

The High 5s Project

Standard Operating Protocol



Safe Management of Concentrated Injectable Medicines



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The following Standard Operating Protocol (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 this SOP has been demonstrated in 16 hospitals in the Netherlands. Its implementation outside of the High-5 testing environment is encouraged.

The Standard Operating Protocol on the Safe Management of Concentrated Injectable Medicines was the primary reference document for hospitals and the Netherlands- Lead Technical Agencies (LTA) participating in the WHO High5s Project. It outlines the standard steps for the safe management of concentrated injectable medicines and provides guidance for implementation, as well as references and suggestions for quality improvement. This document and a Getting Started Kit are provided to assist more organizations to safely manage the use of concentrated injectable medicines.

This SOP was developed under the High5s Project by the former National Patient Safety Agency of the United Kingdom, 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' LTA. The SOP was not implemented by any other participating country LTA. Synthesis and analysis of data from the 16 Dutch hospitals was not part of the overall High5s 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.

Acknowledgement: the High5s Project

The work of the High5s Project was set up 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 Médicament, Dispositifs médicaux et Innovation Thérapeutique), 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.

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1. Description of the patient safety problem to be addressed

Safe management of concentrated injectable medicines is the formal process to prevent medication errors associated with the prescribing, preparation, storage, or administration of concentrated injectable medicines, and to ensure that errors most frequently resulting in death or serious patient harm are prevented.

Adverse drug events (ADE's) are a leading cause of injury and death in all health care systems around the world.^{i ii iii} Several national European studies of adverse events showed that between 6.3–12.9% of hospitalized patients have suffered at least one adverse event during their admission and that between 10.8–38.7% of these adverse events were caused by medication error and were preventable.^{iv}

It is well known that ADE's are a leading cause of injury and death in health care.^{v,vi, vii,viii} The cost estimates from Europe and North America, have found that medication overuse, underuse and misuse costs billions of dollars. Yet, little work is being undertaken to understand and address this problem.^{ix} In the United States of America costs related to the 1.5 million people that are harmed and thousands that die as a result of medication errors are estimated at 3.5 billion annually.^x

Evidence from around the world demonstrates that use of concentrated injectable medicines has been involved in medication incidents resulting in patient death or serious harm. These have been frequently caused by:

- Selection of the wrong medication due to look-a-like labelling and packaging, where concentrated injectable medicines are mis-selected and used instead of other injectable medicines, e.g. when concentrated (or undiluted) potassium chloride solution is injected accidentally instead of the intended 0.9% sodium chloride.
- Dose and rate of administration errors. This may involve incorrect calculation, measurement and dilution.

Between 2005 and 2006, the UK National Patient Safety Agency received around 800 reports a month relating to injectable medicines with 25 accidents of death and 28 accidents of serious harm being reported.¹ In Canada, 23 incidents involving KCl [potassium chloride] mis- administration occurred between 1993 and 1996.

Leotsakas A et al. High 5s: Addressing excellence in patient safety World Hospitals and Health Services, 2009, 19-22



Unsafe Medication Incidents



Look Alike Labelling and Packaging



Dose and Rate Administration Errors

Concentrated injectable medicines commonly reported as causing harm from errors in prescribing, transcribing, dispensing, administering, compounding and monitoring of medicines include:

1. Concentrated potassium solutions.
2. Sodium heparin >1,000 units/ml.
3. Injectable opioid preparations.

The Management of Concentrated Injectable Medicines Standard Operating Protocol (SOP) addresses the prevention of medication errors associated with the preparation, storage, or administration of concentrated injectable medicines.

Patient Example “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.

<http://www.medpagetoday.com/Pediatrics/GeneralPediatrics/7469> Accessed 12 May 2015

The implementation effort focuses on the three injectable medicines that are most frequently associated with errors resulting in death and serious patient harm:

1. Concentrated potassium chloride solutions.
2. Sodium heparin >1,000 units/ml.
3. Injectable morphine preparations.

This SOP seeks to prevent these errors by minimizing the storage and use of concentrated injectable medicine products in clinical units by:

- Replacing them with ready-to-use injectable products that do not need to be diluted before use;
- 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.

“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^{xi}

Rationale of the SOP

The the risks of patient harm from the administration of concentrated injectable medicines can be reduced by:

- Replacing concentrated injectable medicine products in clinical units with ready-to-use pre-diluted products; and
- Improving the safety of the storage, prescription, dispensing, administration, preparation and monitoring of concentrated preparations of potassium, heparin and morphine injections.

The Scope of the Safe Management of Concentrated Injectable Medicines SOP

The SOP applies to all clinical areas in the hospital setting. It covers implementing safe management of concentrated injectable medicines hospital wide.

Full Implementation of the SOP

In order to define the term “full implementation,” of the SOP there is a distinction between *performance* of the process that the SOP seeks to standardize and *implementation* of that process. The SOP defines the process to be implemented, the scope of applicability of that process and a structured approach to implementing the process. In this context, to *implement the process* means to put into effect the procedures and resources necessary to perform the process. Once the process is implemented, *performance of the process* means the degree to which it is consistently executed. The extent of *implementation* is determined primarily through ‘Implementation Experience’ evaluation (questionnaires and interviews). *Performance* is determined primarily through the High 5s performance measures. Given a certain scope of implementation, the degree to which the process is consistently executed within this scope (the full scope of implementation as defined by the SOP), will be measured by the relevant performance measures.

The SOP defines the expected full scope of implementation as:

- (1) all of the required steps in the process to be standardized;
- (2) all of the locations where those steps are to be put into effect; and
- (3) the population of patients to which those steps will apply (i.e. the eligible population).

For Concentrated Injectable Medicines this means the exclusion from clinical areas of:

- Concentrated potassium chloride solution (>0.04 mmol/ml)
- Unfractionated heparin >1,000 units/ml, and
- Injectable morphine >15 mg/ml from all unapproved units (In the Netherlands defined as >15mg/container and >1mg/ml ready-to-use).

The actual extent of implementation of the SOP is expected to change over time. Initially, it may include all or most of the required steps but in only a few of the required locations or a portion of the full eligible population. Spread of the implementation to the remaining locations and eligible population will occur over the ensuing months. Only when the implementation has reached the full scope as defined in the SOP will the hospital be considered at “full implementation.” For purposes of analyzing and reporting evaluation data, hospitals will report their level of implementation as “Full implementation” only if throughout the entire time period for which the data are being reported, all of the process steps in the SOP have been in place in all of the locations required by the SOP and available to the entire defined eligible population.

2. A word about standardization

The basic assumption that was tested in the High5s initiative is that process standardization will improve patient safety. We know that in a general sense, the tendency for a process to fail is diminished in relation to the consistency with which it is carried out; that is, the degree to which it is standardized. Despite this, efforts in recent years to standardize health care processes through the introduction of practice parameters, protocols, clinical pathways, and so forth have been met with limited enthusiasm among practitioners and are only slowly affecting the actual delivery of care. Achieving process consistency while retaining the ability to recognize and accommodate variation in the input to the process (for example, the patient's severity of illness, co-morbidities, other treatments, and preferences) is one of the major challenges to standardization in health care. Process variation to meet individual patient needs is an essential principle of modern medicine; variation to meet individual health care organization or practitioner preferences need not be. The thesis that has been tested in the WHO High5s initiative is that standardization will be advantageous—will get better overall results more safely—even if we concede that each practitioner working independently could get better results than the others by using a personally favored, but different, process than the others. The reason, of course, is that in modern medicine, practitioners do not work independently. Clinical results are determined by the complex interrelationships among practitioners, supporting staff and services, and the clinical environment. Assuming each preferred practice is a good practice, it matters less which process is selected as the basis for standardization; it is the standardization that matters most. Standardization produces better results than a variety of “best practices” when it comes to safety. And the WHO High5s initiative has taken standardization a couple of steps further than the usual efforts to minimize variation—it not only sought to standardize certain processes among individuals within a health care organization but to standardize them in multiple organizations in multiple countries around the world. The WHO High5s Project asked the following: Is it possible to standardize on this scale? If it is, will it measurably improve the safety of care? These questions have now been answered in the affirmative. The first of these questions has now been answered as a qualified affirmative. Hospitals in the Netherlands participating in the WHO High5s Project were able to successfully implement the key components of the Management of Concentrated Injectable Medicines SOP. Hospitals identified the prescriptions, protocols, use and storage of CIMs at inpatient clinical areas. Bases upon the patient population in each hospital (and the specific inpatient clinical area), the availability and use of the three CIMs differed. Depending on the size of the hospital the SOP was implemented hospital wide or at specific pilot-wards, using as key element the replacement of the CIM with a ready to use product. In general, both nurses and doctors were very positive and the buy-in was very high, because of the awareness that the SOP principles reduce potential hazards by taking CIMs off the floor stock. In some cases nurses were a bit shivery, because they preferred to have CIMs on the floor stock. The SOP was extended to other CIMs and drugs in some hospitals. Challenges were found in preventing look-a-like errors using ready to use products and the availability of suitable ready to use products for each patient group. If a CIM was still needed at a ward, separate storage and label warning were proposed in the SOP. However, labeling could introduce an alarm fatigue hazard, so some hospitals decided not to label warnings. For separate storage of CIMs at inpatient clinical areas, sometimes adaption of storage space is needed. This is also an issue when CIMs are replaced by RTU and RTA products that are large.

The High5s SOPs are now available for general implementation. In the interest of improving patient safety, WHO encourages all its Member States to promote implementation of the Management of Concentrated Injectable Medicines SOP.

3. Guiding principles for the safe management of concentrated injectable medicines

The basis for effective safe management of concentrated injectable medicines is the development, maintenance and communication of a process for minimizing the storage and use of concentrated injectable medicines by replacing them with ready-to-administer or ready-to-use injectable products that do not need to be diluted before use.

Guiding Principle 1:

Minimise the range of injectable medicines available in 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 prescriptions and orders for concentrated injectable medicines so as to have a complete and unequivocal ordering system for nursing and pharmacy staff.

The Netherlands identified how CIMs are prescribed by simplifying and standardizing CIM prescriptions and orders, including information on the formulation, dosage and administration.^{xii}

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-administer¹ or ready-to-use² injectable products that do not need to be diluted before use.

¹ Ready-to-administer injectable products require no further dilution or reconstitution and are presented in the final container or device, ready for administration or connection to a needle or administration set e.g., an infusion in a bag with no additive required.

² Ready-to-use injectable products require no further dilution or reconstitution before being transferred to the administration device, e.g. a liquid in an ampoule/vial, of the required concentration, that only requires to be drawn up into a syringe.

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 acknowledged labelling strategies such as Tall Man lettering, to prevent errors (<https://www.ismp.org/tools/tallmanletters.pdf>).
- 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.

Appendix A provides in tabular form a list of each step identified in the flow diagram, additional details on how it will be done, who will do it, when it should be done, what tools are needed, and the inputs and outputs of each step.

Appendix B provides: (i) a simple flow diagram of the usual (and undesirable) approach to the management of concentrated injectable medicines (i.e., storage and preparation on the patient care unit); and (ii) a flow diagram of the steps that need to be considered when changing from the supply of concentrated injectable medicines to ready-to-use injectable medicines.

4. The context of safe management of concentrated injectable medicines

The safe management of concentrated injectable medicines (CIM), while not especially complex, may represent a significant change in prescribing, purchasing, preparation, supplying and administering of these medicines. As such, the change may be resisted if not implemented in a systematic manner with appropriate oversight, resources, and early engagement of the participants in the process.

The context (or environment) in which the CIM SOP is implemented will influence the success of its implementation. External factors such as health policy, national guidelines and accreditation requirements for safe management of CIM will have an influence, as will the internal factors that are the unique features of the individual health care organization. Factors such as the culture, leadership, size and structure of the organization, ownership of the intervention, and the availability of resources can affect the success of the implementation and should be considered when planning the implementation strategy.

In order to better understand the influence of context in successful quality improvement work it is recommended that leadership and the implementation team review this resource for the project team. See: Health Foundation - Context www.health.org.uk/publications/perspectives-on-context/

Permissible variations in the concentrated injectable medicine management process:

In this Standard Operating Protocol, we seek uniformity of the basic steps in the process, their interdependencies, and the minimum documentation and measurement requirements, while allowing flexibility in the assignment of tasks to specific professional disciplines and the format of the documentation and measurement tools. The SOP accommodates those organisations that do not have on-site pharmacy services, pharmacy intravenous additive services or pharmacy services that operate out of hours, as well as the special clinical circumstances for which concentrated injectable medicines must be stored and prepared in a clinical area.

5. Patient and family involvement

Patients should be educated about the importance of participating in the process of medication administration by e.g. speaking up if they believe that a near miss or mistake has been made with their medicines or if health care workers don't follow routine checking procedures, including confirming patient identification prior to administering medicines.

Patients should also be engaged in other steps of the concentrated injectable medicines process. For example before administering any medication, clinicians should review the medication, its purpose, and the dose with the patient and ask him/her to verify that all are correct. The patient should have the opportunity to ask questions or raise concerns.^{xiii} They should be informed of new medicines commenced and any changes made to their medication regimen.

6. Education and training of staff

A comprehensive staff education program is considered one of the four key success factors for safe management of concentrated injectable medicines. All staff involved in the concentrated injectable medicines process need to be trained in their areas of responsibility. This requires an ongoing commitment by the organization to:

- training all new staff
- providing ongoing training.

All staff involved in prescribing, preparing and administering concentrated injectables should be knowledgeable of the guidelines/protocols in their institution, and instructed to adhere to these protocols. Training of doctors and nurses should include an explanation of the risks involved in the administration of concentrated injectables and the precautions taken to prevent these risks. Regular evaluation and follow-up of incidents, including near misses, with the use of concentrated injectables, with feedback to staff can help reinforce commitment.

Ongoing education of staff is a significant investment for health service organizations. Some of this training can be undertaken by professional organizations and by universities.

Since it is necessary to train many staff during initial implementation, using a train the trainer approach may be helpful. Hospitals pilot testing the SOP may consider using those staff trained during the pilot testing to become the trainers for the rest of the hospital staff when the new process is ready for full implementation.

7. Implementation Strategy for safe management of concentrated injectable medicines

It is important to understand the existing processes that may interface with safe management of concentrated injectable medicines in the organization. There should be uniformity in:

- basic steps in the process and their interdependencies
- minimum documentation and measurement requirements

It may be possible to allow flexibility in:

- assignment of tasks to specific professional disciplines
- format of the documentation and quality improvement assessment.

It is recommended that a quality improvement approach be taken in implementing the Concentrated Injectable Medicines SOP. The following describes the implementation methodology used in the High5s Project. Additional guidance can be found in the “WHO High5’s Safe management of concentrated injectable medicines: Concentrated Injectable Medicines Implementation Guide.”

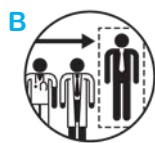
8. Oversight of the implementation

- a. Identify an Oversight Group for the 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. The senior leader should understand that there are resource implications to implementing the Concentrated Injectable Medicines SOP. This individual should have direct accountability for outcomes related to safe management of concentrated injectable medicines.
- c. Assign one or more representatives of the professional disciplines involved in medication management—at a minimum, physicians, nurses, and pharmacists—and depending on the size of the hospital eventually select pilot wards to guide the design, testing, and roll-out of the safe management of concentrated injectable medicines 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 quality improvement methods and with project management skills—to develop and manage the project work plan.

OVERSITE OF THE IMPLEMENTATION



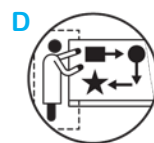
Identification of the oversight group



Assign a leader for direct oversight



Assign professional discipline teams



Assign a facilitator

9. Project work plan

- a. Develop a detailed task list for design, testing, training, implementation, and measurement of the safe management of concentrated injectable medicines process. (See CIM SOP Implementation Guide for a sample task list. Details may vary from one facility to another).
- b. Identify 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. Identify dependencies and time frames for each of the project tasks.
- d. Identify deliverables and due dates for each of the project tasks.
- e. Assign resources to each of the tasks.

PROJECT WORK PLAN



Develop a task list



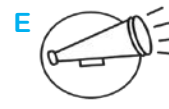
Identify milestones and target dates



Identify dependencies and time frames



Identify deliverables and due dates



Develop communication plan

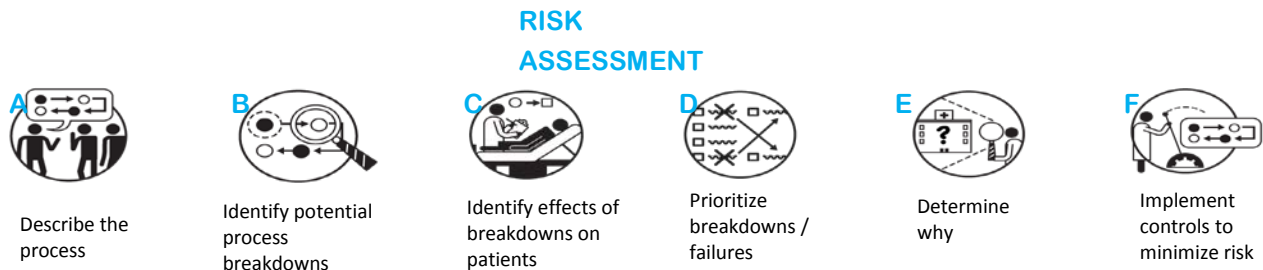


Assign resources

10. Risk Assessment of the proposed process

It is suggested that the proposed process be evaluated in order to identify the ways that it might fail prior to implementation. One tool that could be used is Failure Modes and Effects Analysis (FMEA) which is “a systematic, proactive method for evaluating where and how a process might fail and to assess the relative impact of different failures, in order to identify the parts of the process that are most in need of change.”³

- a. Describe the process (for example, through the use of a flowchart).
- b. Identify for each of the steps in the process and for each linkage between steps, the ways that the process could break down or fail to perform its desired function.
- c. Identify the possible effects that a breakdown or failure of the process could have on patients and the seriousness of the possible effects.
- d. Prioritize the potential process breakdowns or failures.
- e. Determine why the high priority breakdowns or failures could occur.
- f. Implement controls, warnings, or protections to minimize the risk of harm to patients.



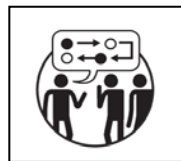
³ Information on FMEA process and the FMEA tool is available from

<http://www.ihl.org/resources/Pages/Tools/FailureModesandEffectsAnalysisTool.aspx>

11. Pilot test of the safe management of concentrated injectable medicines process (recommended, but optional)

- a. Identify one or more pilot test sites, frequently a general medical inpatient unit that is representative of the overall functioning of the hospital.
- b. Collect baseline data on current processes for the pilot test site(s) prior to introducing the concentrated injectable medicines SOP process using the measures described in the Metrics section of the implementation guide.
- c. Engage representatives from the pilot test site(s) to participate in the test design and implementation.
- d. Integrate the proposed process for managing concentrated injectable medicines into the work flow of the pilot test site with adaptation, as necessary, to the unique features of the pilot test site.
- e. Train the staff who will be participating in the pilot test 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. (See section Education and Training of Staff).
- f. Implement the new process on the pilot test unit.
- g. Measure consistency and timeliness of implementation of each of the steps in the process.
- h. Measure impact on other related or interfacing activities.
- i. Measure impact on patients.
- j. Analyze pilot 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 on the pilot test site(s), and should result in sustained improvement before considering expanded implementation.



**ENGAGE REPS TO
PARTICIPATE IN THE
TEST DESIGN**



TRAIN PARTICIPANT STAFF



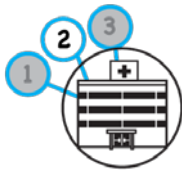
**IMPLEMENT AND
MEASURE**



**ANALYZE PILOT TEST
DATA**

12. Spread methodology

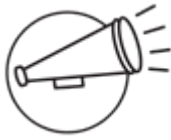
- a. Determine the sequence and timing of implementation in other areas of the organization.
- b. When the process is stable in the pilot test site(s) and measurement reflects sustained improvement, consider spread of methodology to other areas of the organization. Sequential implementation, rather than concurrent implementation (the phased-in approach described above), is recommended to provide for adequate pre-implementation training, oversight and coaching during the early phases of implementation, and monitoring of the new process.



DETERMINE THE
SEQUENCE AND
TIMING OF SPREAD

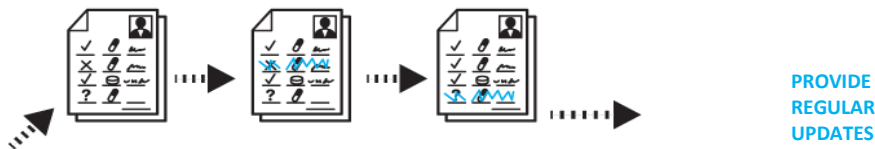
13. Communication plan

- a. Announce the organization's decision and commitment to implement safe management of concentrated injectable medicines.



- b. Provide rationale for participation in the initiative:
 - i. Description of the problem to be addressed, share stories of concentrated injectable medicines failures and the results found in the baseline data collection phase.
 - ii. The proposed solution (SOP for concentrated injectable medicines).
 - iii. The costs and benefits of participation.
 - iv. Incentives to clinical staff to participate (improved safety for patients, efficiencies and lower risk exposure for staff).
 - v. Country accreditation requirements.

- c. Provide regular updates to all staff on the progress of the project work plan.



- d. Provide feedback to all staff on the measurement data collected and analyzed throughout the pilot test and implementation phases of the project. This will enhance buy-in and will highlight the effects of the improvements they are making over time.



PROVIDE
FEEDBACK TO
ALL STAFF

- e. Develop material for front line staff to engage them in the new process for safe management of concentrated injectable medicines.
- f. Recognize the contributions and successes of all staff participating in the project.

14. Process management strategy

Successful implementation and sustained performance of this process will require information. In developing and testing the High5s SOPs, three complementary approaches to information gathering were used and are provided here and in accompanying materials as a resource for organizations that choose, 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, and still others not applicable for 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 the management strategy will also be valuable for providing feedback to participating staff. The following components of a process management strategy can be used:



MANAGE THE PROCESS USING
QUALITATIVE & QUANTITATIVE
MEASUREMENT

a. SOP Implementation Evaluation – self-reported information regarding the implementation experience.



IDENTIFY AND ANALYZE
ADVERSE EVENTS

b. Performance Measures – quantitative measurement of processes and outcomes associated with the SOP.

c. Event Analysis – identification and analysis of any adverse events directly associated with/related to the SOP or its implementation.

Additional information on these process management tools is available in the Implementation Guide.

15. Maintenance and improvement strategy

- a. Once the redesigned safe management of concentrated injectable medicines process is fully implemented, regular monitoring of key parameters should continue to support sustained consistent performance and provide feedback to organization leadership and participating staff.
- b. Opportunities to improve efficiency and effectiveness of the process should be identified, prioritized and, as appropriate, acted upon.
- c. Evidence of “drifting” from the intended procedures should be analyzed to identify the reasons and to determine an appropriate response – for example: additional training; process redesign; and technical support.

Selected References and Resources

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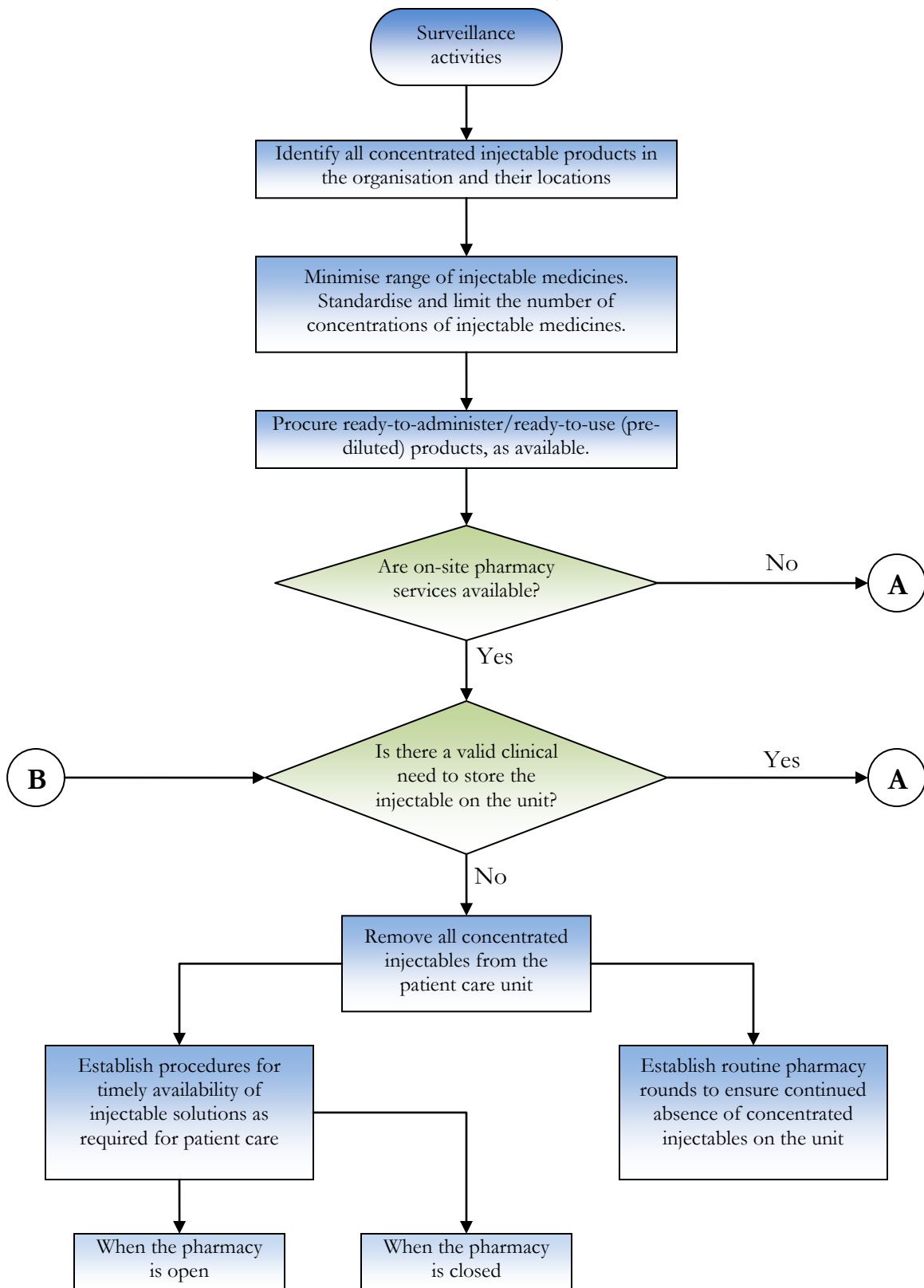
Appendix A Tabular Listing of Steps in the Safe Management of Concentrated Injectable Medicines Process- Detailed Specifications

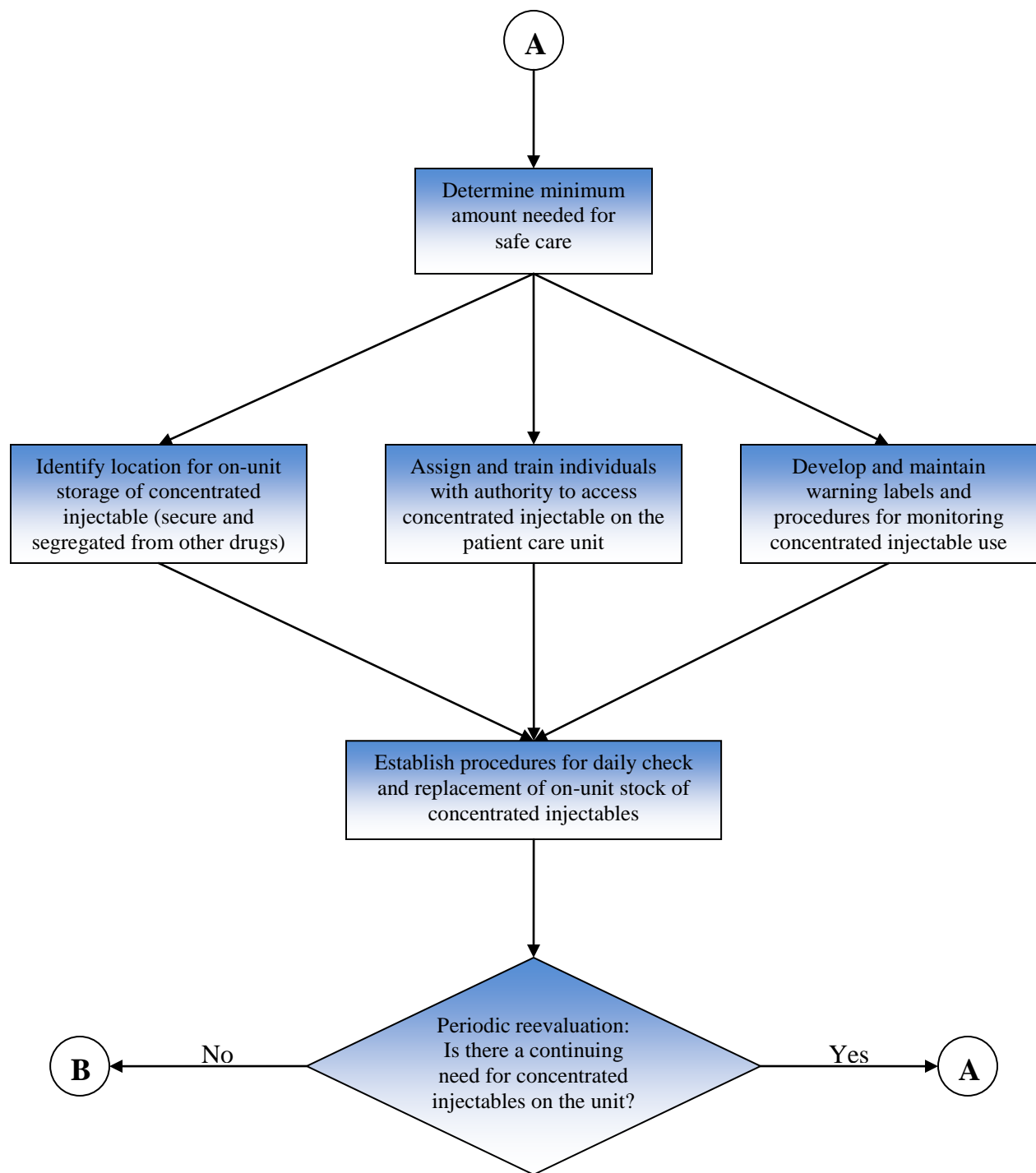
#	Step of process	Detail	Who? *	When?	Tools *	Input	Output
1	Identify all types of concentrated injectable medicines (CIMs) and where they are kept	Include drugs listed in formulary, non-formulary items and other preparations brought in by caregivers	Pharmacist/ Doctor/Nurse	Start of process and annually thereafter	Formulary; Questionnaires for physicians and nurses	Formulary info, questionnaire & interview results, direct observations	List of all types and preparations of concentrated injectables and where located
2	Evaluate need for each type of CIM	If not clinically necessary, remove from formulary.	P&T* Committee	Start of process and annually thereafter			
3	For needed CIMs, standardize and limit the number of concentrations	>1 concentration must be based on patient need, not practitioner preference	P&T Committee	Start of process and annually thereafter			
4	Procure ready-to-administer or ready-to-use injectables	May be available from manufacturer or distributor	Pharmacist	Ongoing			
5	Are on-site pharmacy services available?	Yes: Continue #6 No: Go to #9					
6	Are CIMs needed on the patient unit?	Yes: Go to #9 No: Continue #7		Start of process and annually thereafter			
7	Remove CIMs from patient care units	Remove from all locations except those with proven	Pharmacist	Start of process and re-check at least annually	Provision for safe storage in the pharmacy	List of types and locations of CIM preparations	Relocation of CIMs from patient care units to the

		clinical need		thereafter			pharmacy
#	Step of process	Detail	Who? *	When?	Tools *	Input	Output
8	Provide timely availability of injectable solutions	Must meet clinical needs of patients for safe, effective care	Pharmacist	Whenever needed, whether pharmacy is open or closed	Consider pre-mixed, diluted injectable medicine preps	Orders for fluid and electrolyte solutions and other injectables	Availability of correct solutions when and where needed for the pt.
9	Determine clinical need to store CIMs on patient care unit	Must be based on patient safety, not practitioner convenience	Medical leaders with input from pharmacists and nurses	Start of process and at least annually thereafter	Clinical practice guidelines	Requirements of relevant clinical process	Decision to make concentrated injectable medicines available on unit
10	Provide for safe storage of CIMs on designated special care units	Secure location segregated from other medications; limited access; warning labels	Pharmacist; nurses	Limit nursing access. Pharmacist will replenish stock as used	Keys/codes for secure limited access; Log for tracking use of CIMs		
11	Assign and train individuals with authority to access CIMs	Limit to pharmacist and senior registered nurse(s)	Pharmacist; nurse educator	Start of process and at least annually thereafter			
12	Implement policy & procedures for access and preparation of on-unit CIMs	Limited access; independent double-check of preparation	Pharmacist; nurses	Review at least annually			
13	Implement policy & procedures for daily check of on-unit stock of CIMs	Replenish stock as needed to maintain level	Nurse/ Pharmacist	Daily			

- P&T committee: Pharmacy and Therapeutics Committee

Appendix B Flow charts of the concentrated injectable medicines process





Appendix C Other Miscellaneous 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.youtube.com/watch?v=SCYghxtioI>, <http://www.youtube.com/watch?v=6MIUqdulNwQ&feature=relmfu>
- PDSA Cycle You Tube Video, (Clip 1 & 2), Institute for Healthcare Improvement <http://www.youtube.com/watch?v=-ceS9Ta820&feature=youtu.be>, http://www.youtube.com/watch?v=eYoJxjmv_QI&feature=relmfu
- Quality Improvement Tools and Resources, Health Quality Ontario <http://www.hqontario.ca/quality-improvement/tools-and-resources>

End notes

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- ^{xii} Van den Bemt, PMLA, Egberts ACG. **Drug related problems: definitions and classification.** *EJHP Practice* 2007;13:62-64 <http://www.eahp.eu/publications/archives>
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