines SOP

The Safe Management of Concentrated Injectable Medicines Standard Operating Protocol (CIM SOP) was developed and tested for use within the context of the Action on Patient Safety, High-5s initiative, an internationally coordinated, limited participation activity for testing the feasibility of implementing standardized patient safety protocols and determining the impact of the implementation on certain specified patient safety outcomes. The efficacy of the CIM SOP has been demonstrated in 16 hospitals in the Netherlands. Its implementation outside of the High-5 testing environment is encouraged.

2.1 Scope

Three concentrated injectable medicines were chosen to be included in the High 5s Project, because they are high-risk drugs that are widely used internationally and most frequently associated with errors resulting in death and serious patient harm. The implementation effort of the High 5s CIM SOP focuses on the following three concentrated injectable medicines:*

1. Concentrated potassium chloride solution > 0.04 mmol/ml.
2. Unfractionated heparin >1,000 units/ml.
3. Injectable morphine >15 mg/ml.[7]

** However, hospitals that choose to implement the CIM SOP are encouraged to include other high risk concentrated injectable medicines in addition to those listed above. For example including all concentrated opioid injections and expanding to other high risk/alert medicines.*[8]

The CIM SOP addresses the prevention of medication errors associated with the preparation, supply, storage, preparation or administration of concentrated injectable medicines and is applicable to all patient care areas within a hospital, including special care units and central and satellite pharmacy services. This SOP seeks to prevent errors by minimizing the storage and use of concentrated injectable medicine products in clinical units by:

1. Replacing them with ready-to-use injectable products that do not need to be diluted before use;
2. Improving the safety of the storage, prescription, dispensing, administration, preparation and monitoring of concentrated preparations of potassium, heparin and morphine injections; and

---

[7] In the Netherlands concentrated injectable morphine was defined as >15mg/container and a concentration of >1mg/ml ready-to-use preparations.

[8] High-alert medications are drugs that bear a heightened risk of causing significant patient harm when they are used in error. Institute of Safe Medication Practice. ISMP List of High Alert Medications in Acute Care Settings. www.ismp.org/tools/institutionalhighAlert.asp

3. Undertaking risk assessments and implementing systems for reducing risk of errors relating to use of concentrated injectable medicine products in critical areas where high doses and concentrations are required.

2.2 Guiding principles for safe management of concentrated injectable medicines

The six guiding principles for the safe management of the concentrated injectable medicines in the CIM SOP describe the process changes that need to occur to fulfill the SOP requirements.

Guiding Principle 1

Minimise the range of injectable medicines available on clinical units by standardizing and limiting the number of concentrations of injectable medicines.

Guiding Principle 2

Simplify and rationalise therapeutic protocols requiring the use of concentrated injectable medicines.

Guiding Principle 3

Standardise the prescription and order sets for CIM, including information on the formulation, dosage and administration, in order to have a complete and unequivocal order for nursing and pharmacy staff.[1]

Guiding Principle 4

Use a standardised infusion form to record administration rate of a continuously administered infusion, in relation to outcome parameters (e.g. pain scores during morphine infusion or coagulation parameters during heparin infusion).

Guiding Principle 5

Minimise the storage and use of concentrated injectable medicine products on clinical units by replacing with ready-to-administer[1] or ready-to-use[1] injectable products that do not need to be diluted before use.

Where possible, procure these products from the pharmaceutical industry as licensed medicines. If licensed medicines of this type cannot be purchased, supply unlicensed products prepared by contract pharmaceutical manufacturers or in the hospital pharmacy department.

Guiding Principle 6

Where a concentrated injectable medicine must continue to be stored and prepared in a clinical area, the risks of using this product should be minimised as follows:

a. Implement multidisciplinary policies and procedures on how to prescribe, store, prepare and administer these medicines safely.
b. Minimise look-alike labelling and packaging of concentrated injectable medicines through the use of "purchasing for safety" policies.
c. Segregate storage of concentrated injectable medicines from other medicines
d. Limit the amount of concentrated injectable drugs stored in the clinical area to the least that will reasonably be needed to treat patients, based on the historical frequency of need and the timely availability of replacement of used drugs
e. Provide staff with ready access to essential clinical and technical information concerning the preparation and administration of these products.
f. Providing dose calculation tools. For example, dosage charts for a range of body weights that eliminate the need for calculating doses.
g. Train all staff and assess the competency of staff to prescribe, prepare and administer concentrated injectable medicines safely.

The CIM SOP is outlined in the flow charts in Figures 1 of this Guide.

Further information on the processes to be followed to implement the CIM SOP are available in **The High 5s Standard Operating Protocol. Safe Management of Concentrated Injectable Medicines:**

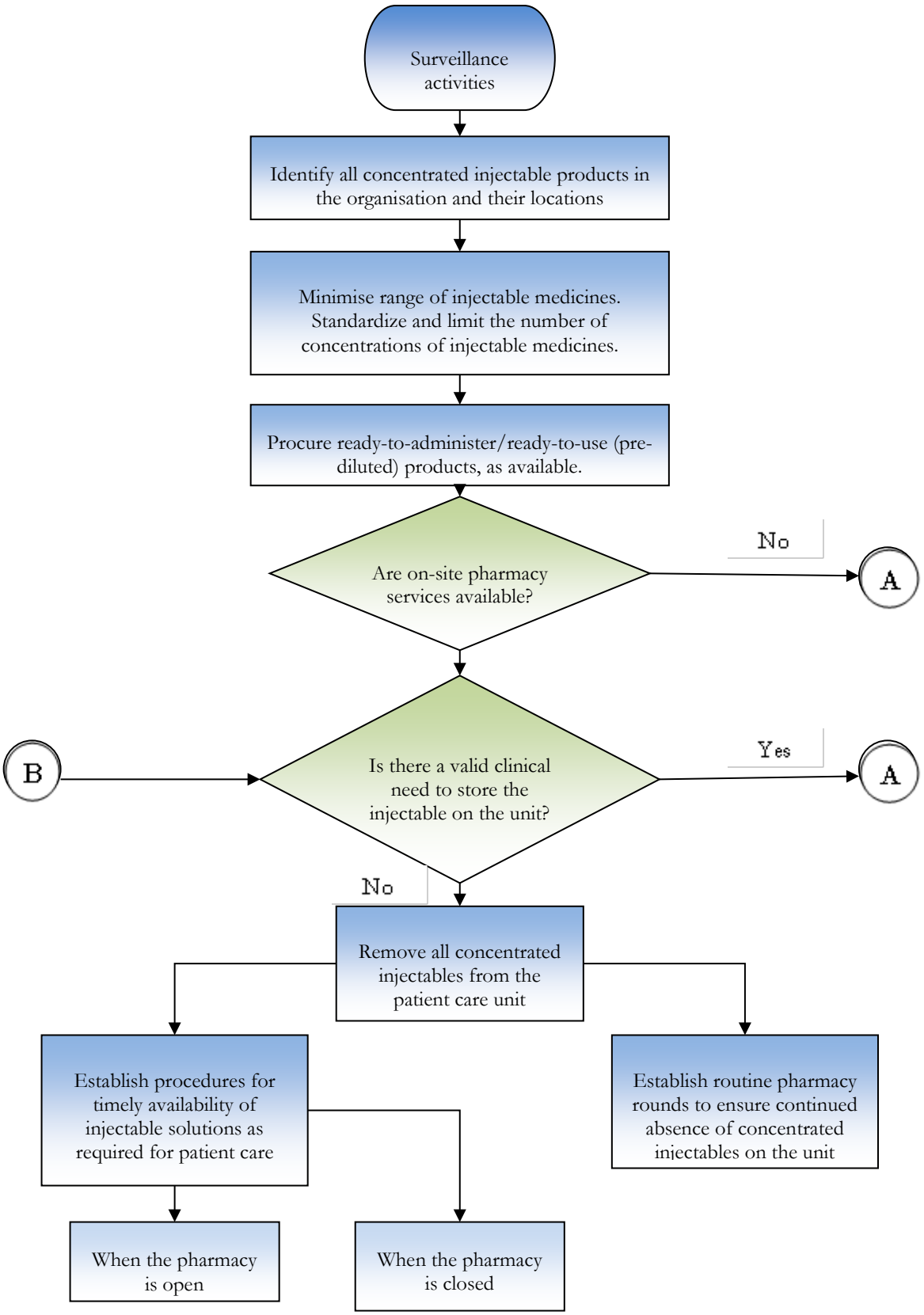
Appendix A Tabular listing of steps in the safe management of concentrated injectable medicines process – detailed specifications.

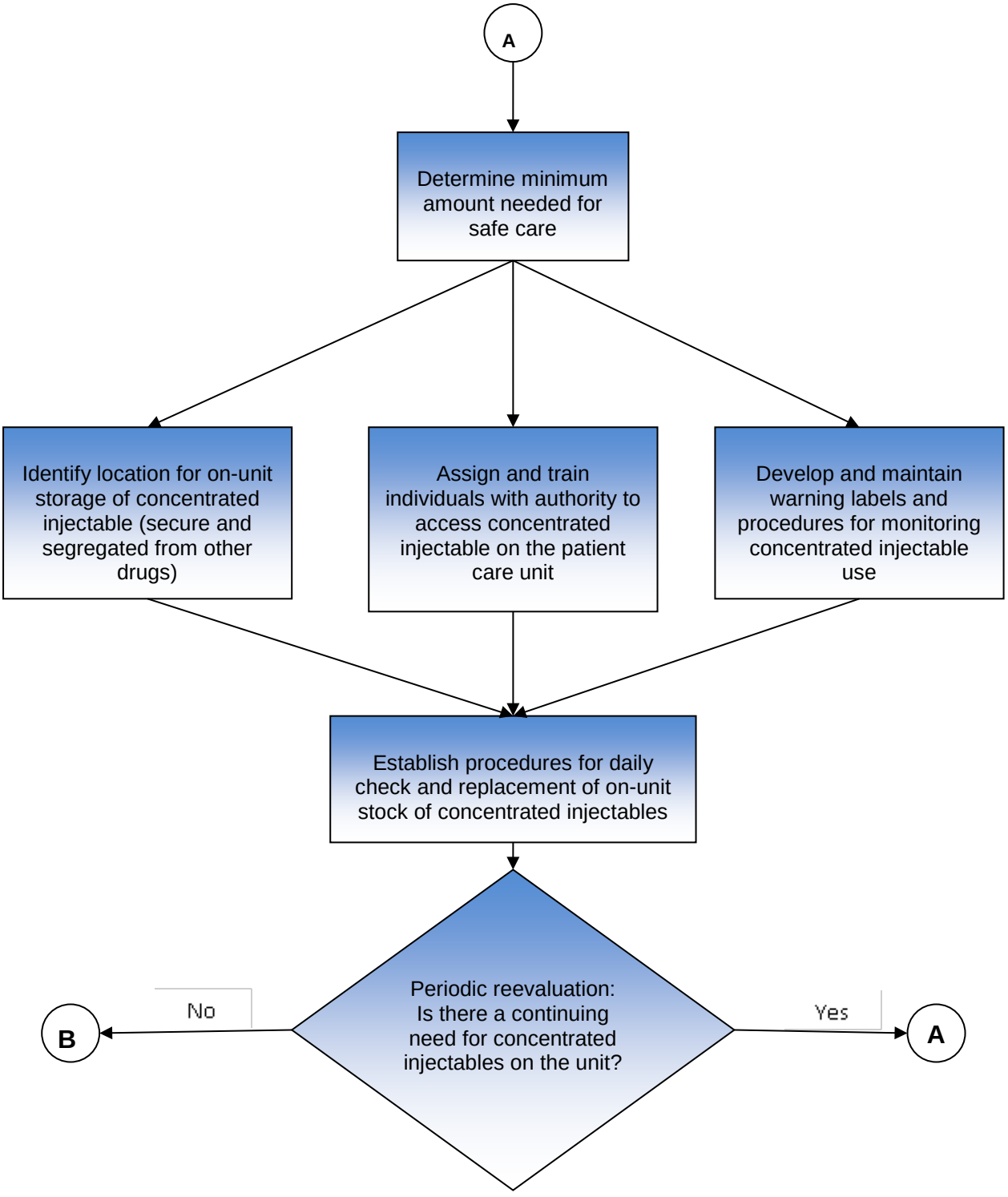
2.3 What is the added value of this Standard Operating Protocol if we already have guidance?

The safety of patient care should be everyone's top priority. Every effort should be made to ensure that patient care is as safe as it possibly can be. However, despite the wealth of research and information to improve patient safety, putting the recommended changes into practice often falls short of their envisioned potential. This is a well-recognised gap that exists between what we know should be done based on evidence and what we actually do in practice.

Unsafe care has resulted in hundreds and thousands of individual tragedies every year, with both patients and those that provide their care suffering the consequences. We therefore need to redouble our efforts to implement systems and interventions that actively and continuously reduce risks to patients. As much time should spend on ensuring guidance is implemented as it does on producing the advice. By adopting the approach suggested in this toolkit, and by using the SOP, implementation will be more effective in leading to sustained reductions in risks and harm.

Figure 1. Flow charts of the concentrated injectable medicines process




A
Determine minimum amount needed for safe care
Identify location for on-unit storage of concentrated injectable (secure and segregated from other drugs)
Assign and train individuals with authority to access concentrated injectable on the patient care unit
Develop and maintain warning labels and procedures for monitoring concentrated injectable use
Establish procedures for daily check and replacement of on-unit stock of concentrated injectables
Periodic reevaluation: Is there a continuing need for concentrated injectables on the unit?
No
B
Yes
A

3. Implementing the Safe Management of Concentrated Injectable Medicines SOP

Sustained implementation is dependent on the interrelated group of activities set out below:

- **Diffusion** - the process by which the guidance is communicated – this is a passive approach.
- **Dissemination** - the process which is a more proactive process of communication.
- **Adoption** - the decision by others to adopt the guidance.
- **Implementation** - when new ways of working are acted upon and changes are made to behaviour and or practice.
- **Spread** - the transfer of the new ways of working between organizations or within organizations – spreading implementation from one place to another.
- **Sustainability** - when the new ways of working and improved outcomes become the norm, it becomes part of everyday practice i.e. implementation is sustained.

3.1 What is the problem?

The overarching finding from the literature in the last 15 years is that effective implementation of knowledge, research and information into practice remains an unconquered challenge. Implementation of the now increasing numbers of guidelines continues to be a challenge for many individuals and organizations.

Organizations and individuals have a key role to play in implementing safer practices in order to improve the safety of patient care. There are numerous directives and documents and research outcomes which people have to make sense of and to prioritize what they do and perhaps what they don't.

Concentrated injectable medicines have been involved in medication incidents resulting in death or serious harm, yet hospitals have sometimes been hesitant to remove them from patient care units. This may be based on necessity in which case precautions can be taken to help limit the risk of the inappropriate use of concentrated injectables. Concentrated injectables should never be stored on a patient unit merely for convenience. Individuals compound the problem, by "borrowing" concentrated injectables from areas authorized to store them as a necessity and leaving them in unauthorized areas for convenience sake. Put simply, there is little point in developing guidance or interventions if no one puts them into practice. This wastes the research, the work to develop the safer practice, the time and the money. Most importantly, we fail to make a difference to the safety of patient care.

3.2 Quick-Start Check List — Are You Ready?

The sections that follow lay out the basic strategy for implementing the WHO High5s Concentrated Injectable Medicines (CIM) SOP.

- The first step is to determine what needs to be done.
- Who should be involved and what are their roles and responsibilities?
- What is the time line for implementation?

- What are the major milestones and deliverables along the road to full implementation?
- Should a pilot test be done?
- How is a full, successful, and sustainable implementation achieved?

Here is a short check list of pre-implementation activities and necessities that will put you in good position to move forward with a smooth and successful implementation. Each of the following items should be completed as soon as possible and definitely before starting the actual process of implementation:

- Secure senior leadership commitment;
- Appoint a project coordinator;
- Form an implementation team;
- Confirm availability of team members;
- Convene the team;
- Define the problem and the goals; and
- Develop a work plan.

Oversight of the implementation process

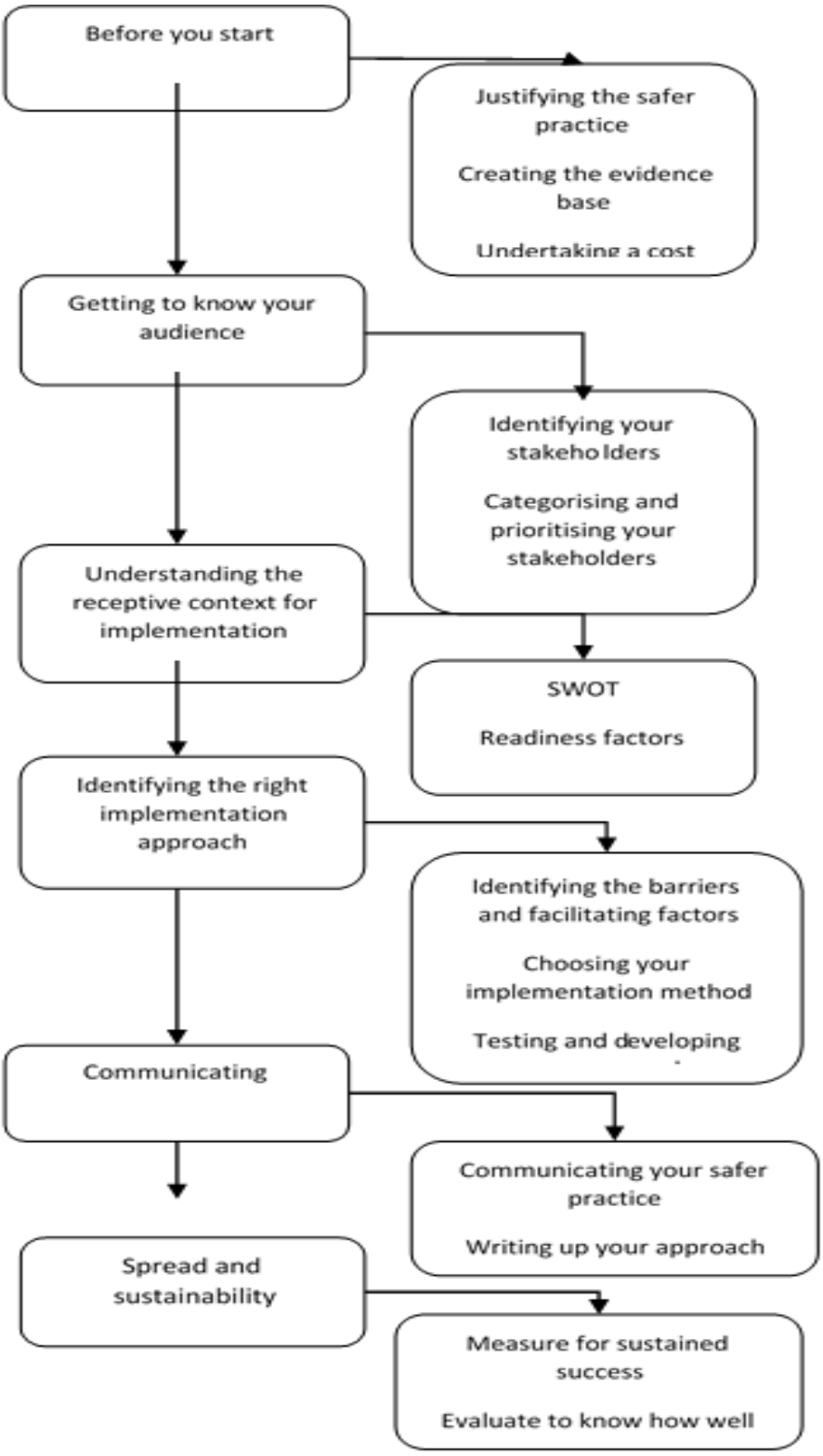
The CIM SOP recommends establishing a team to lead the work, as below;

a. Identify an Oversight Group for the implementation project (governing body or senior leadership group).
b. Assign a senior administrative leader to provide direct oversight of the implementation activities, assignment of staff, allocation of time for staff to do the work, and allocation of other resources.
c. Assign one or more representatives of the professional disciplines involved in medication management—at a minimum, physicians, nurses, and pharmacists—to guide the design, testing, and roll-out of the concentrated injectable medicines management process and to serve as role models and "champions" of the new process for their respective disciplines.
d. Assign a facilitator—a person with knowledge of the medication management process and project management skills—to develop and manage the project work plan.

The implementation methodology described in this section may provide further support.

The flow diagram in Figure 2 outlines the implementation process.

Figure 2. Flow Diagram of the Implementation Process



3.3 Getting to know the audience - Identifying stakeholders

It is important to seek stakeholders' views of the both the problem and potential ideas for the CIM SOP and the proposed implementation approach and methods. The stakeholders can provide insights and understanding of what would help or hinder implementation. They can also help by supporting, endorsing and promoting the CIM SOP. Stakeholders are persons, groups or organisations:

- Primary stakeholders are those ultimately affected by the process/practice to be adopted; and
- Secondary stakeholders are those who aid implementation.

Tips:

1) Target the proposed safer practice to the people who need it.

2) Achieve 'buy in' by producing the safer practice with the individuals who will be using it.

3) Develop a clear understanding of:

- The people to target [these are the key stakeholders];
- The barriers that may be encountered; and
- What can be done to address those barriers as well as the facilitating factors.

Addressing the issues above will help the development of a communication strategy and plan.

How to undertake a stakeholder analysis

This is a targeted analysis that will help identify the targeted audience, the people, groups and organisations that can influence actions to implement the CIM SOP (either positively or negatively). This helps focus activity and identify the level of effort and energy needed to best engage the stakeholders, as well as the most appropriate strategy to engage them.

- Think of all the people who will be affected by the CIM SOP, and who can affect or influence the proposed practice changes. Consider people by job designation as well as by clinical area. At a minimum, stakeholders for this analysis should include pharmacists, nurses and physicians.
- Identify which patient care areas have typically stored concentrated injectable medications such as the emergency room, the operating room/theatre, dialysis or palliative care areas that would help with the analysis? What about areas that may store these medications intermittently like general surgery areas or areas where it would not be expected to find concentrated injectables at all such as general pediatrics? Could they contribute as well?
- Who has influence or power, who has an interest in its successful or unsuccessful conclusion?
- Has anyone been missed out? Often other members engaged in the analysis process can help identify who has not been invited to work on the problem that should have been.
- Make sure that the correct individual stakeholders within a stakeholder organisation have been identified.
- Organise a group to brainstorm.

- Then list the stakeholders.

Stakeholders have the power or influence to block or advance an initiative. Some questions that can help with understanding stakeholders are:

- What specific interests will these stakeholders have in the safer practice? Is it positive or negative?
- What changes does the safer practice require the stakeholders to make?
- Are there any conflicts? What are the barriers? What would help?

Having identified the stakeholders, they should be categorised in terms of their influence and level of support or interest. Guidance on categorising stakeholders is available in Appendix A.

Understanding the theory behind why some people readily adopt change and others wait a while can be useful in determining the approach for implementing the CIM SOP. Information on understanding motivations for change and how to encourage stakeholders to adopt the safer process can be found in Appendix A.

In addition to understanding stakeholders there are a number of other factors that need to be considered that can also affect the success of the CIM SOP implementation:

- Strengths, weaknesses, opportunities and threats [SWOT];
- Readiness factors; and
- Barriers, hindering and facilitating factors.

3.4 Strengths, weaknesses, opportunities and threats [SWOT]

Conduct a SWOT analysis to assess the strengths, weaknesses, opportunities and threats of the practice change and implementation strategy, and to help identify priorities for action. A tool to guide the SWOT analysis is provided in Appendix A.

3.5 Readiness factors

Are the stakeholders ready to implement? To ensure smooth implementation it is essential to assess the environment in which the implementation will take place and to develop an implementation strategy based on findings.

There are specific characteristics of organisations that can help implementation. For example assessing how change has happened before, what went well, and what could have worked better is important.
A template and guidance on assessing the readiness of the organisation to implement the CIM SOP is provided in Appendix A.

Identifying the facilitating factors and barriers

Implementation is a complex process. There are factors that help implementation and factors that hinder, defined as barriers. It is important to identify barriers to introducing the CIM SOP and facilitating factors (enablers).

Examples of barriers:

- Scepticism among key individuals, whether they be clinical, managerial or support staff, can affect the spread of new practices. Understanding motivations and concerns and tailoring the approach to individuals offers a key to influencing them. Use opinion leaders and peers to help influence people to change their minds.
- Sceptics dislike the theory and language associated with the quality, safety and improvement initiatives. Try not to use jargon and provide practical examples that demonstrate benefits for their practice, patients and organisation.
- By not targeting the safer practice appropriately it will increase resistance to change, lengthen the time it takes for the practice to spread, increase the chances of rejection and reduce the opportunities for success.

Examples of facilitating strategies:

- Describing clearly the safer practice, the evidence and benefits to the audience and to their patients.
- Undertaking a stakeholder analysis to find out who the right people or organisation are will significantly increase the chances of adoption.
- Choosing multiple approaches to communicating the safer practice and providing practical support.

Factors which facilitate implementation amongst clinical staff:

- The change has a positive impact on the clinical process and a positive impact on patient outcomes;
- The change is compatible with shared norms and values;
- Clinical interest in the topic;
- Peer pressure;
- Use of opinion leaders and champions;
- Collaboration;
- Appropriate training;
- The change is aimed at both clinicians and managers; and
- Monitoring of progress at a clinical level.

Information on how to identify facilitating factors and barriers and approaches to support change can be found in Appendix A. This builds on the work done so far by:

- Being creative –a safer practice that grabs peoples' attention, interest, desire and will to change.

- Acquiring evidence, reviewing the facts, data and information to support the case. Providing those concerned with the evidence. Note: if there is no robust data people will need to be persuaded by engaging their hearts and minds.
- Identifying stakeholders and developing an understanding of them.
- Taking an active approach to change management – by starting to understand the psychology of change and the social and behavioural factors which need to be understood and addressed in the implementation strategy, for example:

    - The state of readiness of the target audience;
    - The obstacles to change, the barriers, the facilitating factors as perceived by the target audience.

Tip: The UK National Institute for Health and Clinical Excellence (NICE) has produced resources to help put NICE guidance into practice that can be applied to implementing the CIM SOP. These can be found on the NICE website; http://www.nice.org.uk/

A consistent finding in the research is that designing and using effective implementation strategies is essential to supporting changes in behaviour and practice. There is however, no one approach or strategy that applies in every situation.

The implementation approach needs to fit the safer practice. The choice will be influenced by the type of safer practice, in this case the implementation of a solution supported by good and available evidence, the CIM SOP. **T**he UK National Patient Safety Agency (NPSA) directive to reduce the availability of concentrated potassium chloride solutions in acute hospitals in England and Wales was found to be an effective approach for rapid implementation.[9] This demonstrated that a top down directive works if there is a simple message, with an irrefutable solution which has clear advantages for patients and staff. It is facilitated by senior management endorsement, strong backing by peers and opinion leaders and offering (in this case nurses) staff with a solution to a worrying problem and thereby providing 'peace of mind'.

[9] Alert on potassium chloride solutions. National Patient Safety Agency (UK), 23 July 2002. http://www.nrls.npsa.nhs.uk/resources/collections/never-events/core-list/potassium-chloride/ Accessed 12 May 2015

4. Project plan

The CIM SOP recommends that a project work plan is developed. This should be signed off by the implementation oversight group and include:

a. Detailed task list for design, testing, training, implementation, and measurement of the concentrated injectables management process

b. Milestones and their target dates to include at least the following:

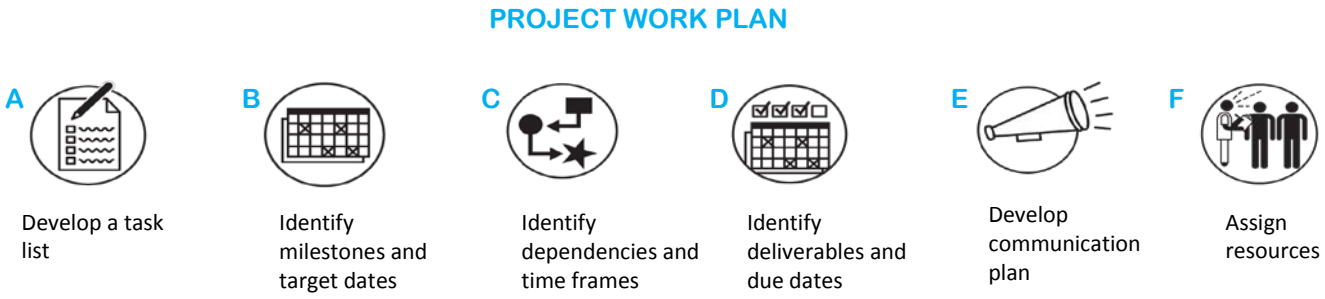
i. Approval of the project work plan;
ii. Approval of the pilot test design;
iii. "Go-live" date for the pilot test;
iv. Presentation of pilot test results to the oversight group;
v. "Go-live" date for full implementation.

c. Dependencies and time frames for each of the project tasks.

d. Deliverables and due dates for each of the project tasks.

e. Resources assigned to each of the tasks.

A sample task list for implementing the CIM SOP for use as the basis for a project work plan is provided in Appendix B.



5. Risk assessment

The CIM SOP requires changing existing processes and it is necessary, for the sake of safety and efficiency, to undertake a risk assessment of the new process before it is fully implemented throughout the hospital.

A risk assessment is the assessment of potential risks that could directly or indirectly affect the safer CIM management practice and implementation strategy and the likelihood of the occurrence of the risks. It should be used when developing safer practices, when developing the implementation strategy and to assess the risks associated with the safer practice and the implementation approach considered.

The purpose of the risk assessment is to identify any potential unintended consequences of the new/redesigned process and to make appropriate changes or develop/insert controls to ensure that the new process will be safe and efficient.

A methodology for conducting a risk assessment derived from the *Seven steps of patients safety* is provided in Appendix C.

Alternatively hospitals may choose to use the Failure Modes and Effects Analysis promoted by the Institute of Healthcare Improvement. Information is available at www.ihi.org/resources/Pages/Tools/FailureModesandEffectsAnalysisTool.aspx

Hospitals implementing the CIM SOP are strongly encouraged to complete the *Risk assessment for the preparation and administration of injectable medicines in clinical units* developed by the former UK National Patient Safety Agency provided in Appendix D.

6. Testing the safe management of concentrated injectable medicines process (optional)

Does a pilot need to be done? Unlike other High 5s SOPs the CIM SOP can be implemented throughout the hospital without conducting a pilot in part of the hospital. Hospitals may find it easier to implement the changes for one CIM at a time. Hospitals that elect to pilot the CIM SOP in one or more areas of the hospital should select areas that are representative of the overall functioning of the hospital such as a general medical inpatient unit. However they need to consider the risks of introducing the new process in only part of the hospital (e.g. pilot units) and the potential harm that could result from confusion amongst staff in clinical units unaware of the practice changes. Many of the Netherlands' hospitals in the High 5s Project implemented the SOP process across all units in their hospitals simultaneously.

Testing the CIM SOP

Having made the decision of where to test the SOP, in part or all of the hospital, the following steps should be followed to test the new process:

a. Collect baseline data on current processes prior to introducing the CIM SOP process using the measures described in the section 9.*
b. Engage representatives from the pilot test site(s) to participate in the test design and implementation.
c. Integrate the proposed process for managing concentrated injectable medicines into the work flow of the pilot test site/hospital with adaptation, as necessary, to the unique features of the pilot test site/hospital.
d. Train the staff who will be participating in the testing of the new process - consider that these individuals may become the trainers for the rest of the hospital staff when the new process is ready for full implementation.
e. Implement the new process in the pilot test unit/hospital.
f. Measure consistency and timeliness of implementation of each of the steps in the process.
g. Measure impact on other related or interfacing activities.
h. Measure impact on patients.
i. Gather feedback from all the participating staff, analyze test data and present to oversight group for decision on next steps, including possible redesign of the process.

Any significant redesign of the process should be fully documented, retested, and should result in sustained improvement before considering expanded implementation.

* *Prior to gathering baseline data, it will be necessary to make a list of each unit in the hospital and determine whether it is authorized to store concentrated injectable medicines. The stakeholder group could be helpful in establishing criteria for allowing an area to be authorized to stock concentrated injectable medicines. This list will serve as a reference throughout data gathering.*

Adaptation of the SOP

At times it may be necessary to modify the SOP in order for it to be successfully implemented. A modification that has a local impact for a specific hospital or group of hospitals is considered an *adaptation*. An adaptation to an SOP does not change the SOP itself. It may alter the way the SOP is implemented in a specific hospital because of local considerations that may make it impossible to implement the SOP in the

way that it is explicitly written. The process for requesting an adaptation to the CIM SOP should require review and approval by hospital leadership or other oversight body.

7. Spread

The implementation approach should enhance both spread and sustainability. By this is meant – can the change be sustained in the long term? Is it a lasting change?

- Spread refers to the transfer of the safer practice within or between organisations.
- Sustainability is when the safer practice and improved outcomes become the norm, it becomes part of everyday practice i.e. implementation is sustained.

When the process is stable and measurement reflects sustained improvement, consider spreading the CIM SOP to other areas of the organization (if only tested on specific areas of the hospital) and/or to a wider range of medicines e.g. other high alert/risk medicines.[10]

8. Communication plan

An effective communications approach will assist in developing and implementing the safer practice. It is likely that the project team will need to communicate what has been achieved at a number of stages in the development and implementation of the SOP:

- To let stakeholders know there is work occurring on safer management of concentrated injectable medicines;
- To seek input and views from stakeholders;
- To advise of the introduction of practice changes; and
- To encourage implementation of the new process.

Communications should raise awareness, increase knowledge and understanding and create the will to change. Prepare a simple communications plan by answering the following questions:

1. What do you need to communicate?
2. Why do you need to communicate this?
3. Who do you need to communicate this to (e.g.: who are your stakeholders)?
4. When do you need to tell them?
5. How are you going to tell them?

[10] High-alert medications are drugs that bear a heightened risk of causing significant patient harm when they are used in error. Institute of Safe Medication Practice. ISMP List of High Alert Medications in Acute Care Settings. www.ismp.org/tools/institutionalhighAlert.asp

How to communicate the approach

There are a number of ways to communicate with stakeholders, and usually a mix of channels will be used. The analysis of stakeholders should be used to assist in selecting the most appropriate communication channels:

- Face-to-face consultations; focus groups; presentations/seminars;
- External advisory references groups;
- Websites (organization's website or other); Newsletters; Direct mail;
- Advertising in industry magazines; and
- Department of health publications.

Consideration should also be given to evaluating whether the communication has been successful. There are a number of ways this can been done. Some common measurement methods are:

- Paper or online survey to stakeholders asking a range of questions e.g.: have you seen the CIM SOP guidance, have you acted on it, etc.
- Track number of downloads/printed copies distributed;
- Tracking and analysis of queries to the guidance; and
- Track compliance with guidance.

9. Process management, evaluation and feedback

Successful implementation and sustained performance of this standardized process for managing concentrated injectable medicines will require qualitative and quantitative information. In developing and testing the High 5s SOPs, three complementary approaches to information gathering were used and are provided here as a resource for organizations choosing not only to *implement* the SOP but to *manage* its ongoing performance. Of the various methods and tools provided, some may be useful in the early stages of implementation, others in the later maintenance of the process, whilst others may not applicable to the individual organization.

Decisions about how best to monitor and manage the process should be made by the designated oversight body with input from individuals who are involved in the process itself. The information obtained through this management strategy will also be valuable for providing feedback to participating practitioners and staff. The following components of a process management strategy have been thoroughly tested in the High 5s Project:

a. SOP Implementation Experience – self-reported information regarding the implementation experience in the pharmacy and a sample of patient care units.
b. Performance Measures – quantitative measurement of processes and outcomes associated with the CIM SOP.
c. Event Analysis – identification and analysis of any adverse events directly associated with or related to the CIM SOP or its implementation.

9.1 SOP Implementation Experience

It will be useful, especially during the early stages of CIM SOP implementation, to use an implementation experience questionnaire to gather information directly from the individuals engaging in CIM SOP implementation. Observing the process and interviewing key staff can provide further insight into how the well the process is working.

The purpose of collecting information about implementation experience is to:

1. Determine if the CIM SOP can be implemented as designed and intended;
2. Gain a better understanding of what it takes to implement and sustain implementation of the CIM SOP;
3. Identify barriers to implementation and sustainability of the CIM SOP and strategies for overcoming those barriers; and
4. Determine the perceived impact of the CIM SOP upon relevant processes of care, patient outcomes and patient safety.

Implementation Experience Questionnaire

The Implementation Experience Questionnaire used in the High 5s Project consisted of eight sections, each corresponding directly with an implementation component described in the SOP.

- **Section 1**, focuses on the oversight of the SOP implementation – was there an implementation oversight group? Was it multidisciplinary? Were there individuals that served as role models or champions for the implementation of this SOP?
- **Section 2**, the Project Work Plan, focuses on experiences with developing a specific task list to successfully implement the SOP.
- **Section 3**, relates to risk assessment - identifying potential areas for breakdown or failure and controls or warning systems developed to minimize process failures related to the identified risk points.
- **Section 4**, applies to those hospitals that conducted a pilot test prior to proceeding with full implementation. If a pilot test was conducted, what was learned? If a pilot test was not done, in hindsight, would it have been helpful?
- **Section 5**, looks at how the SOP was implemented throughout the hospital sites (ie. Spread Methodology).
- **Section 6**, focuses on how the information about the SOP and its implementation was disseminated throughout the hospital and whether staff involved in implementing the SOP were recognized for their contributions. This is the hospital's "communication plan".
- **Section 7**, relates to the experience of implementing the High 5s evaluation activities
- **Section 8**, maintenance and improvement strategy focuses on sustainability of the SOP implementation.

The complete *Implementation Experience Questionnaire* used in the High 5s Project was 19 pages long and, as such, impractical for general implementation of the SOP. However, a "short version" Implementation Experience Questionnaire was developed by the French High 5s Lead Technical Agency and its participating hospitals. It has been translated to English and is provided in Appendix E as a means for tracking the implementation experience efficiently and with minimal resource requirements.

Observation and interview

First-hand observation has two benefits. First, observation provides insight into how processes "actually" work, and second, observation by individuals not directly involved in the process on a regular basis allows for the discovery of issues or behavior that have become routine or hidden to those engaged in any part of the process. In order to take advantage of this, hospital leaders and other oversight bodies should consider conducting structured interviews with hospital clinical and administrative staff that play strategic roles in carrying out the SOP. Interview questions are broken into three sections:

1. *Section 1 – Prior to Implementation* – These questions relate to the hospital's expectations before implementing the SOP.
2. *Section 2 – During Implementation* – These questions relate to the hospital's current experience with implementation (e.g., what additional resources are required; were adaptations to processes required; were there barriers to implementation; were there pleasant surprises once the SOP was implemented; has the SOP had an impact [hopefully positive] on processes of care, patient outcomes and levels of patient safety).
3. *Section 3 – After reaching full implementation* – These questions relate to impact on patient safety, sustainability and long-term lessons learned.

A guide for interviewing point-of-care staff and project leaders is provided in Appendix F.

9.2 Performance Measures

The SOP measure sets that were used in the High 5s Project contain process and outcome measures for determining the extent to which implementation of the SOP:

(a) Consistently follows the protocol as designed.
(b) Impacts the specific targeted patient outcomes.

Hospitals are encouraged to use some or all of the measures to support effective management of the implementation process. As a means of easing the burden of data collections and analysis, hospitals may choose to use a subset of these measures. The Netherlands hospitals recommended collecting data on CI-P3 and CI P4 at a minimum. Hospitals may choose to include additional measures if there are specific aspects of the SOP implementation that need to be tracked in the hospital. The full set of these measures include:

Process measures

CI P1 Concentrated injectable medicines stored in unauthorized clinical areas: Measures how effectively the SOP is being implemented (Type: Process, Proportion)

CI P2 Concentrated injectable medicines supplied to unauthorized clinical areas: Measures reduction in supplies and compliments P1, removal of ward stock (Type: Process, Ratio)

CI-P3 Ready-to-administer and ready-to-use injectable medicines supplied to clinical areas: the supply should increase as the stock of concentrates decreases, a measure of success (Type: Process, Ratio) *****

CI-P4 The number of clinical areas storing concentrated injectable medicines according to selected SOP specifications: Measures effective implementation of the SOP (Type: Process. Proportion) *****

** Depending on time, resources and the hospital information system available for implementing and evaluating the SOP, the 16 pilot hospitals in the Netherlands found data collection for the full set of measures to be complex and time consuming for daily practice. They recommend measuring at least P3 & P4 during baseline and ongoing performance measurement combined with implementation evaluation questionnaires and a risk assessment.*

Outcome measures

CI-O1 Time between concentrated injectable adverse events (Type: Outcome, Central Tendency).

CI-O2 Time between adverse drug events related to delay or omission of administration of concentrated injectable medicines (Type: Outcome, Central Tendency)

CI-O3 Number of adverse events for specified concentrated injectables per 1000 patient days (Type: Outcome, Ratio)

Table 1 outlines the differences between the performance measures in terms of the type of measure, the direction of the improvement, the population being surveyed and the method of data collection.

Detailed guidance on using the measures for determining any improvement in the safe management of concentrated injectable medicines following implementation of the CIM SOP is provided in Appendix G. It

includes suggested data collection and analysis methodologies for each measure as well as guidance on using the data to further improve the process of safely managing concentrated injectable medicines.

Table 1. Differences between the performance measures

ID #	Performance Measure Name	Construct	Direction of Improvement	Population	Method of Collection
CI-P1	Concentrated injectable medicines stored in unauthorized clinical areas *Measures how effectively the SOP is being implemented*	Proportion	Decrease in rate (goal 0)	Unauthorized clinical area	Observation
CI-P2	Concentrated injectable medicines supplied to unauthorized clinical areas *Measures reduction in supplies and compliments P1 removal of ward stock*	Ratio	Decrease in rate	Unauthorized clinical area	Retrospective review of pharmacy records
CI-P3	Ready-to-administer & ready-to-use injectable medicines supplied to unauthorized clinical areas *The supply should increase as the supply of concentrates decreases, a measure of success*	Ratio	Increase in rate (goal 100)	Unauthorized clinical area	Retrospective review of pharmacy records
CI-P4	Number of clinical areas storing concentrated injectable medicines according to selected SOP specification *Measures effective implementation of SOP*	Proportion		All clinical areas (pharmacy excluded)	Observation
CI-O1	Time between concentrated injectable adverse events	Central Tendency	Extended length of time	All adverse drug events	Retrospective review of Medical Record, variance reports, etc.
CI-O2	Time between adverse drug events related to delay or omission of administration of concentrated injectable medicines	Central Tendency	Extended length of time	Events for delay or omission of administration	Retrospective review of Medical Record, variance reports, etc.
CI-O3	Number of adverse events for specified concentrated injectable per 1000 patient days	Ratio	Decrease in rate	All adverse drug events	Retrospective review of Medical Record, variance reports, etc. Daily patient day count

Forms and tools for data collection and analysis are provided in Appendix H.

The measures should be collected at baseline over a one month period (prior to testing/implementing the SOP), then monthly until the change is sustained (e.g. 3 months) and then repeated once or twice a year to assess whether the practice change is embedded into practice and continues to be sustained.

9.3 Event Analysis

Event analysis can be used as an intervention to optimize the implementation of the SOP. It may not be possible to analyze all events, but the process of event analysis will assist to assess the success and reliability of implementation. Who does event analysis is important and any event analysis involving medications should involve a pharmacist engaged in the quality and safety committee.

The goal of implementing the CIM SOP is to ensure that patients do not experience events related to the misadministration of concentrated injectable medicines that are within the scope of this SOP. These events could result in unnecessary harm to a patient.
The purpose of event analysis may be two-fold – to analyze the process and to determine whether implementation is effective, or to analyze the events that have occurred

There are four types of events:

1. Hazard: a circumstance, agent or action with the potential to cause harm.
2. Near miss/Close Call/Good Catch: an event which did not reach the patient.
3. No-harm Event: an event which reached a patient but no discernable harm resulted.
4. Adverse Event: an event which resulted in harm to a patient.

Event analysis is a systematic process whereby the facts, contributing factors and recommendations arising, are identified and reported as a result of investigating an event or group of events. This learning is then integrated with other sources of information to inform hospital risk management and quality improvement processes.

The purpose of conducting event analysis on events related to the SOP is to identify and understand whether the SOP contributed to the occurrence of the event. Such events would include the misadministration of concentrated injectable medicines that are within the scope of this SOP and "near miss" incidents. Event analysis seeks to answer the following key questions:

- Was the event causally related to activities addressed by the SOP?
- If so, was the SOP itself flawed in a way that led to the event or did the event result from a failure in implementation of the SOP?
- If the latter, was the implementation failure an isolated occurrence or an example of a consistent incorrect implementation of the SOP?

The answers to these questions will help to identify ways to improve the SOP and/or the approach to its implementation.

Type of Event Analysis

a. Comprehensive (traditional approach such as Root Cause Analysis).
b. Concise (abbreviated approach that focuses primarily on four aspects: the agreed upon facts, key

contributing factors and findings, actions for improvement (if any) and evaluation).
c. Aggregate and cluster (for analysing groups of the same type of event).

Event analysis before SOP implementation

Hospital leaders may decide to implement the CIM SOP as a targeted improvement strategy following the identification and analysis of a medication event(s). Sharing this baseline information will help the leaders to build the knowledge and desire for change across the organization.

Event analysis during SOP implementation

A quality improvement approach to implementing the SOP within the hospital should include a strategy for analyzing some medication event(s) related to the SOP. In particular, Event Analysis can provide important insight into events related to CIM SOP implementation. The event maybe identified:

1. By the patient, family member, or healthcare professional; or
2. During retrospective review of medical records such as when collecting data for outcome performance measures.

The event can be analysed using the organizations event analysis methodology or one of the methodologies available internationally. Engaging healthcare professionals, patients and family members in an analysis of one or more of these events will enable the identification of key contributing factors that are negatively impacting the implementation of the SOP. Targeted, evidence based strategies can then be tested to improve the CIM SOP process and resources can be efficiently re-aligned for broader implementation. Without event analysis, anecdotal perceptions may be used to inform decisions.

Event analysis after SOP implementation

After the SOP is fully implemented, Event Analysis can be used to review events to determine if there are any key issues with maintaining SOP implementation. Mechanisms for identifying the events are the same as those used during implementation.

Refer to the WHO High5s Interim Report for a complete description of the WHO High5s Event Analysis methodology and findings. http://www.who.int/patientsafety/implementation/solutions/high5s/en/

9.4 Hospital collaboratives

Implementing the CIM SOP as part of a hospital collaborative with oversight of data management and interventions employed has benefits for participating hospitals and was recommended by the Netherlands hospitals. As well as providing information on the effectiveness of the CIM SOP on achieving the aim of minimising storage and use of concentrated injectable medicines in clinical units the collaborative provided a forum for hospitals to exchange ideas and learn from each other.

10. Maintenance and improvement

Once the concentrated injectables management process is implemented throughout the organisation, regular monitoring of key parameters as outlined in section 9.2 and Appendix H should continue on an ongoing

basis to ensure the patient safety benefits are maintained. The performance measures and event analysis should be incorporated into the hospital's quality and safety plan and reported to the clinical governance/quality and safety unit. They can also form part of the evidence of quality improvement during accreditation reviews.

Opportunities to improve the efficiency and effectiveness of the process should be identified, prioritised and acted upon.

Evidence of "drifting" from the intended procedures should be analysed to identify the reasons and to determine an appropriate response. For example: additional training; process redesign; technical support.

Appendix A. Further information on implementation

In Section 3 Implementing the Concentrated Injectable Medicines SOP the implementation process was presented along with some guidance on engaging with stakeholders and other factors known to influence the introduction of safer practices. This Appendix contains further guidance on the implementation process and includes a range of tools to help project teams successfully engage with stakeholders, assess the organisations readiness for change and identify facilitating factors and barriers to implementation.

Categorising and prioritising the stakeholders

Having identified relevant stakeholders as outlined in Section 3 the next step is to categorise the stakeholders. An easy way of doing this is to use a stakeholder grid.

	High Support/Interest	**Low Support/Interest**
High Influence	Those who have high influence and are highly supportive can be counted on to most positively influence dissemination, adoption and implementation. These are the people who must be fully engaged and the greatest efforts made to satisfy them. They need information and attention to maintain level of support. Strategies: • Collaborate • Involve and or provide opportunities for support • Nurture • Encourage feedback • Empower	Those who have high influence and are low in support need the greatest amount of attention in order to get them on board. Put enough work in with these people to keep them satisfied, but not so much that they become bored with the message.. Strategies: • Collaborate • Involve at some level • Encourage participation • Encourage feedback • Empower
Low influence	Those that have low influence but are highly supportive need a great amount of attention to prevent them from becoming neutral or negative towards the change. Keep these people adequately informed, and talk to them to ensure that no major issues are arising. These people can often be very helpful with the detail of the project but can negatively affect dissemination and adoption. Strategies: • Build relationships and consensus • Recognise needs • Involve at some level • Show the evidence	Those who have low influence and low support are lowest on the priority list but still require engagement to ensure at least a neutral position. Monitor these people, but do not bore them with excessive communication. Strategies: • Build relationships and consensus • Recognise needs • Involve at some level

The grid uses two identifiers, influence and support, to separate stakeholders into groups e.g. those who can influence implementation and who will lead, support and champion the implementation. Different headings can be used such as power and influence or interest and support and so on. The grid will help assess the actions that can be taken with each stakeholders once categorised. In simple terms this is:

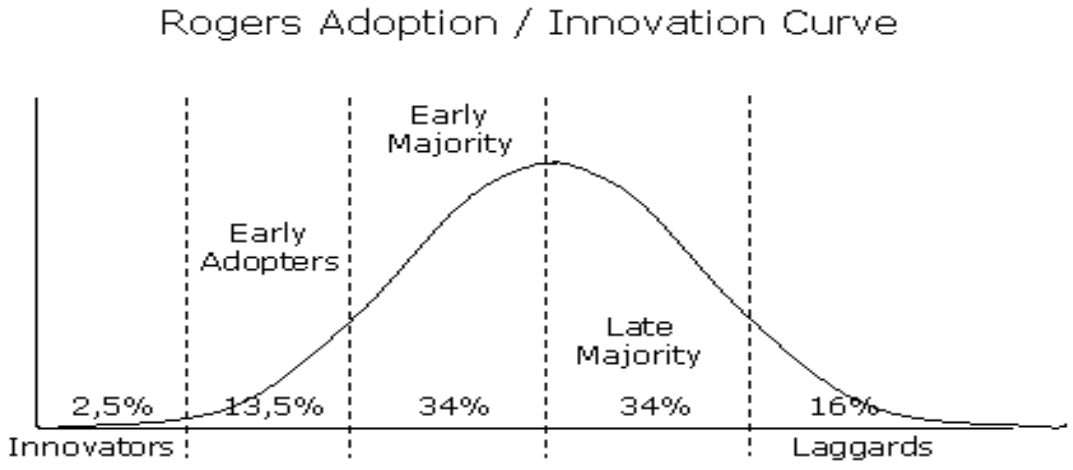
	High Support/Interest	**Low Support/Interest**
High Influence/Power	Manage closely with maximum effort	Keep satisfied
Low influence/Power	Keep informed	Monitor with minimal effort

Remember to revisit the stakeholder analysis at key stages as it is time sensitive. Some stakeholders may not appear to be highly influential now but as the guidance is developed their influence may increase.

Understanding the audience

Adopters and adoption

Adoption is the decision by others to adopt the safer practice or change. It is a process rather than an event. Understanding some of the theory behind why some people change and others wait a while can be helpful. Rogers has identified five adoption 'types'.[11]



[11] Everett M Rogers. Diffusion of Innovations 4th Ed. 1995

An alternative is to view individuals' readiness to change:

	Pre-contemplative	**Contemplative**	**Action**
Behaviour	Can't see the need for change Not interested Low awareness of change	Thinks some change is needed Requires information and evidence	Wants to change Wants to do it now

How to categorise the audience

The following table lists the characteristics of the different types of audiences are in relation to patient safety.

Category	**Definiton**	**Characteristics relating to patient safety**	**Potential barriers**
Innovators	Brave, pulling change, very important communicators.	Information seekers. Already undertaking significant activities to address patient safety issues and achieving significant improvements. Potentially could be a participant in patient safety initiatives. Could be positioned as a role model and a mentor.	Already ahead of the game, what is benefit to them? Risks associated with putting themselves forward as an example. Too busy doing existing work.
Early adopters	Respectable, opinion leaders, try out new ideas in a careful way.	Open to ideas and acive experimenters. Already undertaking activity to address patient safety issues and seeing some improvement. Likely to benefit from tools and resources but also potential to provide mentoring and / or learning to other organisations.	May think existing work is better than anything offered. Wants to do it on their own.

Category	Definiton	Characteristics relating to patient safety	Potential barriers
Early majority	Thoughtful, careful but accept change more quickly than the average.	May already be undertaking activity (or about to) to address patient safety issues. May have seen some improvement but perhaps not widespread or sustained. Need personalised information and support. Will gain significant benefit from the tools and resources. Can be influential on peers and make opinion leaders.	May not feel ready to take on the challenge. May want to do it on their own.
Late majority	Sceptics, will use new ideas or products only when the majority is using them.	May be undertaking some activity but hesitant to make large scale changes, not convinced about some interventions and/or improvement processes. May be wanting to commence activity but don't know where or how to start.	May not feel ready or want to take on the challenge. Need convincing of worth, gain and significant benefit.
Late starters	Traditional, care for the 'old ways', are critical to new ideas and will only accept if the new idea has become mainstream or even tradition.	Not convinced about interventions and / or improvement processes, doesn't see reason to change, focused on other priorities.	Under fire on many levels, hard to find time to focus on another new initiative. Lack of staffing and funding. Lack of knowledge and ability across majority of staff. Low morale.

Stages of adoption

The four stages of adoption of change have been categorised as:

1. Awareness;
2. Persuasion;
3. Decision; and
4. Act or reject.

The following table lists st*rategies* for tackl*ing the different* stages of adoption

Phase	**Stakeholder tasks**
Awareness and persuasion	Let people know what you are doing and why Talk to your audience Identify objectives and questions to be answered Determine if consultation is required and the right process for this Is there a level of training and development required?
Decision to act or reject	Identify key concerns, issues and collect information Communicate emerging findings Demonstrate the evidence; the benefits and the levels of participation required Use peers or opinion leaders to help persuade or deliver the message
Approach to implementation	Consult with those responsible for implementation.. Seek views on the different options for implementation Communicate the chosen option

Other factors to be considered

In addition to understanding the stakeholders there are a number of other factors that need to be identified that can also affect the success of the implementation of the CIM SOP:

a. Strengths, weaknesses, opportunities and threats [SWOT];
b. Readiness factors; and
c. Barriers, hindering and facilitating factors.

Strengths, weaknesses, opportunities and threats [SWOT]. Conduct a SWOT analysis using the tool below to assess the strengths, weaknesses, opportunities and threats of the practice changes and implementation strategy, and to help identify priorities for action.

SWOT Analysis Tool

Strengths ▪ How can you enhance the implementation further to increase its success? ▪ How can you demonstrate its value compared to the current system? ▪ What are its advantages? ▪ What is its unique selling point?	**Weaknesses** ▪ What are the weak aspects of your guidance? ▪ What weaknesses were identified by testing and what can you do to improve it as a result? ▪ What are the disadvantages?
Opportunities ▪ How can you test the guidance on a small scale, learning lessons so as to enhance the probability of implementation? ▪ What are the opportunities that your guidance creates for local practice?	**Threats** ▪ What could go wrong when you try to implement? ▪ How can you avoid these risks? ▪ Who will raise objections and what might these be? ▪ What are the political issues; legislative issues; is there a demand? ▪ What are the obstacles you face?

Readiness factors. Are the stakeholders ready to implement? To ensure smooth implementation it is essential to assess the environment in which the implementation will take place and to develop an implementation strategy based on findings.

There are specific characteristics of organisations that can help implementation. For example assessing how change has happened before, what went well, and what could have worked better is important.

The following provides an example of a template that can be used to assess how ready the organisation is for the planned changes.

Template on how to undertake a readiness factor analysis

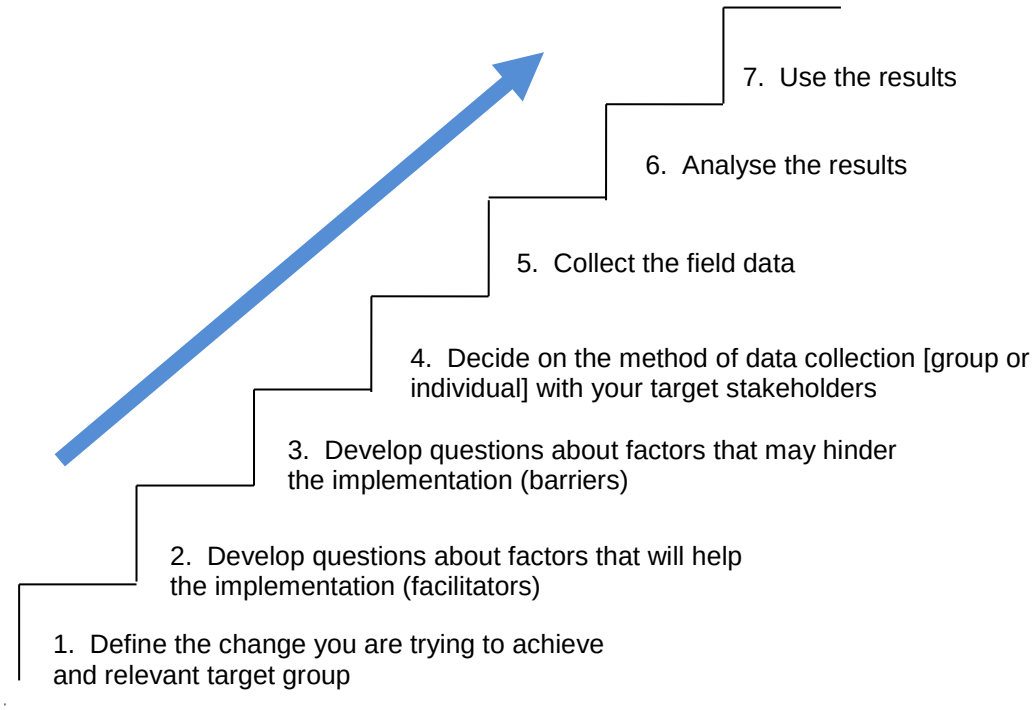
Element [Examples]	Question [Examples]	Facilitating factors [Examples]	Hindering factors [Examples]
Structure: staffing practices, physical facilities and available resources	Are there enough staff to support the change process	Multidisciplinary team approach	Lack of time to attend meetings
Workplace culture: values, beliefs, and how they are expressed in day to day activities	To what extent is the intervention consistent with the values, attitudes and beliefs of those required to implement the change?	Use of opinion leaders	Lack of evidence or benefits not clearly demonstrated
Communication: both formal and informal processes for information exchange, the interdisciplinary relationships especially between managers and clinical staff	Are there adequate formal and informal communication systems?	Email updates, regular bulletins, newsletters, meetings, events	Limited opportunity to communicate
The influencers: the presence of influential champions or opinion leaders within the organisation	Who are the influences for this particular subject?	Use to front up the work – influences others to change	One opinion leader to one person is not necessarily the right opinion leader for someone else
Knowledge, skills and attitudes of target group: those who will be required to implement the change in practice recommended, their motivation towards adoption of new idea and practices, whether they have the skills required	Does the staff have the necessary knowledge and skills?	Faculty Training Simplicity	Complexity creating resistance
Leadership: the extent to which the leaders and managers at all levels will influence and enable the changes recommended	To what extent do the leaders support the change?	Chief Executive support clearly evident	Change not shown as a priority
Available resources: financial or human requirements necessary to achieve the changes	Are there necessary human, financial resources available?	Dedicated time Lead roles for implementation Business case development	Competing priorities Limited resources

Facilitating factors and barriers

Implementation is a complex process. There are factors that help implementation and factors that hinder, defined as barriers. It is important to identify facilitating factors (enablers) and challenges/barriers. Examples of some of these barriers and enablers are provided in Section 3.5.

How to identify facilitating factors and barriers

The following assessment tool can be used to identify behavioural barriers and the factors that help change happen.



Options that could be taken to gather the information:

- Observe current practice in action to assess people's behaviour in their working environment.
- Use a questionnaire to explore the knowledge, beliefs, attitudes and behaviour of the targeted group.
- Brainstorm with small groups.
- Run a focus group through a facilitated discussion of small groups of no more than 10 people.

This should be carried out after the stakeholder analysis so that the particular stakeholders relevant to the CIM SOP are involved.

Tip: The National Institute for Health and Clinical Excellence (NICE) provides details of how to understand barriers to change in the Putting Guidance into Practice section on the NICE website http://www.nice.org.uk/

Factors that facilitate implementing safer practice

Organisational issues	**Tools and support**	**Behavioural**
Commitment from the leadership of the organisations	Evidence provided at the outset	Sense that the change would work
Low cost	Progress reports	Voluntariness
Effective teamwork and communication	Reminder systems	Experience of a previous serious event related to the topic
Multidisciplinary teamwork	Access to experts	Involvement of the end user
Collaborative approach	Learning from peers	Recognition of the benefits
No new skills required	Education interventions which are integrated with a targeted approach and the use of opinion leaders	Compatibility with shared norms and values of health professionals
No significant resources required	Multi-faceted interventions targeting different barriers to change rather than single interventions	Perceived importance of initiative
Action by senior managers to support changes by clinical staff	Educational outreach visits	Will to change
Managers to understand the clinical world	Interactive workshops	
Organisation wide mechanisms to support implementation	Strong backing by opinion leaders and champions	
Participatory and flexible culture	Simple to implement	
New ways matched with and integrated into current systems	Customise the messages and strategies	

Approaches that support change

The following table provides examples of approaches that have been shown to support change

Implementation Method	Description	Why choose this method
Building local consensus	Inclusion of local staff in the development of the guidance or intervention.	This approach will help you target your audience, generate ideas for the solution and guidance. It engages all levels of staff from board to ward. *Note: It can be time consuming*
Educational outreach visits	Trained individuals and experts visit healthcare staff in their workplace to offer information, support and instruction to explain the desired change.	This approach is effective in tackling certain types of change, such as practice changes. It increases in effectiveness if there are more than one visit. It is more effective when combined with reminders and or interventions aimed at patients and when tailored to individual barriers and situations. *Note: The identity of the outreach visitor may have an impact on its effectiveness (positively or negatively). It is not proven to be effective for complex change. Time and resources are needed.*
Reminders	Manual and computerised reminders to prompt behaviour change; reminder notes on medical notes; computer aided decision support.	This approach is effective for reminding individuals of best practice. They remind healthcare staff to take or avoid a certain action. They are effective in changing behaviour if given at the point of decision making. Increasing the frequency can increase effectiveness – although too many alerts mean result in the alert being ignored and over ridden
Interactive educational meetings	Facilitated meetings involving learners in discussion and active participation. Provide training modules, define the competencies required	This approach works for small scale meetings such as workshops and training courses where the participants take a more active role in learning. It stimulates problem based learning for change. The more interactive a meeting, the more effective it is to changing behaviour and practice. *Note: It is reliant on interaction – which requires specific skills from the facilitator.*

Implementation Method	Description	Why choose this method
Multifaceted interventions integrating audit and feedback, reminders and marketing principles	Assessment of clinical performance charted over time. Combined with feedback in the form of outcomes of care, costs, trend analysis, promoting achievement.	Audit can be a positive way of generating change. The quality and type of data are important – it needs to be clinically rich in order to be interesting to clinical staff. This approach is more effective if staff buy-in to the process, and they have an active role to play. Feedback needs to be delivered by those who are respected. It needs to be timely, and combined with educational materials and meetings. Marketing processes help you to target the guidance and intervention using marketing principles in development, planning, design, advertising, promotion, dissemination and evaluation.
Opinion leaders	Respected individuals or peers who can influence others to change behaviour and practice.	This approach is an effective way of disseminating information and works if the right well respected opinion leaders are used – these need to be either peers, role models or recognised experts who can make a positive difference by adding signature, delivering speeches, writing articles in influential journals and undertaking outreach visits. *Note: It is difficult to identify the appropriate opinion leaders – an opinion leader for some is not necessarily an opinion leader for all.*
Collaboratives	Providing structured networks to bring organisations and individuals together to learn and share from each other.	This approach is effective for encouraging a partnership approach to the implementation of your safer practice. It creates a network and supportive system for implementation. *Note: Works best when there is leadership support and regular and repeated attendance*

Implementation Method	Description	Why choose this method
Patient-mediated strategies	By giving information to patients and the wider public we can help change the behaviour of healthcare staff.	This approach uses patients as influencers. For example communicating with patients and informing them of the latest evidence based practice through mass media campaigns. This works best if the campaigns are aimed at informing and educating professionals and patients together.

The following approaches have been found to be less successful at creating sustained change.

Implementation Strategy	Description	Why choose this method
Educational/printed materials on their own	Books, leaflets, journal supplements, CDs, videos, DVDs, online tools.	This approach raises awareness of the change. It is a low cost choice. It is most effective when combined with other methods. *Note: While it disseminates and shares information it does not usually change practice. It is a passive approach and therefore reliant on healthcare staff to read. It is therefore considered only appropriate for raising awareness and short term change only.*
Didactic educational meetings	Conferences, workshops, training courses, lectures or presentations with healthcare staff; usually passive.	This approach raises awareness about the desired change on a large scale. There is little or no interaction *Note: Similar to the printed material dissemination it is less effective at making change happen and achieves short term change only.*

Appendix B. Sample task list for managing the implemenation of the CIM SOP

Key Milestone	Task name	Duration	Start date	Finish date	Dependencies	Responsibility
1. Define and assign oversight responsibilities	Identify oversight group					
	Identify senior administrator "contact" for resource decisions					
	Assign representatives from each professional discipline					
	Assign facilitator					
2. Development & approval of work plan	Draft of current CIM storage & prep process					
	Draft of redesigned CIM storage & prep process					
	Assign responsibilities for new or revised steps					
	Identify milestones for pilot test and subsequent implementation					
	Set dates for periodic reporting to oversight group					
	Review and revision of					

Key Milestone	Task name	Duration	Start date	Finish date	Dependencies	Responsibility
	draft work plan					
	Approval of the work plan by oversight group					
3. Risk assessment of the process to be implemented	Identification & prioritization of failure modes					
	Proposal for adaptation or redesign of the process					
	Approval of adaptation/redesign					
4. Pilot test of the process	Identify test site(s)/unit(s)					
	Collect baseline data					
	Train staff					
	Implement new process					
	Implement evaluation strategy					
5. Communication plan	Develop draft plan					
	Develop communication tools					
	Implement					

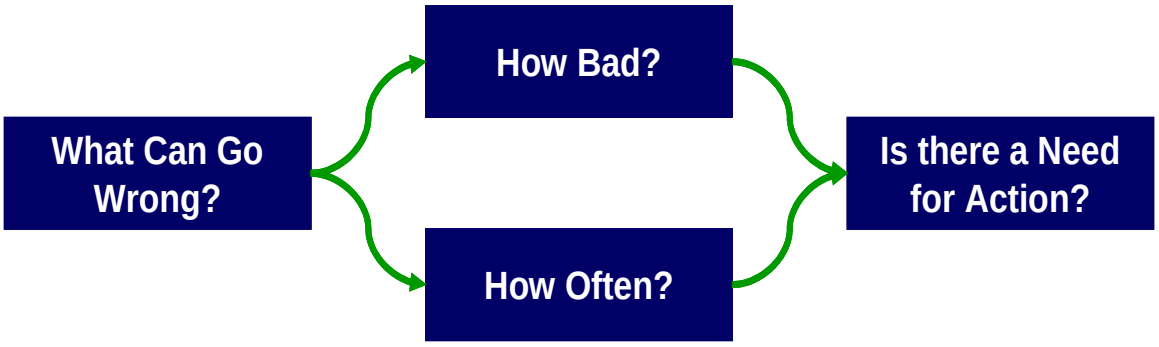
Key Milestone	Task name	Duration	Start date	Finish date	Dependencies	Responsibility
	communication plan					
6. Spread Plan	Determine sequence, timing & resources					
	Develop draft plan					
	Implement plan					

Appendix C Risk Assessment

Seven Steps to Patient Safety[12] describes the importance of an integrated approach to risk management and the use of risk assessment as an improvement tool. Risk assessment should be used when developing safer practices and the implementation strategy to assess the risks associated with the safer practice and the implementation approach considered.

Risk assessment is the assessment of potential risks that could directly or indirectly affect the safer practice and implementation strategy and the likelihood of the occurrence of the risks. These risks can be clinical, environmental, financial, economic, political, and those affecting public perceptions and reputation.

The process of risk assessment seeks to answer four simple, related questions.



For each **hazard** identified, it is important to decide whether it is significant and whether appropriate and sufficient controls or contingencies are in place to ensure that the **risk** is effectively minimised.

HAZARD – a situation with the potential to cause harm

RISK – the combination of likelihood and consequence of hazards being realised

Benefits of Risk assessment:

- Strives for the optimal balance of risk by focusing on the reduction or mitigation of risk while supporting and fostering innovation so the greatest returns can be achieved with acceptable results, costs and risks.
- Supports better decision-making through a solid understanding of all risks and their likely impact.
- Helps to plan for uncertainty, cope with the impact of unexpected events and increase staff, patient and public confidence.

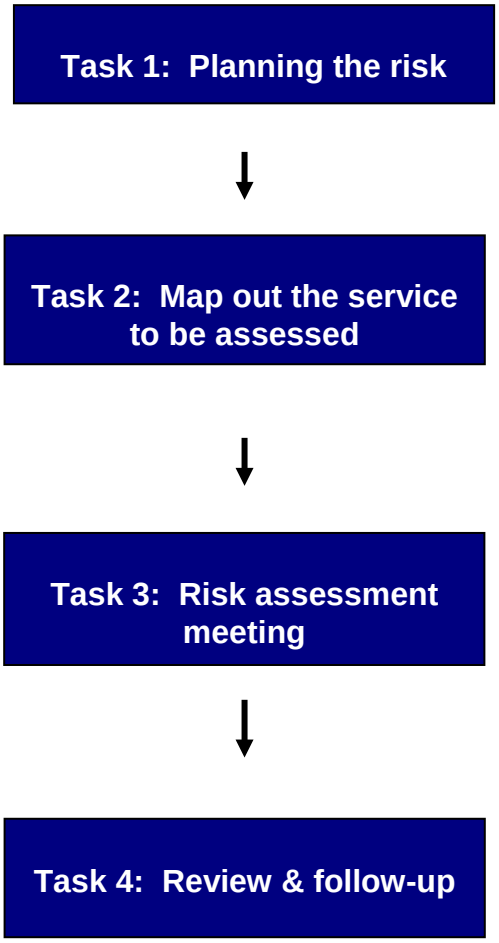
[12] Seven steps to patient safety guidance was developed by the former NPSA of the UK NHS to help organisations ensure that the care provided is as safe as possible, and that when things do go wrong the right action is taken. www.nrls.npsa.nhs.uk/resources/collections/seven-steps-to-patient-safety/. Accessed 15 June 2015

- Highlights the weakness and vulnerability of practice or policy change

How to do a risk assessment

This section provides a step-by-step description of the risk assessment process. Past risk assessment experience is not necessary. Ideally a multidisciplinary team is brought together who will be affected by the safer practice and the implementation approach considered.

Essentially the process is composed of four main tasks:



TASK 1 Planning the risk assessment

Start by defining the risk assessment's objective and scope. Key considerations when planning risk assessments:

- **Estimating probability**: assess the chances of a risk happening. This can be highly subjective, so when estimating probability the assessor needs to take into account the fact that memorable events seem more common and constant feedback is necessary to ensure accuracy of predictions. There is also the potential to over or underestimate the possible impact of an incident. The use of incident data, literature and other sources of intelligence will help with this.
- **Balance of analysis:** Don't concentrate exclusively on the most serious risks while ignoring the low-to-moderate risks, which occur much more frequently. There is something to learn from all levels of risk.

TASK 2 Map the safer practice and implementation approach to be assessed

Mapping means breaking the task down into its component parts. It is recommended that this is done by:

1. Listing or mapping out the activities;
2. Identifying interactions with all component parts; and
3. Identifying other changes resulting from the proposals.

Figures C1 and C2 are examples of flow diagrams of the **existing** (undesirable) process for managing the concentrated injectables selected and the **redesigned** (preferred) process incorporating the use of pre-diluted injectable medicines.

TASK 3 Conduct the risk assessment

'What if': Develop a set of 'what if' questions to provide prompts and aid identification of hazards, risks and their causes.

	The risk assessment process
Step 1	The team reviews the process map. The most knowledgeable person in the room describes each activity.
Step 2	Team review the prompts ("what if" questions) and further develop the hazards/risks relevant to each activity.
Step 3	The team selects a hazard to assess.
Step 4	The team identify potential causes, consequences and controls for the selected hazard.
Step 5	The team assess the hazard's risk using their risk matrix, and determine if further mitigation is required.

Step 6	The team develop relevant recommendations to control the high/medium risk hazards, and re-assess the risk, given their recommendations are in place. If the risk is still high, further recommendations should be developed. If the team cannot identify any practical means of mitigating the risk, the risk should be escalated for acceptance in accordance with the organisation's risk management procedures.
Step 7	Repeat steps 4 to 7 until all the hazards have been assessed
Step 8	Repeat steps 1 to 8 until all the activities have been assessed.

Task 4 Review and follow-up

The outcome of the risk assessment should be addressed. Subsequent to the risk assessment meeting, the team should review the recommendations from the assessment meeting and agree whether to implement them as they stand or to modify them.

The team will also need to agree how they should be implemented

The hazards and risks identified and the actions agreed will need to be placed either on a risk register (or other record as appropriate) with the action owner identified.

Figure C1: Example flow chart of use of concentrated injectable medicines (undesirable)

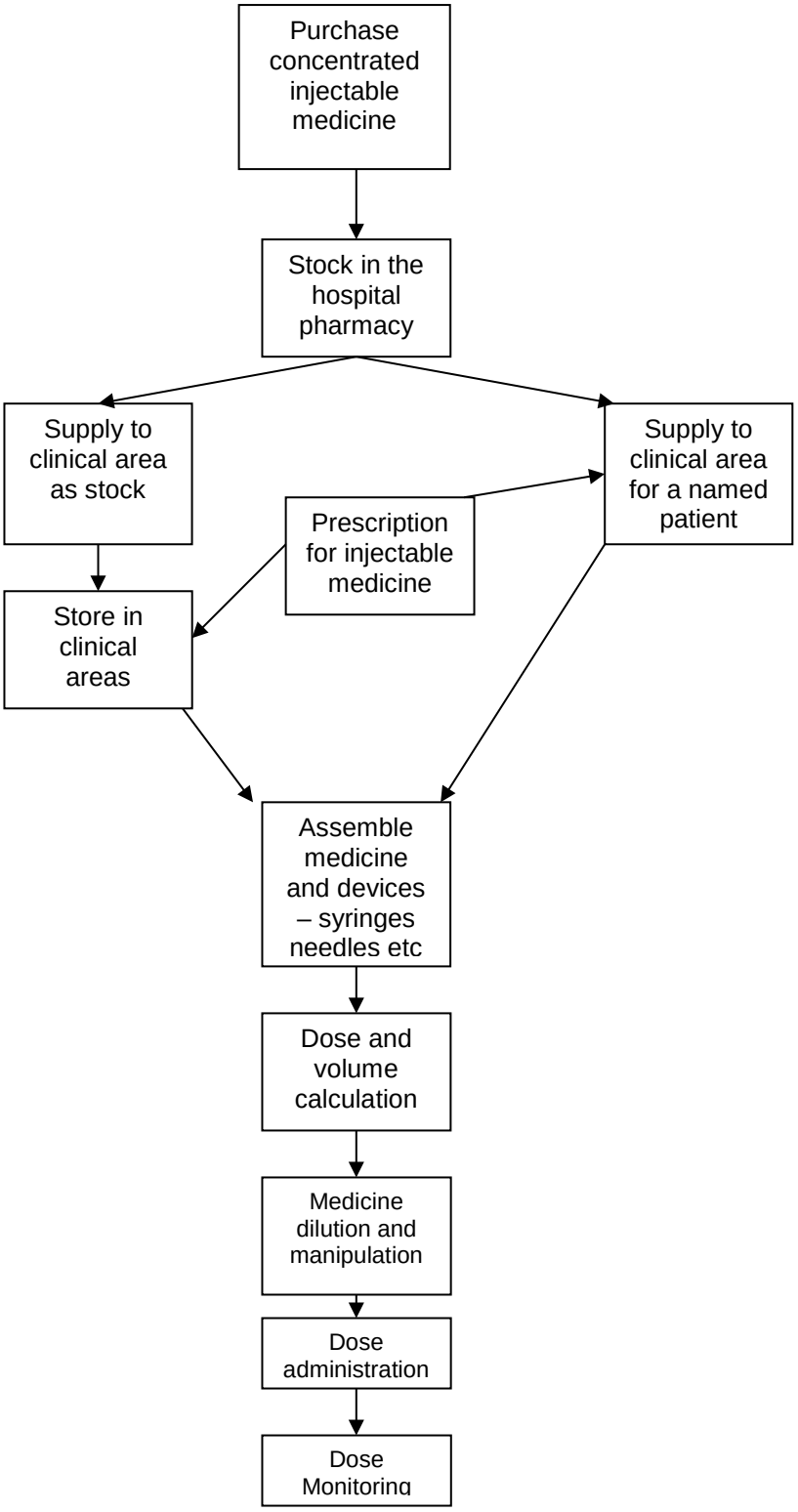
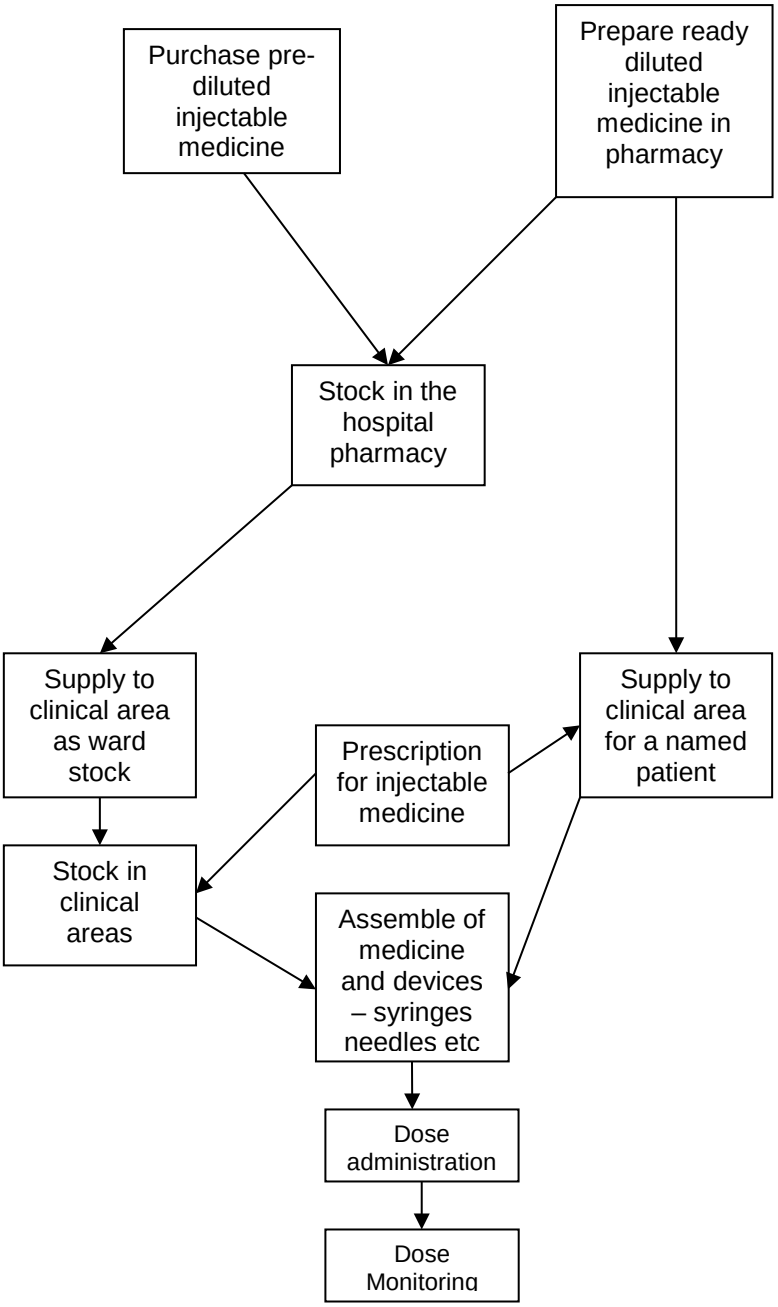


Figure C2:Example flow chart of use of pre - diluted injectable medicines (preferred)



Appendix D. Sample Risk Assessment Tool for Concentrated Injectable Medicines

Suggested risk reduction methods that can be used to minimise risks with injectable medicines. (See Step 7 of Risk assessment process below)

1. Simplify and rationalise the range of products and presentations of injectable medicines. Where possible, reduce the range of strengths of high-risk products and provide the most appropriate vial/ampoule sizes.

2. Provide ready-to-administer or ready-to-use injectable products – this will minimise preparation risks and simplify administration

3. Provide dose calculating tools – for example, dosage charts for a range of body weights that eliminate the need for dose calculations.

4. Provide additional guidance on how to prescribe, prepare and administer high-risk injectable medicines.

5. Consider the provision of pre-printed prescriptions or stickers – this will help to ensure that information on the prescription about preparation and administration of high-risk products is clearer.

6. Provide locally approved protocols that clarify approved unlicensed and 'off-label' use of injectable medicines.

7. Use double-checking systems – an independent second check from another practitioner and/or the use of dose-checking software in 'Smart' infusion pumps and syringe drivers.

8. Use an infusion monitoring form or checklist – this will help to ensure that infusions are monitored throughout administration.

The risk assessment process

1. Carry out a risk assessment in all clinical areas where injectable medicines are prepared and administered
2. A pharmacist and a senior clinical practitioner from the area being assessed should carry out the risk assessment
3. Risk assessments should be conducted annually, and when new injectable products or practices are introduced
4. Risk assess local practice, i.e. how injectable medicines are prepared and administered (see proforma 1)
5. Risk assess individual injectable medicine products used in the clinical area (see proforma 2) – there are examples to assist with this
6. A summary of products with high and moderate risk assessments should be completed (see proforma 3)
7. Identify risk reduction methods to minimise these risks (see guidance)
8. Where possible, implement appropriate risk reduction methods
9. Re-assess high and moderate-risk practices and products, and record the new scores following the introduction of risk reduction methods (see proformas 1 and 3)
10. Identify any remaining high-risk products and practices for consideration by the Drugs and Therapeutics Committee (or equivalent) and, if these risks cannot be minimised, they should recorded in the organisation's risk register

Proforma 1: Risk assessment of injectable medicine procedures – how medicines are prepared and administered

	Clinical area:		**Clinical directorate:**	**Hospital site:**	
	Date of first assessment:			**Date of second assessment:**	
	High-risk practice **Tick when high-risk practice is found**	✓	**Suggested risk reduction method**	**Comments/revised score** **Tick if high-risk practice remains unchanged**	✓
1	Inadequate technical information or written procedures for preparing and administering injectable medicines		Provide essential technical information and written procedures		
2	Use of unlabelled bolus syringes (including flushes) and infusions – see guidance in multidisciplinary standard		Reinforce and audit policy to ensure all syringes and infusions containing injectable medicines that leave the hands of practitioners during use are labelled		
3	Use of 'open systems'. Is the injection or infusion transferred into an open container?		Introduce 'closed systems'		
4	Preparation of a cytotoxic drug outside of the pharmacy department		Prepare all cytotoxic drugs in the pharmacy department or use closed system products designed for use in clinical areas		
5	Preparation of, or addition to, total parenteral nutrition (TPN) outside of the pharmacy department		Prepare and make all additions to TPN in the pharmacy department or use closed system products designed for use in clinical areas		

	High-risk practice **Tick when high risk-practice is found**	✓	**Suggested risk reduction method**	**Comments/revised score** **Tick if high-risk practice remains unchanged**	✓
6	Administration of an injectable medicine, prepared more than 24 hours previously in the clinical area		Introduce procedures to ensure that all injectable medicine products prepared in clinical areas have expiry dates of 24 hours or less to minimise the risk of microbial contamination unless specifically permitted by a written organisationally approved protocol		
7	Admixture of two or more active medicines without information from the pharmacy service concerning compatibility of the medicines		Obtain compatibility information or administer as separate infusions		
8	Failure to use infusion pump or syringe driver for injectable medicines that require their rate of infusion to be controlled		Ensure that adequate numbers and types of infusion pumps and syringe drivers are available for use, and users have knowledge and training of when and how this equipment should be used		
9	Use of an injectable medicine ampoule, vial or infusion to prepare more than a single dose (unless the product is specifically licensed for use in this way)		Reinforce and audit policy to ensure that single-use products are only used to prepare a single dose (unless specifically permitted by an organisationally approved protocol)		
10	Unauthorised use of unlicensed medicines or 'off-label' use of licensed medicines (unless specifically permitted by a written organisationally approved protocol or BNF-C)		Reinforce and audit policy on the use of unlicensed or 'off-label' injectable medicines. Ensure approved protocols are used, include BNF-C recognised off-label usage		
	Total number of high-risk practices identified in baseline assessment			**Total number of high-risk practices remaining after risk reduction initiatives**	

Proforma 2: Risk assessment of individual injectable medicine products prepared in clinical areas

Clinical area:	Directorate:	Hospital site:	Date:

Name and strength of prepared injectable product	Diluent	Final volume	Bag or syringe

	Risk factors	Description	✓
1	**Therapeutic risk**	Where there is a significant risk of patient harm if the injectable medicine is not used as intended.	
2	**Use of a concentrate**	Where further dilution (after reconstitution) is required before use, i.e. slow iv bolus not appropriate.	
3	**Complex calculation**	Any calculation with more than one step required for preparation and/or administration, e.g. microgram/kg/hour, dose unit conversion such as mg to mmol or % to mg.	
4	**Complex method**	More than five non-touch manipulations involved or others including syringe-to-syringe transfer, preparation of a burette, use of a filter.	
5	**Reconstitution of powder in a vial**	Where a dry powder has to be reconstituted with a liquid.	
6	**Use of a part vial or ampoule, or use of more than one vial or ampoule**	Examples: 5ml required from a 10ml vial or four x 5ml ampoules required for a single dose.	
7	**Use of a pump or syringe driver**	All pumps and syringe drivers require some element of calculation and therefore have potential for error and should be included in the risk factors. However it is important to note that this potential risk is considered less significant than the risks associated with not using a pump when indicated.	
8	**Use of non-standard giving set/device required**	Examples: light protected, low adsorption, in-line filter or air inlet.	
	Total number of product risk factors	Six or more risk factors = high-risk product (Red). Risk reduction strategies are required to minimise these risks. Three to five risk factors = moderate-risk product (Amber). Risk reduction strategies are recommended. One or two risk factors = lower-risk product (Green). Risk reduction strategies should be considered.	

Risk assessment undertaken by:	Name of pharmacist:	Name of clinical practitioner:

A summary of all high and moderate-risk injectable products should be completed for each clinical area. (See Proforma 3)

Proforma 3: Risk assessment summary for high and moderate-risk injectable medicines products

Name of clinical area	Directorate:	Date:

Risk factors															
Prepared injectable medicine	**Strength**	**Diluent**	**Final volume**	**Bag/syringe**	**Therapeutic risk**	**Use of concentrate**	**Complex calculation**	**Complex preparation**	**Reconstitute vial**	**Part/multiple container**	**Infusions pump or driver**	**Non-standard infusion set**	**Risk assessment score**	**Risk reduction method(s)**	**Revised score**
					✓	✓	✓	✓	✓	✓	✓	✓			

Risk assessment undertaken by:	Name of pharmacist:	Name of clinical practitioner:

Appendix E. Implementation experience questionnaire

The complete **Implementation Experience Questionnaire** used in the High 5s Project was 19 pages long and, as such, impractical for general implementation of the SOP. However, a "short version" Implementation Experience Questionnaire was developed by the French High 5s Lead Technical Agency and its participating hospitals. It has been translated to English and can be used as a means for tracking the implementation experience efficiently and with minimal resource requirements. The abbreviated format can be used for eliciting either written (questionnaire) or oral (interview) responses.

Implementation experience questionnaire (Short version)

"Track the improvement and be ready to act"

We suggest this short questionnaire to help the project team adjust its actions and project plan, and track the project's improvement.

Which units are currently included in the High 5s SOP implementation?

Do we need to plan any actions to improve or maintain this situation?

What communication has been done on the project? Inside the hospital (patients /professionals/management) and outside the hospital (local/national/international)?

Do we need to plan any actions to improve or maintain this situation

What successes did we obtain in the last 3 (or 6) months in the High 5s implementation?

What barriers are we (still) encountering in the High 5s implementation?

Do we need to plan any actions to improve/maintain High 5s implementation?

Did the results (indicators, observational audits, success stories…) of our hospitals correspond to our objectives?

What do we decide to do to improve our results?

What objectives do we set for the next 3 (or 6) months?

Have we noticed any positive/negative impact of the project in the last 3 (or 6) months?

For example: patient safety, patients' experience, organization, culture, institution…

How are we going to share and use the lessons learned?

Appendix F. Template for conducting interviews with staff

High 5s Lead Technical Agency Interview Summary		
Motivations	Why did you decide to participate in the High 5s project? What did you expect the benefits of implementing and sustaining the SOP would be to your organization?	
Resources	What resources did you foresee being need to implement and sustain the SOP? What resources were actually required to implement and sustain the SOP? Were the resources readily available? What additional resources were needed in order to implement and sustain the SOP?	
Organization	What adaptations to your environment, organizational culture or current processes were required to implement and sustain the SOP? If adaptations were made to implement the SOP, why were such adaptations necessary?	
Barriers	What barriers to implementation did you encounter? How did you address them?	
Impact	Were there unintended consequences as a result of the implementation of the SOP? How did you address them? What impact did the SOP have on patient safety at your organization? {insert something about performance measures} Were there any events potentially or actually related to the SOP for which an event analysis was required? If yes, did the hospital complete an analysis for each one? Were the event analyses performed concise or comprehensive or a combination of these approaches? Did specific recommendations arise from these analyses? If so, Were the recommendations fully implemented? Was there actual evidence of resulting improvement in patient care? If an event analysis was not done, why?	

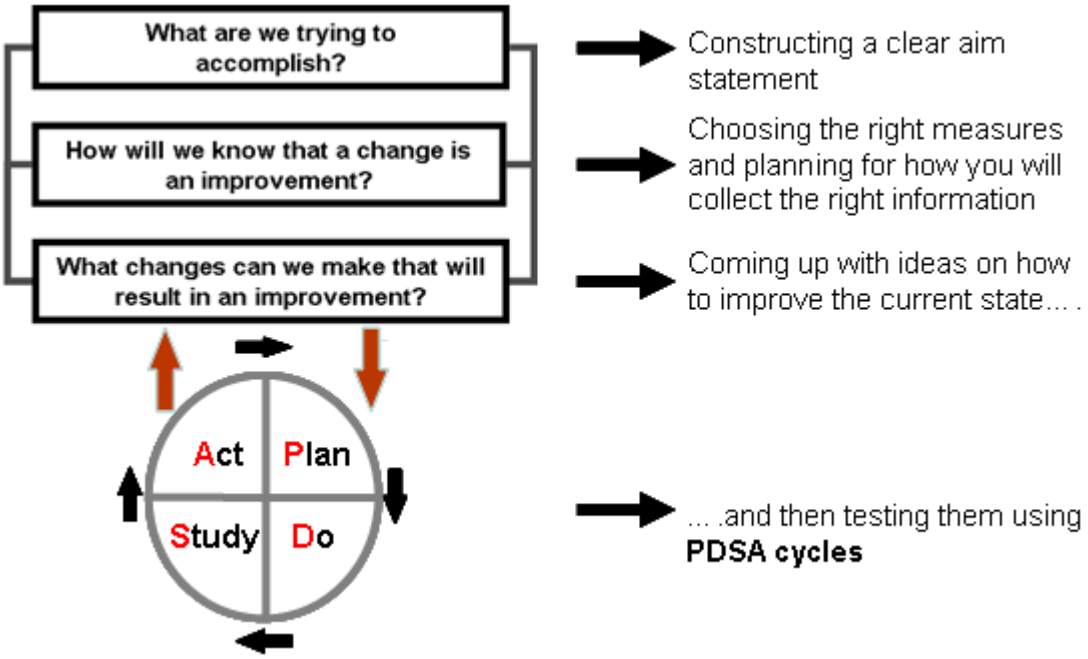
Considerations for future sustainability	What key lessons were learned that will facilitate the dissemination and implementation of the SOP in other settings? What is your impression of the SOP implementation process? Include positive and negative perceptions. Do you believe implementation of the SOP is sustainable in your organization? Would you recommend implementation of this SOP to other hospitals? Why or why not? If yes, what advice would you provide to the other hospitals? Is your organization going to continue carrying out this SOP?	

Appendix G. Measuring for quality improvement

How to measure for improvement - The Model for Improvement

The basis of measurement for improvement falls naturally out of the Model for Improvement developed by Associates for Process Improvement, USA, (available at www.apiweb.org). It provides a framework around which to structure improvement activity to ensure the best chance of achieving goals and wider adoption of ideas.

Figure G 1 The Model for Improvement



The answers to the three questions are provided within this SOP. But it is recommended that a pilot is done on how the SOP works in the hospital through using Plan-Do-Study-Act (PDSA) cycles.[13]

Small tests of changes that will have an impact on the rate of harm need to be measured well. This part of the model is shown in an iterative way as improvements / measures do not always work first time. The testing process not only tells how well the changes are working but how good the measure and its collection process is. Following a test it may be evident that the method of sampling or data collection needs refining.

Implementing changes takes time and money so it's important to test changes and measures on a small scale first because:

---

[13]The PDSA cycle guides the test of a change to determine if the change is an improvement. For more information on PDSA cycles go to www.ihi.org/resources/Pages/HowtoImprove/ScienceofImprovementHowtoImprove.aspx

- It involves less time, money and risk
- The process is a powerful tool for learning which ones work and which ones don't. How many questionnaires or an audit forms have been designed that didn't give the information needed? This may have been because the information that was requested wasn't quite right, the way people interpreted the questions or simply that the form itself wasn't clear enough for a person to complete without guidance
- It is safer and less disruptive for patients and staff. There can be an idea of the impact on a small scale first and work to smooth out the problems before spreading the changes more widely
- Where people have been involved in testing and developing the ideas, there is often less resistance.

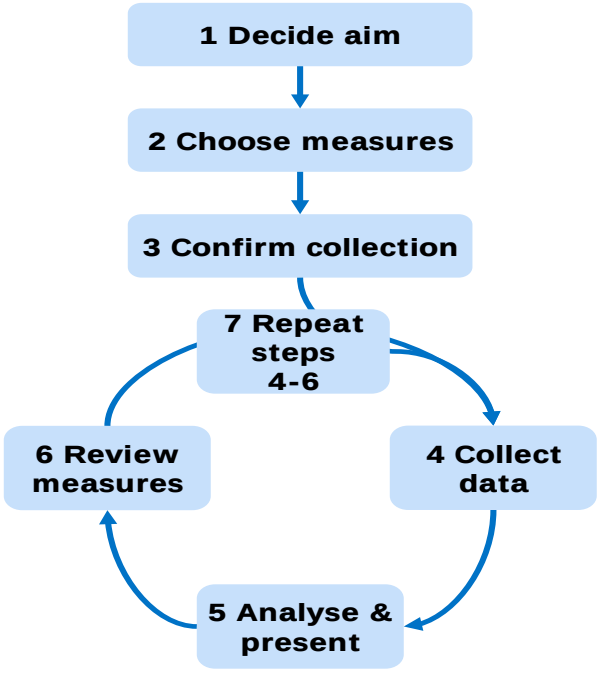
Measurement for safety improvement does not have to be complicated. Tracking a few measures over time and presenting the information well is fundamental to developing a change that works well and can be spread.

Measurement can show a number of important pieces of information:

- How well the current process is performing;
- Whether an aim has been reached;
- How much variation is in the data/process;
- Whether a small test change is going in the correct direction;
- Whether the changes have resulted in an improvement; and
- Whether a change has been sustained.

There are seven steps to measuring for improvement. These are outlined in Figure G 2.

Figure G 2 Seven steps to measuring safety improvement



Step 1 – Decide on the aim

For this SOP, the aim is already set. In simple terms the aim is to implement the CIM SOP and minimize the storage and use of concentrated injectable medicine products in clinical units.

Step 2 – Choose measures - What are the core measures ?

These measures have already been selected. See table G 1 below and section 9 for further information. Details of the data elements to be collected are provided in the Appendices G and H.

Hospitals may chose to include additional measures if there are specific aspects of the SOP implementation that need to be tracked in the hospital.

Table G 1 Core performance measures for CIM SOP

Type of Measure	Description of Core Measures
Process	CI-P1 Concentrated injectable medicines stored in unauthorized clinical areas CI-P2 Concentrated injectable medicines supplied to unauthorized clinical areas CI-P3 Ready-to-administer and ready-to-use injectable medicines supplied to unauthorized clinical areas CI-P4 Prevalence of clinical units storing concentrated injectable medicines
Outcome	CI-O1 Time between concentrated injectable adverse events (due to administration of drug or antidote) CI-O2 Time between adverse events resulting from delay or omission of administration of injectable medicines CI-O3 The number of adverse events for specified concentrated injectables per 1000 patient days

Refer to section 9 for further information on the performance measures.

Designating authorized areas

Prior to gathering the data it will be necessary to make a list of each unit in the hospital and determine whether it is authorized to store concentrated injectable medicines. The stakeholder group could be very helpful in

establishing criteria for allowing an area to be authorized. Remember, concentrated injectables should never be stored on a patient unit merely for convenience. This list will serve as a reference throughout data gathering.

A decision should be made as well as to what will be done with concentrated injectable medicines found in unauthorized areas or stored incorrectly in authorized areas. Will the observer remove them? Who will the observer report this to?

Step 3 Confirm how data will be collected

Who should collect the data?

Appoint one or more independent observer(s) to collect the data who is:

- Able to verbalise the meaning of the data elements they are collecting;
- Familiar with the clinical areas;
- Knowledgeable about where concentrated injectables might be stored in those areas;
- Understands what proper storage entails for those area authorised to store concentrated injectable medicines; and
- Able to identify concentrated injectable medicines.

The individual should be a pharmacist or other clinician not responsible for routine operations in the clinical area under review.

For the P (process) measures, a ward/clinical pharmacist or other designated member of staff from the pharmacy department such as a pharmacy technician/assistant would be appropriate.. For the O (outcome) measures, the project lead, risk manager or other similar member of staff, not working in the area, may be the best person to collect the data.

How is the data collected?

Plan how to collect, analyse and review data. For example, for measures CI P1 and CI P4, decide if the ward pharmacist/technician will collect the data by checking the numbers of the three concentrated injectable medicines on the ward on the first Monday of the month (or other suitable day). Reflect how data can be presented in a way that helps the project team and stakeholders understand progress, for example, using a simple run chart. The Measures Project Checklist template in Appendix H has been provided to assist with the planning.

Data collection sheets for the three concentrated injectable medicines in the SOP are provided in appendix H. There are three forms.

Measure	**Form**
CI P1, CI P4	Storage of concentrated injectable products in unauthorised areas
CI P2. CI P3	Concentrated injectable medicines supplied to unauthorised areas

CI O1, O2, O3	Adverse drug events: concentrated injectable medicines

Process measures P1 and P4 can be collected at the same time. Data should be collected on all clinical units including the pharmacy. The observer will visit all units and look for concentrated injectables where medications are routinely stored and other areas in the unit where they might be kept. They will need to know beforehand what concentrated injectable medicines, if any, the area is authorized to stock. Once on the unit, the observer will document if any concentrated injectable medicines were found and if found, whether they were stored according to the SOP directions. This information is on the bottom of the data collection sheet for easy access. See Appendix H for data collection forms. The observer ticks the appropriate box on the form.

Process measures CI P2 and CI P3 are collected in the pharmacy. The observer can extract information from the pharmacy records, or, the pharmacy can complete the data collection sheets concurrently.

The outcome measures will be collected in conjunction with adverse reporting systems within the organization. All events should be reported for this measure independent of whether they caused harm or were the subject of event analysis such as Root Cause analysis.

Step 4 – Collect baseline data

Use the data collection forms in Appendix H to collect baseline line data. This should be done before introducing the new CIM SOP process..

Step 5 – Analyse and present data

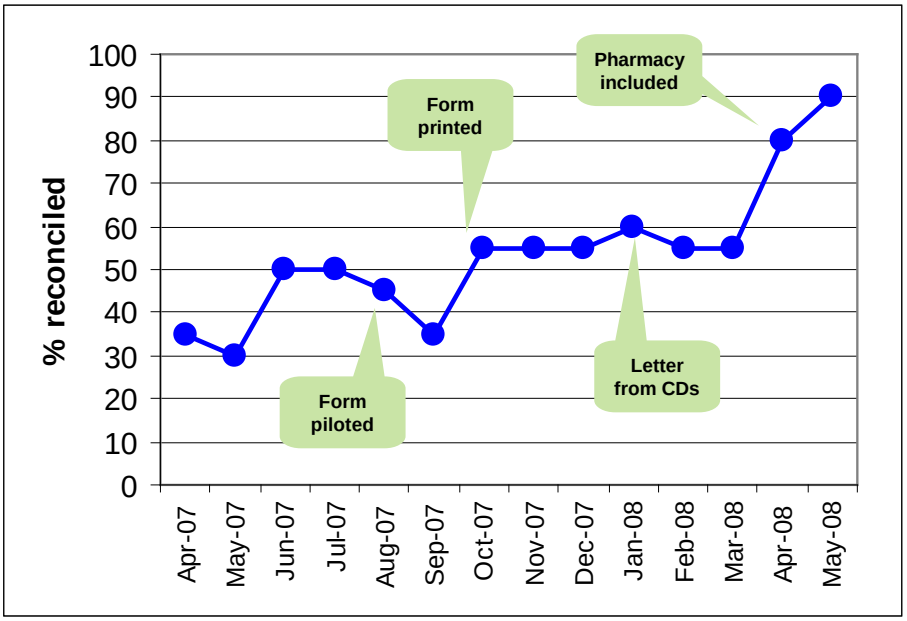
A spreadsheet tool has been developed to help analyse and present combined data. Data collection forms for all the core measures are provided in Appendix H at the end of this toolkit. Hospital may prefer to develop their own data collection tools or systems.

Presenting the data

The way collected data is analysed and presented is important. **Run charts** are a good way to show how much variation there is in the process over time. Also, plotting data over time is a simple and effective way to determine whether the changes that have been made are leading to improvement.

Figure G 3 shows the percentage of medicines reconciled on a medical admissions unit over a 12 month period following the implementation of a medication reconciliation process. It has also been annotated with the dates that specific changes were tested or introduced to the medicines reconciliation process on the ward.

Figure G 3 Run chart of percentage of medicines reconciled



In the first few months, the percentage reconciled varied between 30% and 50%. Once a new form was introduced in October 2007, performance rose slightly and seemed to stabilise at 55%. The letter from the Clinical Director (CD) does not seem to have had much effect whereas the inclusion of pharmacy in the process had a more obvious one. It is too early to tell from this data whether the improvement is permanent, several more months of data showing 90% would be needed to be confident about that. Nevertheless the run chart shows clearly which interventions had an impact and which ones didn't. This is important to know to avoid spending time and energy pursuing something that is not helping.

One more thing that would help in using this chart is the addition of a goal or target line that represents where the team is trying to get to. Keeping the *goal line* on every graph ensures everyone viewing the graph can see at a glance where the work is at in relation to achieving the aim.

Knowing whether changes are an improvement

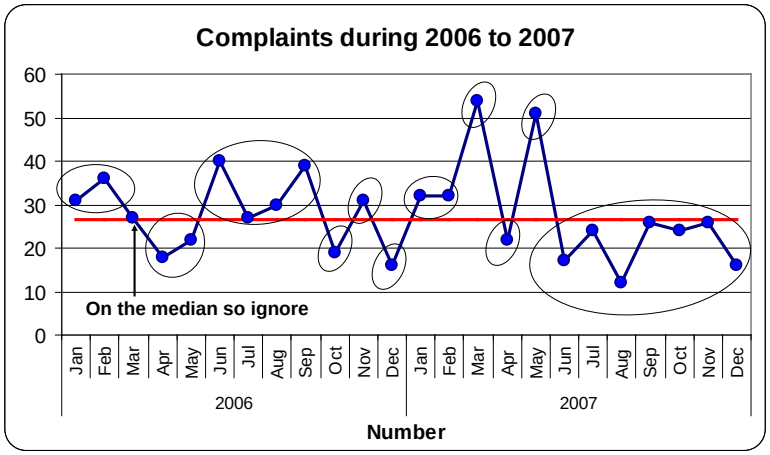
As can be seen from the previous example graphs may go up and down but it is important to know whether this is just random chance or the result of a real change. There are 4 tests that can be applied to run charts to help identify what's happening after change is made and therefore determine whether it is really an improvement. Two of the tests make use of the median value of the data and also the concept of a 'run'. The median is simply the middle value of all values if they were arranged in order. If own charts are created, the median should be calculated and plotted on the chart. A 'run' is a consecutive series of points that are above the median or below it. Count them up by circling the runs as in the example below. Note that any points that fall on the median should be ignored.

The tests are:

- **Test 1**: Six or more consecutive points above or below the median. This indicates a shift in the process. Values are still varying but they are doing so around a new median or average value. If this is a shift in the right direction, it is likely that the change made is having a beneficial effect. This is the most frequent type of change in the data.
- **Test 2**: Five or more consecutive points all increasing or decreasing. This indicates a trend and suggests that the change made is having an effect but it is not known yet where performance will become stable again. It is needed to keep measuring to find out. This situation is more likely to occur if a change is rolled out over a period of time.
- **Test 3**: Too many or too few 'runs'. If the number of 'runs' is inside the range this is what might be expected by chance. If the number falls outside the range then some external factor is having an effect. Too many runs suggests the process has become less consistent and it is possible that the change has had a detrimental effect. Too few runs suggests a more consistent process.
- **Test 4**: An "astronomical" data point, or outlier. Use own judgement to assess whether the value in question really is 'odd'. Often such outliers are caused by data collection or data definition problems so check that first. If the data seems OK then try to find out what might have caused such an odd result. Think about creating a contingency plan for such an occasion if it arose again.

Step 6 – Review the data to decide what it is telling

It is vital that time is set aside to look at what the measures are telling. This can be incorporated into the oversight group meeting. Remember that the purpose of measurement is to lead to making the right decisions about the improvement project.



Step 7 – Keep going!

Repeat steps 4, 5 and 6 each month or more frequently until the aims have been achieved. Refer to Table 1 Differences between the performance measures in Section 9.

- Concentrated injectable medicines are stored in unauthorized clinical areas (decrease in rate: goal 0%);
- Concentrated injectable medicines are supplied to unauthorized clinical areas (decrease in rate);
- Ready-to-administer and ready-to-use injectable medicines supplied to unauthorized clinical areas (increase in rate: goal 100%); and
- Number of clinical areas storing concentrated injectable medicines according to selected SOP specification.

Once the measures indicate that the aim has been achieved and the process is sustained for at least 3 repeated measures then the oversight group can determine how often the measures should continue to be monitored (e.g. once or twice a year to audit the process of safe management of CIM SOP).

Appendix H: Performance measures forms and calculation templates

1. Measures process checklist
2. Data collection forms
3. Calculation Templates for Managing Concentrated Injectable Medicines

1. Measures Process Checklist

Collect	Is the data available? *Currently available / Available with minor changes / Prospective collection needed*
	Who is responsible for data collection?
	What is the process of collection?
Analyse *Calculate measure and present results*	What is the process for presenting results? *E.g. create run chart in Excel*
	Who is responsible for the analysis?
	How often is the analysis completed?
Review	Where will decisions be made based on results?
	Who is responsible for taking action?

2. Data collection forms:

Adverse Drug Events: Concentrated Injectable Medications

(Both concentrated or ready diluted products)

Set Measure ID: H5sCI-O1, O2 and O3

Page Number: _____ of _____

Please enter date of event and tick the appropriate medicine and type of harm caused

	Injectable medicine			Type of harm							Did this result from a delay or ommission of administration of the injectable medication? (Box 2)
Date of event (Box 1)	Morphine >16mg/ml	Heparin>1,000 units/ml	Potassium >0.04mmol/ml	Death	Severe Permanent Harm	Permanent Harm	Temporary Harm	Additional Treatment	Emotional Distress or Inconvenience	No Harm	
											☐ Yes ☐ No
											☐ Yes ☐ No
											☐ Yes ☐ No
											☐ Yes ☐ No
											☐ Yes ☐ No
											☐ Yes ☐ No
											☐ Yes ☐ No
											☐ Yes ☐ No
Totals (Box 3) –>											

Type of Harm

Instructions on how to use Type of Harm scale

1. Death
2. Severe Permanent Harm: Severe life-long bodily or psychological injury or disfigurement that interferes significantly with functional ability or quality of life.
3. Permanent Harm: Life-long bodily or psychological injury or increased susceptibility to disease.
4. Temporary Harm: Bodily or psychological injury, but likely not permanent.
5. Additional Treatment: Injury limited to additional intervention during admission or encounter and/or increased length of stay, but no other injury.
6. Emotional distress or inconvenience: Mild and transient anxiety or pain or physical discomfort, but without the need for additional treatment other than monitoring (such as by observation, physical examination, laboratory testing, including phlebotomy, and/or imaging studies).
7. No Harm

Storage of Concentrated Injectable Products in Unauthorised Areas

Set Measure ID: H5sCI-P1 and P4

Date of Audit: Audit Performed by: Page Number ______ of ________

Supply Period (month and dates):

Column 1	Column 2	Column 3	Column 4	Column 5	Column 6	Column 7	Column 8	Column 9	Column 10
	Is this area authorised to store concentrated injectables?			Were concentrated injectable products found ?			Were all concentrated injectables stored correctly according to the SOP? (answer n/a if none found)		
Name of Clinical Area	**Morphine >15mg/ml**	**Heparin>1,000units/ml**	**Potassium >0.04mmol/ml**	**Morphine >15mg/ml**	**Heparin>1,000 units/ml**	**Potassium >0.04mmol/ml**	**Morphine >15mg/ml**	**Heparin>1,000 units/ml**	**Potassium >0.04mmol/ml**
	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No ☐ N/A	☐ Yes ☐ No ☐ N/A	☐ Yes ☐ No ☐ N/A
	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No ☐ N/A	☐ Yes ☐ No ☐ N/A	☐ Yes ☐ No ☐ N/A
	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No ☐ N/A	☐ Yes ☐ No ☐ N/A	☐ Yes ☐ No ☐ N/A
	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No ☐ N/A	☐ Yes ☐ No ☐ N/A	☐ Yes ☐ No ☐ N/A
	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No ☐ N/A	☐ Yes ☐ No ☐ N/A	☐ Yes ☐ No ☐ N/A
	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No ☐ N/A	☐ Yes ☐ No ☐ N/A	☐ Yes ☐ No ☐ N/A
	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No ☐ N/A	☐ Yes ☐ No ☐ N/A	☐ Yes ☐ No ☐ N/A
	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No ☐ N/A	☐ Yes ☐ No ☐ N/A	☐ Yes ☐ No ☐ N/A
	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No ☐ N/A	☐ Yes ☐ No ☐ N/A	☐ Yes ☐ No ☐ N/A
	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No ☐ N/A	☐ Yes ☐ No ☐ N/A	☐ Yes ☐ No ☐ N/A
	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No ☐ N/A	☐ Yes ☐ No ☐ N/A	☐ Yes ☐ No ☐ N/A
Total number indicated as YES per column	A	B	C	G	H	I	J	K	L
Total number indicated as NO per column	D	E	F						
From the subset of <u>unauthorised clinical areas</u> (in columns 2, 3 or 4), count only the number of <u>unauthorised clinical areas</u> in which concentrated injectables were found (in columns 5, 6, or 7)				M	N	O			

Correct Storage means that all of the following conditions are met:

Stored concentrated injectables segregated from other drugs

A prominent warning label is affixed to each unit of the concentrated injectable medicine.

Essential clinical and technical information regarding the preparation and administration is posted and accessible to staff

Dose calculation tools are readily available

Concentrated Injectable Medications Supplied to Unauthorised Areas

Set Measure ID: H5sCI-P2 and P3

Date of Audit: Audit Performed by: Page Number: _____ of _____

Supply Period (month and dates):

Column 1	Column 2	Column 3	Column 4	Column 5	Column 6	Column 7	Column 8	Column 9	Column 10
	Is this area authorised to store concentrated injectables?			The total number of ampoules, vials, prefilled syringes and infusions supplied as a concentrated injectable medicine as stock, non-stock, emergency or a named patient supply.			The total number of ampoules, vials, prefilled syringes and infusions supplied as ready-to-administer injectables		
Name of Clinical Area	Morphine >15mg/ml	Heparin>1,000units/ml	Potassium >0.04mmol/ml	Morphine >15mg/ml	Heparin>1,000 units/ml	Potassium >0.04mmol/ml	Morphine ≤ 15mg/ml	Heparin ≤1,000 units/ml	Potassium < 0.04mmol/ml
	□ Yes □ No	□ Yes □ No	□ Yes □ No						
	□ Yes □ No	□ Yes □ No	□ Yes □ No						
	□ Yes □ No	□ Yes □ No	□ Yes □ No						
	□ Yes □ No	□ Yes □ No	□ Yes □ No						
	□ Yes □ No	□ Yes □ No	□ Yes □ No						
	□ Yes □ No	□ Yes □ No	□ Yes □ No						
	□ Yes □ No	□ Yes □ No	□ Yes □ No						
	□ Yes □ No	□ Yes □ No	□ Yes □ No						
	□ Yes □ No	□ Yes □ No	□ Yes □ No						
	□ Yes □ No	□ Yes □ No	□ Yes □ No						
	□ Yes □ No	□ Yes □ No	□ Yes □ No						
Total number indicated as NO per column	A	B	C						
From the subset of <u>unauthorised clinical areas</u> (in columns 2, 3 or 4), count only the number of <u>unauthorised clinical areas</u> in which concentrated injectables were found.				D	E	F	G	H	I

3. Calculation Templates for Managing Concentrated Injectable Medicines

The Calculation Sheets are used to aggregate data for reporting. Data in the labeled areas (e.g., "Area O1a") were entered into the High 5's Information Management System during the High 5s Project only (see screen print on final page to view the system and how to use the calculations).

High 5s Concentrated Injectables(H5sCI) Calculation Sheet

Set Measure ID: H5sCI-O1

Performance Measure Name: Time between concentrated injectable adverse events

Collected From: Adverse Drug Events Worksheet

Date of Event (collected from Box 1 on of the "Adverse Drug Events" worksheet) and list them here for the particular month.	Days since last event (you may need to look at last months date)
1	
2	
3	
4	
5	
6	
7	
8	
9	
10	
All days between events added together:	

Area O1

The Number of Events = _____ (Area O1a)

(count of events this month)

All days between events added together† = _____

CI-01 Continuous Variable Data Element for Transmission

All days between events† = _____ (Area O1b)

The Number of Events

Please note: The first event for data collection is day 0 and the count begins there. Any date of event is counted as a day. For example, if the first event happens on Jan.1 and the second event on Jan. 10, 9 days have passed between events. If another event happens on Jan. 20, another 10 days have passed. If two events happen on the same day, 0 days have passed between them.

† Instructions for calculating "All days between events"

1. If the "Number of Events" = 0 for the month, leave the "All days between events" field blank.
2. If "Number of Events" = 1, AND this is the first event identified during the High 5s project, then leave the "All days between events" field blank (it is not possible to calculate the "days between events" without a previous event).
3. If the "Number of Events" = 1, AND this is NOT the first event of the project, then please calculate the number of days between this event and the event immediately preceding it (even if the initial event occurred in a previous month or year).
4. If the "Number of Events" = 2 or more, calculate the number of days between the first event and the event immediately preceding it (even if the event occurred in a previous month or year). Then calculate the number of days between the first event and the second event. Do this for each additional event. Add the "All days between events" together. Divide this number by the total number of events and enter the value in area O1b.

Set Measure ID: H5sCI-O2

Performance Measure Name: Time between adverse drug events due to delay or omission of administration of injectable medicines

Collected From: Adverse Drug Events Worksheet

Date of Event only as a result of omission or delay (collect events that are checked yes in Box 2 of the "Adverse Drug Events" worksheet and list them here)	Days since last event (you may need to look at last months date)
1	
2	
3	
4	
5	
6	
7	
8	
9	
10	
All days between events added together:	

Area O2

The Number of Events = _____ (Area O2a)

(count of events this month)

All days between events added together† = _____

CI-02 Continuous Variable Data Element for Transmission

All days between events† = _____ (Area O2b)

The Number of Events

Please note: The first event for data collection is day 0 and the count begins there. Any date of event is counted as a day. For example, if the first event happens on Jan.1 and the second event on Jan. 10, 9 days have passed between events. If another event happens on Jan. 20, another 10 days have passed. If two events happen on the same day, 0 days have passed between them.

† Instructions for calculating "All days between events"

1. If the "Number of Events" = 0 for the month, leave the "All days between events" field blank.
2. If "Number of Events" = 1, AND this is the first event identified during the High 5s project, then leave the "All days between events" field blank (it is not possible to calculate the "days between events" without a previous event).
3. If the "Number of Events" = 1, AND this is NOT the first event of the project, then please calculate the number of days between this event and the event immediately preceding it (even if the initial event occurred in a previous month or year).
4. If the "Number of Events" = 2 or more, calculate the number of days between the first event and the event immediately preceding it (even if the event occurred in a previous month or year). Then calculate the number of days between the first event and the second event. Do this for each additional event. Add the "All days between events" together. Divide this number by the total number of events and enter the value in area O1b.

Set Measure ID: H5sCI-O3

Performance Measure Name: The number of adverse events for specified concentrated injectables per 1000 patient days

Collected From: Adverse Drug Events Worksheet

Abstractors may use one of 2 methods for calculating patient days:

1. Midnight Census - This is accurate for units that have all inpatient admissions. It is the least accurate method for units that have both in-patient and short stay patients. The daily number should be summed for every day in the month

2. Midnight Census + Patient Days from Actual Hours for Short Stay Patients - This is an accurate method of units that have both in-patient and short stay patients. The total daily hours for short stay patients should be summed for the month and divided by 24 which will give you a number of days. Add this number of days to the midnight census to get the full patient days.

Month :

Day	Census – Midnight	Census – Short Stay (total daily hours)
1		
2		
3		
4		
5		
6		
7		
8		
9		
10		
11		
12		
13		
14		
15		
16		
17		
18		
19		
20		
21		
22		
23		
24		
25		
26		
27		
28		
29		
30		
31		
Total	(A)	(B)

Area O3

The number of adverse events associated with administration of concentrated injectables (total the number of adverse events identified under all three injectable medicines in area 3 of the "Adverse Drug Events" worksheet) = _____ (Area O3a)

AND

If using only Midnight Census:
The number of patient days for the calendar month from the midnight census (Total of Box A) = _____ (Area O3b)

OR

If using Midnight Census and Patient Days from Actual Hours for Short Stay Patients:
Divide the Total hours from census – short stay (Total of box B) by 24 hours = _____
Add the number above to the number of days for the calendar month from the midnight census (Total of Box A)

$$\frac{\text{Total of Box B}}{24} + \text{Total of Box A} = \_\_\_\_\_ \text{ (Area O3b)}$$

CI-03 Continuous Variable Data Element for Transmission

$$\frac{\text{The Number of Events}}{\text{Total Number of Patient Days}} = \frac{\text{(Area O3a)}}{\text{(Area O3b)}} = \_\_\_\_\_$$

Multiply by 1000 to get the number of events per 1000 patient days

Set Measure ID: H5sCI-P1

Performance Measure Name: Concentrated injectable medicines stored in unauthorized clinical areas

Collected From: **Storage** of Concentrated Injectable Products in Unauthorised Areas Worksheet
(Please take care to select the correct total from each of the three concentrated injectable medications listed)

Area P1

Element	Total
CI-P1a Numerator Data Element for Transmission The number of unauthorized clinical areas storing ampoules, vials, prefilled syringes and infusions of concentrated injectable Morphine (From the worksheet, for only those areas that were unauthorized to store concentrated injectable products, count the total number of unauthorized areas in which such products were found – The total found in Box M)	(Area P1a)
CI-P1a Denominator Data Element for Transmission The number of clinical areas unauthorized to store Morphine >15mg/ml (The total reflected in Box D of the form)	(Area P1a-1)
CI-P1b Numerator Data Element for Transmission The number of unauthorized clinical areas storing ampoules, vials, prefilled syringes and infusions of concentrated injectable unfractionated heparin > 1,000units/ml (From the worksheet, for only those areas that were unauthorized to store concentrated injectable products, count the total number of unauthorized areas in which such products were found – The total found in Box N)	(Area P1b)
CI-P1b Denominator Data Element for Transmission The number of clinical areas unauthorized to store Heparin > 1,000units/ml in which heparin was found (The total reflected in Box E of the form)	(Area P1b-1)
CI-P1c Numerator Data Element for Transmission The number of unauthorized clinical areas storing ampoules, vials, prefilled syringes and infusions of concentrated injectable potassium chloride (From the worksheet, for only those areas that were unauthorized to store concentrated injectable products, count the total number of unauthorized areas in which such products were found – The total found in Box O)	(Area P1c)
CI-P1c Denominator Data Element for Transmission The number of clinical areas unauthorized to store Potassium >0.04mmol/ml in which potassium was found (The total reflected in Box F of the form)	(Area P1c-1)

Set Measure ID: H5sCI-P2

Performance Measure Name: Concentrated injectable medicines supplied to unauthorized clinical areas

Collected From: Concentrated Injectable Medicines **Supplied** to Unauthorised Areas Worksheet

(Please take care to select the correct total from each of the three concentrated injectable medications listed)

Area P2

Element	Total
CI-P2a Numerator Data Element for Transmission The number of ampoules, vials, prefilled syringes and infusions of Morphine supplied as a concentrated injectable to unauthorized clinical areas. (Add together the total number of containers supplied to unauthorized areas – Total from Box D)	(Area P2a)
CI-P2a Denominator Data Element for Transmission The number of unauthorized clinical areas (The total reflected in Box A of the form)	(Same as Area P1a-1)
CI-P2b Numerator Data Element for Transmission The number of ampoules, vials, prefilled syringes and infusions of Unfractionated Heparin supplied as a concentrated injectable to unauthorized clinical areas. (Add together the total number of containers supplied to unauthorized areas – Total from Box E)	(Area P2b)
CI-P2b Denominator Data Element for Transmission The number of unauthorized clinical areas (The total reflected in Box B of the form)	(Same as Area P1b-1)
CI-P2c Numerator Data Element for Transmission The number of ampoules, vials, prefilled syringes and infusions of Potassium supplied as a concentrated injectable to unauthorized clinical areas. (Add together the total number of containers supplied to unauthorized areas – Total from Box F)	(Area P2c)
CI-P2c Denominator Data Element for Transmission The number of unauthorized clinical areas (The total reflected in Box C of the form)	(Same as Area P1c-1)

Set Measure ID: H5sCI-P3

Performance Measure Name: Ready-to-administer and ready-to-use injectable medicines supplied to unauthorized clinical areas

Collected From: Concentrated Injectable Medicines **Supplied** to Unauthorised Areas Worksheet *(Please take care to select the correct total from each of the three concentrated injectable medications listed)*

Element	Total
CI-P3a Numerator Data Element for Transmission The number of ampoules, vials, prefilled syringes and infusions of morphine supplied as a ready-to-administer and ready-to-use medicine to unauthorized clinical areas. (The total is calculated by adding the total number of ampoules, vials, prefilled syringes and infusions supplied to areas not authorized to store Morphine – Total from Box G)	(Area P3a)
CI-P3a Denominator Data Element for Transmission The number of unauthorized clinical areas (The total reflected in Box A of the form)	(Same as Area P1a-1)
CI-P3b Numerator Data Element for Transmission The number of ampoules, vials, prefilled syringes and infusions of Unfractionated Heparin supplied as a ready-to-administer and ready-to-use medicine to unauthorized clinical areas. (The total is calculated by adding the total number of ampoules, vials, prefilled syringes and infusions supplied to areas not authorized to store Unfractionated Heparin– Total from Box H)	(Area P3b)
CI-P3b Denominator Data Element for Transmission The number of unauthorized clinical areas (The total reflected in Box B of the form)	(Same as Area P1b-1)
CI-P3c Numerator Data Element for Transmission The number of ampoules, vials, prefilled syringes and infusions of Potassium supplied as a ready-to-administer and ready-to-use medicine to unauthorized clinical areas. (The total is calculated by adding the total number of ampoules, vials, prefilled syringes and infusions supplied to areas not authorized to store Potassium– Total from Box I)	(Area P3c)
CI-P3c Denominator Data Element for Transmission The number of unauthorized clinical areas (The total reflected in Box C of the form)	(Same as Area P1c-1)

Set Measure ID: H5sCI-P4

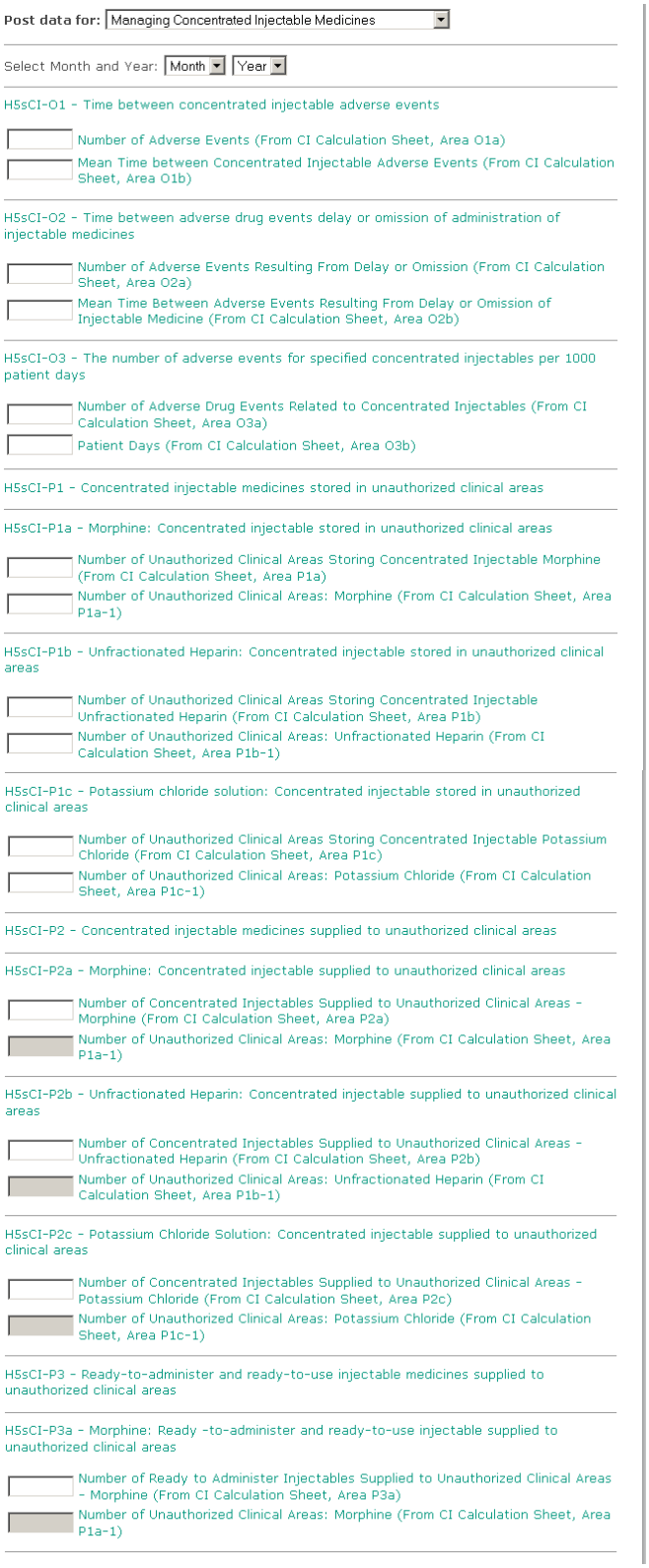
Performance Measure Name: The number of clinical areas storing concentrated injectable medicines according to selected SOP specifications.

Collected From: **Storage** of Concentrated Injectable Products in Unauthorised Areas Worksheet

(Please take care to select the correct total from each of the three concentrated injectable medications listed)

Element	Total
CI-P4a Numerator Data Element for Transmission The number of clinical areas storing concentrated injectable Morphine according to selected SOP specifications (The total reflected in Box J of the form)	(Area P4a)
CI-P4a Denominator Data Element for Transmission The number of clinical areas storing concentrated injectable Morphine (The total reflected in Box G of the form)	(Area P4a-1)
CI-P4b Numerator Data Element for Transmission The number of clinical areas storing concentrated injectable Unfractionated Heparin according to selected SOP specifications (The total reflected in Box K of the form)	(Area P4b)
CI-P4b Denominator Data Element for Transmission The number of clinical areas storing concentrated injectable Unfractionated Heparin (The total reflected in Box H of the form)	(Area P4b-1)
CI-P4c Numerator Data Element for Transmission The number of clinical areas storing concentrated injectable Potassium according to selected SOP specifications (The total reflected in Box L of the form)	(Area P4c)
CI-P4c Denominator Data Element for Transmission The number of clinical areas storing concentrated injectable Potassium (The total reflected in Box I of the form)	(Area P4c-1)

Example of Web-Based Data Entry Form-High 5 Project's Information Management System [Screen Prints]



Post data for: Managing Concentrated Injectable Medicines

Select Month and Year: Month Year

H5sCI-O1 - Time between concentrated injectable adverse events

Number of Adverse Events (From CI Calculation Sheet, Area O1a)

Mean Time between Concentrated Injectable Adverse Events (From CI Calculation Sheet, Area O1b)

H5sCI-O2 - Time between adverse drug events delay or omission of administration of injectable medicines

Number of Adverse Events Resulting From Delay or Omission (From CI Calculation Sheet, Area O2a)

Mean Time Between Adverse Events Resulting From Delay or Omission of Injectable Medicine (From CI Calculation Sheet, Area O2b)

H5sCI-O3 - The number of adverse events for specified concentrated injectables per 1000 patient days

Number of Adverse Drug Events Related to Concentrated Injectables (From CI Calculation Sheet, Area O3a)

Patient Days (From CI Calculation Sheet, Area O3b)

H5sCI-P1 - Concentrated injectable medicines stored in unauthorized clinical areas

H5sCI-P1a - Morphine: Concentrated injectable stored in unauthorized clinical areas

Number of Unauthorized Clinical Areas Storing Concentrated Injectable Morphine (From CI Calculation Sheet, Area P1a)

Number of Unauthorized Clinical Areas: Morphine (From CI Calculation Sheet, Area P1a-1)

H5sCI-P1b - Unfractionated Heparin: Concentrated injectable stored in unauthorized clinical areas

Number of Unauthorized Clinical Areas Storing Concentrated Injectable Unfractionated Heparin (From CI Calculation Sheet, Area P1b)

Number of Unauthorized Clinical Areas: Unfractionated Heparin (From CI Calculation Sheet, Area P1b-1)

H5sCI-P1c - Potassium chloride solution: Concentrated injectable stored in unauthorized clinical areas

Number of Unauthorized Clinical Areas Storing Concentrated Injectable Potassium Chloride (From CI Calculation Sheet, Area P1c)

Number of Unauthorized Clinical Areas: Potassium Chloride (From CI Calculation Sheet, Area P1c-1)

H5sCI-P2 - Concentrated injectable medicines supplied to unauthorized clinical areas

H5sCI-P2a - Morphine: Concentrated injectable supplied to unauthorized clinical areas

Number of Concentrated Injectables Supplied to Unauthorized Clinical Areas - Morphine (From CI Calculation Sheet, Area P2a)

Number of Unauthorized Clinical Areas: Morphine (From CI Calculation Sheet, Area P1a-1)

H5sCI-P2b - Unfractionated Heparin: Concentrated injectable supplied to unauthorized clinical areas

Number of Concentrated Injectables Supplied to Unauthorized Clinical Areas - Unfractionated Heparin (From CI Calculation Sheet, Area P2b)

Number of Unauthorized Clinical Areas: Unfractionated Heparin (From CI Calculation Sheet, Area P1b-1)

H5sCI-P2c - Potassium Chloride Solution: Concentrated injectable supplied to unauthorized clinical areas

Number of Concentrated Injectables Supplied to Unauthorized Clinical Areas - Potassium Chloride (From CI Calculation Sheet, Area P2c)

Number of Unauthorized Clinical Areas: Potassium Chloride (From CI Calculation Sheet, Area P1c-1)

H5sCI-P3 - Ready-to-administer and ready-to-use injectable medicines supplied to unauthorized clinical areas

H5sCI-P3a - Morphine: Ready -to-administer and ready-to-use injectable supplied to unauthorized clinical areas

Number of Ready to Administer Injectables Supplied to Unauthorized Clinical Areas - Morphine (From CI Calculation Sheet, Area P3a)

Number of Unauthorized Clinical Areas: Morphine (From CI Calculation Sheet, Area P1a-1)

H5sCI-P3b - Unfractionated Heparin: Ready-to-administer and ready-to-use injectable supplied to unauthorized clinical areas

Number of Ready to Administer Injectables Supplied to Unauthorized Clinical Areas - Unfractionated Heparin (From CI Calculation Sheet, Area P3b)

Number of Unauthorized Clinical Areas: Unfractionated Heparin (From CI Calculation Sheet, Area P1b-1)

H5sCI-P3c - Potassium Chloride Solution: Ready-to-administer and ready-to use injectable supplied to unauthorized clinical areas

Number of Ready to Administer Injectables Supplied to Unauthorized Clinical Areas - Potassium Chloride Solution (From CI Calculation Sheet, Area P3c)

Number of Unauthorized Clinical Areas: Potassium Chloride (From CI Calculation Sheet, Area P1c-1)

H5sCI-P4 - The number of clinical areas storing concentrated injectable medicines according to selected SOP specifications.

H5sCI-P4a - Number of clinical areas storing morphine correctly

Number of Clinical Areas Storing Concentrated Injectable Morphine Correctly (From CI Calculation Sheet, Area P4a)

Number of Clinical Areas Storing Concentrated Injectable Morphine (From CI Calculation Sheet, Area P4a-1)

H5sCI-P4b - Number of clinical areas storing unfractionated heparin correctly

Number of Clinical Areas Storing Concentrated Injectable Unfractionated Heparin Correctly (From CI Calculation Sheet, Area P4b)

Number of Clinical Areas Storing Concentrated Injectable Unfractionated Heparin (From CI Calculation Sheet, Area P4b-1)

H5sCI-P4c - Number of clinical areas storing potassium cloride correctly

Number of Clinical Areas Storing concentrated Injectable Potassium Chloride Correctly (From CI Calculation Sheet, Area P4c)

Number of Clinical Areas Storing Concentrated Injectable Potassium Chloride (From CI Calculation Sheet, Area P4c-1)

Confirm that Data Quality has been validated: Select...

Ensuring Data Quality for Concentrated Injectable Medicines

Submit Performance Data

Appendix I Selected References and Resources for the Safe Management of Concentrated Injectable Medicines

Medication Error Prevention – Potassium Chloride. *Sentinel Event Alert*, Issue 1, February 27, 1998, Joint Commission on Accreditation of Healthcare Organizations. International Journal of Quality in Health Care 2001;13(2):155

Alert on potassium chloride solutions. National Patient Safety Agency (UK), 23 July 2002. http://www.nrls.npsa.nhs.uk/resources/collections/never-events/core-list/potassium-chloride/ Accessed 12 May 2015

DiPaulo M et al. Accidental death due to erroneous intravenous infusion of hypertonic saline solution for hemodialysis. Int J Artif Organs 2004; 27(9):810-812.

High-Alert Medications and Patient Safety. *Sentinel Event Alert*, Issue 11, November 19, 1999, Joint Commission on Accreditation of Healthcare Organizations. http://www.jointcommission.org/sentinel_event_alert_issue_11_high-alert_medications_and_patient_safety/default.aspx Accessed 12 may 2015

Intravenous potassium chloride can be fatal if given inappropriately. Medication Alert 1, October 2003. Australian Council for Safety and Quality in Health Care http://www.safetyandquality.gov.au/wp-content/uploads/2012/01/kcalertfinal1.pdf. Accessed 12 May 2015

Control of concentrated electrolyte solutions. WHO Patient Safety Solutions Volume 1 Solution 5. 2007 http://www.who.int/patientsafety/solutions/patientsafety/PS-Solution5.pdf Accessed 12 May 2015

More on Potassium Chloride. ISMP Canada Safety Bulletin, Volume 3, Issue 11, November 2003.

Concentrated Potassium Chloride: A Recurring Danger. ISMP Canada Safety Bulletin, Volume 4, Issue 3, March 2004.

Medication Safety Recommendations. *To Err is Human: Building a Safer Health System* Institute of Medicine 2000.

Tisdale JE and Miller DA. Drug-Induced Diseases: Prevention, Detection and Management. American Society of Health-System Pharmacists. 2005

Manasse HR and Thompson KK. Medication Safety: A Guide for Health Care Facilities. American Society of Health-System Pharmacists. 2005

Brown TR. Institutional Pharmacy Practice, 4th Edition. American Society of Health-System Pharmacists. 2006

Potassium chloride safety recommendations summary. ISMP Canada: http://www.ismp-canada.org/download/PotassiumChlorideSafetyRecommendations2005.pdf Accessed 12 May 2015

Swanson D. Implementing an IV potassium policy. Pharm J. 2003; 10:348-352.

Lankshear AJ, Sheldon TA, Lowson KV, Watt IS and Wright J. Evaluation of the implementation of the alert issued by UK National Patient Safety Agency on the storage and handling of potassium chloride concentrate solution. Qual Saf Health Care.2005; 14:196-201

Cousins DH, and Harris W. Risk assessment of anticoagulant therapy. 2006. National Patient Safety Agency. 2006. http://www.nrls.npsa.nhs.uk/resources/?entryid45=59814 Accessed 12 May 2015

National Patient Safety Agency. Patient Safety Alert. Safer Practice with Anticoagulant Therapy. 2007. http://www.nrls.npsa.nhs.uk/resources/?entryid45=59814 Accessed 12 May 2015

Anon. What makes patients safer? Simplicity, standardization succeed in the heparin program. Clin Resource Manag 2000; 1:166-8.

ASHP therapeutic position statement on the institutional use of sodium chloride 0.9% injection to maintain the patency of peripheral indwelling intermittent infusion devices. 2006 http://www.ashp.org/s_ashp/docs/files/BP07/TPS_NaCl.pdf. Accessed 12 May 2015

National Patient Safety Agency. Patient Safety Alert. Safer practice with injectable medicines. 2007. http://www.nrls.npsa.nhs.uk/resources/?entryid45=59812 Accessed 12 May 2015

Adachi W. Lodoice AE. Use of failure mode and effects analysis in improving the safety of I.V. drug administration. Am J Health Syst Pharm 2005; 62:917-20.

Larsen GY. Parker HB, Cash J, O'Connell M, Grant MC. Standard drug concentrations and smart pump technologies reduce continuous medication- infusion errors in pediatric patients. Pediatrics. 2005;116:e21-5.

Apkon M, Leonard J, Probst L, Delizio L, Vitale R. design of a safer approach to intravenous drug solutions: failure mode effects analysis. Qual Saf Health Care 2004;13:265-71.

Hardy L and Mellor L. Risk assessment of parenteral product preparation across secondary care acute trusts in the north of England. Hospital Pharmacist 2007; 14:58-64.

Beaney AM, Black A, Donson CR, Williamson S and Robinson M. Development and application of a risk assessment tool to improve the safety of patients receiving injectable medicines. Hospital Pharmacist. 2005; 12:150-154.

Wheeler DW, Wheeler SJ, Ringrose TR. Factors influencing doctors' ability to calculate drug doses correctly. J Clin Pract. 2007; 6; 189-94.

Appendix J Other Tools and Resources

- Apkon M, Leonard J, Probst L, Delizio L, Vitale R. Design of a safer approach to intravenous drug solutions: failure mode effects analysis. Qual Saf Health Care 2004;13:265-71
- Medication errors in intravenous drug preparation and administration: a multicentre audit in the UK, Germany and France. Cousins DH, Sabatier B, Begue D, Schmitt C, Hoppe-Tichy T. Qual Saf Health Care. 2005 Jun;14(3):190-5
- Model For Improvement You Tube Video (Clip 1 & 2), Institute for Healthcare Improvement http://www.ihi.org/education/IHIOpenSchool/resources/Pages/AudioandVideo/Whiteboard3.aspx
- PDSA Cycle You Tube Video, (Clip 1 & 2), Institute for Healthcare Improvement http://www.ihi.org/education/IHIOpenSchool/resources/Pages/AudioandVideo/Whiteboard5.aspx Quality Improvement Tools and Resources, Health Quality Ontario

  http://www.hqontario.ca/quality-improvement/tools-and-resources