HQCA
Health Quality Council of Alberta

July 2009

Review of Infection Prevention and Control in the High Prairie Health Complex (Focusing on the Re-Use of Single-Use Syringes) A Report to the Minister

As Requested by the Minister of Alberta Health and Wellness and as Mandated by the Health Quality Council of Alberta Regulations 130/2006 of the Regional Health Authorities Act Section 13

Contents

Executive Summary

On October 2, 2008, at the High Prairie Health Complex, it was identified that single-use syringes were commonly loaded with multiple doses of medication and administered through intravenous (IV) tubing to multiple patients during the course of a day in the endoscopy suite and recovery room. This practice had been occurring since 1990 in the High Prairie Health Complex recovery room for dental procedures and since 2004in the endoscopy suite. There is a risk that blood borne pathogens which include Hepatitis B, Hepatitis C and Human Immunodeficiency Virus (HIV) may be transmitted with this practice. As a result, a look back process was implemented by Alberta Health Services to identify the risk and to alert patients who may be at risk.

In accordance with the Health Quality Council of Alberta Regulation 130/2006 of the *Regional Health Authorities Act,* Section 13, the Minister of Alberta Health and Wellness requested the Health Quality Council of Alberta (HQCA) to assess and inquire into the practice cited above in the High Prairie Health Complex endoscopy suite and recovery room and relevant areas as agreed to by the HQCA and Alberta Health and Wellness (AHW). The HQCA is an independent organization legislated under the *Regional Health Authorities Act* whose mission is to promote patient safety and health care quality. The HQCA was charged with identifying cause(s) and contributing factors that led to the practice of using the same single-use syringe for administration of medication to multiple patients and to develop recommendations to ensure these were addressed to improve future patient safety and health quality at the High Prairie Health Complex and the Alberta Health Services - Peace Country Health. The HQCA was also to identify national and international standards, guidelines and best practices for utilization of single-use devices related to medication administration.

A review team was struck by the HQCA, under the direction of Dr. John Cowell, MD, FRCPC, Chief Executive Officer, and led by Linda Poloway, BScPharm, FCSHP, Patient Safety Lead, HQCA. The balance of the Review Team consisted of three individuals experienced in reviewing critical incidents and with expertise in the areas of infection prevention control, patient safety, and quality; Denise Sorel, BScN, RN, CIC, Infection Preventionist, Regional IPC Director, Alberta Health Services - East Central Health, Dr. Tony Taylor, MD FRCP MBA, and Dr. Robert Burns, BSc MD were selected.

Information gathering, fact finding and validation as well as discovery of cause and contributing factors were conducted under the auspices of the Quality Assurance Committee of the HQCA and were protected under Section 9 of the *Alberta Evidence Act.* While the object of the review was the High Prairie Health Complex, it was necessary to involve members from the Alberta Health Services – Peace Country Health (AHS – PCH) and review regional processes that impacted the High Prairie Health Complex. The incident was reviewed with full transparency provided by the administration and staff of the High Prairie Health Complex and the AHS – PCH; candid and open dialogue on use of single-use syringes and other patient safety topics relevant to the incident allowed the Review Team to examine all causal issues and provide a comprehensive report. The commendable participation in the review of individuals from the High Prairie Health Complex and the AHS – PCH is reflective of the organization's clear commitment to improving patient safety and enhancing their patient safety culture.

The review confirmed that the practice of using the same single-use syringe to administer multiple doses of medication through IV tubing to multiple patients had been in place in the High Prairie Health Complex since 1990 in the recovery room and since approximately April 2004 in the endoscopy suite. It is important to clarify that the needle used to administer the medication did not come in contact with the patient's skin or body fluids; the medication was administered through a pre-existing IV line connected to the patient. As the review of operating room surgical practices was within the scope of this review, interview questions addressed the practice of re-use of single-use syringes in the operating room. However, the closure of the operating room since the fall of 2007 and the review timeline did not allow for full examination of operating room surgical practices.

A root cause analysis process that validated a chronological list of events leading to the incident and utilized cause and effect diagramming identified four root causes that all, interdependently, contributed to the incident. The local causes stemmed from a culture of autonomy where the operating room, endoscopy suite, and recovery room staff functioned very independently from the rest of the organization and where conformity to the practices in those areas was an unwritten expectation. That culture, linked with a physical isolation from external influences which would

have exposed the staff to current practices through, e.g. comprehensive orientation to endoscopy practices and on-going education, might have alerted the staff that their practice differed from the accepted standard.

A significant influencing factor was that the practice of using the same single-use syringe for multiple patients was generally a relatively common practice in anesthesia in the early 1990's. That belief was validated by review of the literature where surveys about this practice were completed in various jurisdictions around the world. The self-reported prevalence of reusing either syringes or some portion of the IV circuit was estimated as being between 2 - 60%. Over the past 15 years, the prevalence of this practice decreased from 61% in 1990[1], 19.2% in 1995[2] and 2.2% in 2006[3]. This practice in anesthesia was perceived to support a similar nursing practice.

The practice of using the same single-use syringe to administer medications to multiple patients by nurses[4] began in the recovery room, and it set a precedent for that practice to continue in the endoscopy suite many years later. The specific timing of initiation of this practice in the endoscopy suite was directly linked to an introduction of a needle-safe IV administration system in March 2004 and the misunderstanding by some nurses that this system included a one way valve that minimized the risk of contamination.

Both the lack of clarity for accountability and expectations for local supervision of clinical practices in the endoscopy suite and the absence of a regional program that included endoscopy, and which should have introduced review of current practices with comparison to standardized best practices, supported the perpetuation of the practice under review. Historically, other single-use devices had been re-used in the High Prairie Health Complex without consequence from an administrative perspective. Lack of integration of infection prevention and control, quality, safety, and clinical risk management resulted in a fragmented approach to overall quality and safety and further increased the likelihood that high risk activities such as re-use of single use devices would not have been identified and broadly examined.

The lack of recognition that the syringes were single use devices implies a misinterpretation of the Alberta Health & Wellness *Standards for Single-use Devices (D2-2008)*.

Lastly, the 2007 Canadian Society of Anesthesia guidelines are vague on the re-use of syringes. When the College of Physicians and Surgeons of Alberta issued a memo October 28, 2008 to its members advising them of the risk of re-use of syringes, the supportive information relied on the 2002 American Society of Anaesthesiologists Recommendations for Infection Control for the Practice of Anaesthesiology (Second Edition).

The four root causes generated 12 recommendations. Twelve contributing factors that reflected weaknesses in the system and facilitated the practice to continue for a significant timeframe yielded 24 recommendations. The recommendations identify broad scope opportunities for improvement in infection control, quality and patient safety that are applicable throughout the health care system on a local, provincial, national and even international basis. While specific operational changes are targeted at the High Prairie Health Complex and the AHS – PCH, many of the recommendations are directed at provincial and national health care organizations as well as manufacturers of patient care supplies.

It is hoped this report will inform the Alberta Health Ministry of the systemic factors that allowed an unacceptable practice to be integrated into patient care and the means to ensure discontinuation of the practice and monitoring of changed practice across the province. Optimistically this report will provide greater insight into practices regarding syringe use and others that can improve patient safety and health care quality.

[1] Kantor G and Chung F. Anesthesia drug cost, control and utilization in Canada. *Can J Anaesth* 1990;43(9-16)
[2] Tait AR and Tuttle DB .Preventing Perioperative Transmission of Infection: A Survey of Anaesthesiology Practice. *Anesth Analg* 1995;80:764-9.
[3] Ryan AJ *et al.* A national survey of infection control practice by New Zealand anaesthetists. *Anaesth Intensive Care* 2006;34:68-74.
[4] "Nurse" or "nurses" refers to Registered Nurse(s) unless otherwise stated

Introduction and Context

On October 2, 2008, at the High Prairie Health Complex, it was identified to Alberta Health and Wellness that single-use syringes were commonly loaded with multiple doses of medication and administered through IV tubing to multiple patients throughout a single day in the endoscopy suite and recovery room. This practice had been occurring since 1990 in the High Prairie Health Complex recovery room for dental procedures and since 2004 in the endoscopy suite. There is a risk that blood borne pathogens which include Hepatitis B, Hepatitis C and Human Immunodeficiency Virus (HIV) may be transmitted with this practice. As a result, a look back process was implemented by Alberta Health Services to identify the risk and to alert patients who may be at risk.

In accordance with the Health Quality Council of Alberta Regulation 130/2006 of the *Regional Health Authorities Act,* Section 13, the Minister of Alberta Health and Wellness requested the Health Quality Council of Alberta (HQCA) to assess and inquire into the practice cited above, and as identified in the High Prairie Health Complex endoscopy suite and recovery room and relevant areas as agreed to by the HQCA and Alberta Health and Wellness (AHW). The HQCA was charged with identifying cause(s) and contributing factors that led to the practice of using the same single-use syringe for administration of medication to multiple patients and to develop recommendations to ensure these were addressed to improve future patient safety and health quality at the High Prairie Health Complex and the Alberta Health Services - Peace Country Health. The HQCA was also to identify national and international standards, guidelines and best practices for utilization of single-use devices related to medication administration.

A review team was struck by the HQCA, under the direction of Dr. John Cowell, MD, FRCPC, Chief Executive Officer, and led by Linda Poloway, BScPharm, FCSHP, Patient Safety Lead, HQCA. The balance of the Review Team consisted of three individuals experienced in reviewing critical incidents and with expertise in the areas of infection prevention control, patient safety, and quality; Denise Sorel, BScN, RN, CIC, Infection Preventionist, Regional IPC Director, Alberta Health Services- East Central Health, Dr. Tony Taylor, MD FRCP MBA, and Dr. Robert Burns, BSc MD were selected.

Information gathering, fact finding and validation as well as discovery of cause and contributing factors were conducted under the auspices of the Quality Assurance Committee of the HQCA and were protected under Section 9 of the *Alberta Evidence Act.* While the object of the review was the High Prairie Health Complex, it was necessary to involve members from the Alberta Health Services – Peace Country Health (AHS – PCH) and review regional processes that impacted the High Prairie Health Complex.

The incident was reviewed with full transparency provided by the administration and staff of the High Prairie Health Complex and the AHS – PCH; candid and open dialogue on use of single-use syringes and other patient safety topics relevant to the incident allowed the Review Team to examine all causal and incidental issues and provide a comprehensive report. The commendable participation in the review of individuals from the High Prairie Health Complex and the AHS – PCH is reflective of the region's clear commitment to improving patient safety and enhancing their patient safety culture.

The objectives of the review were to:

1. Identify the factors which led to the practice identified in the High Prairie Health Complex Recovery Room, Endoscopy Suite, and other relevant areas, involving re-use of a single-use syringe utilizing numerous methodologies including but not limited to review of relevant documents, interviews with staff and patients, review of environments where the incident occurred and re-enactment of work processes relevant to this incident.

2. Utilize a root cause analysis process, if appropriate, to identify the contributing factors and root cause(s) that led to the practice involving re-use of a single-use syringe.

3. Identify national and international standards, guidelines and best practices for use of single-use devices related to medication administration to multiple or single patients.

4. Make recommendations to ensure the contributing factors and root cause(s) of the practice are addressed and to improve future patient safety and health quality at the High Prairie Health Complex and the Peace Country Health Region.

5. Upon agreement with Alberta Health and Wellness, share findings and recommendations with other health care institutions within the province and across Canada.

Root Cause Analysis – An Overview of the Process

As defined in the Canadian Root Cause Analysis Framework[5], root cause analysis is "an analytical tool which can be used to perform a comprehensive, system based review of critical incidents. It includes the identification of the root and contributory factors, determination of risk reduction strategies, and development of action plans along with measurement strategies to evaluate the effectiveness of the plans".

A multi-disciplinary root cause analysis team is established involving individuals with firsthand knowledge of the subject as well as higher level authority and responsibility in the matter. It is optimal to involve individuals with decision making ability in order to facilitate implementation of the recommendations once the analysis is completed.

The Root Cause Analysis (RCA) team first blueprints the events in chronological order to establish facts surrounding the issue. Questions asked are, "what happened", "why did it happen", and "what can we do to prevent it from happening again". The "why" questions result in a series of cause and effect diagrams that identify numerous causes and contributing factors. Those contributing factors and causes are prioritized and the root cause is identified by answering the following question: "If you eliminate or control this cause will you prevent the event from recurring?" In some cases, there is more than one root cause. Causative statements are then developed that show cause and effect relationship and are worded to identify systemic contributing factors. Systemic issues move beyond the individuals involved in the incident and examine safety culture, the working environment, communication between health care providers and the patient, fatigue and scheduling of health care workers, training and education of health care providers and compliance to policies and procedures. Recommendations for action evolve from the causative statements and attempt to incorporate strategies that include strong interventions. A hierarchy of actions (see Figure 1) supports use of strong actions that would eliminate the event from recurring; an example would be a forcing function that utilizes physical barriers to prevent error and provides alarms when a wrong procedure is attempted. Issuing of a memo requesting practice change would be an example of a least effective type of intervention. Changing organizational structure to support patient safety would constitute an action that would reduce the likelihood of recurrence of the event but not eliminate it.

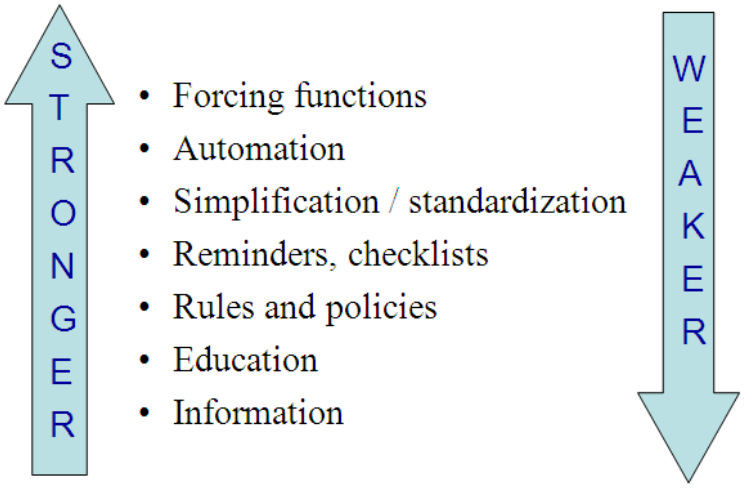


Figure 1. Hierarchy of Action

All activities of the RCA including development of causes, contributing factors and recommendations are arrived at by consensus of the RCA team.

[5] Canadian Root Cause Analysis Framework, Canadian Patient Safety Institute, 2006.

Methodology

The review was conducted in the following phases:

a) Off-site preparation and information gathering
b) Individual interviews
c) On-site review of operating room, endoscopy suite, and recovery room and re-enactment of syringe use
d) Root cause analysis (RCA) team meetings to validate facts, identify causes and contributing factors and concurrent information gathering
e) Continued off-site information gathering and the analysis of the RCA information
f) Development of recommendations
g) RCA team review and sign off of report

Objectives a) to e) above were conducted under the auspices of the Quality Assurance Committee of the Health Quality Council of Alberta (HQCA) and were protected under Section 9 of the *Alberta Evidence Act.* Development of recommendations and sign off of report [objectives f) and g)] occurred outside the quality assurance arena.

a) Off-site preparation and information gathering

Relevant documents were provided by the High Prairie Health Complex and Alberta Health Service – Peace Country Health (AHS – PCH) for review by the Review Team. These included but were not limited to:

- quality and safety framework and strategies
- quality reports
- quality and safety audits
- policies and procedures addressing infection prevention and control, quality and safety
- terms of reference and minutes from quality and safety committees
- accreditation report from Accreditation Canada
- accountability reports re: AHW directive on single use devices
- incident reports
- standing orders for surgery, endoscopy
- orientation guidelines for nursing in endoscopy, surgery, ambulatory care
- educational resources for nursing

Additional documentation reviewed included:

- standards and guidelines on use of syringes and other single-use devices
- standards and guidelines on anesthetic practice
- standards and guidelines on nursing practice as it relates to syringe use
- AHW directive and standard on accountability for infection prevention and control
- AHW directive and standard on single-use items

b) Individual interviews

Interviews were conducted with individuals ranging from direct care providers to senior executive positions as well as physicians to understand the commencement and evolution of the practice of using a single-use syringe for IV administration of medications to multiple patients in the operating, endoscopy and recovery rooms. Interviews provided additional insight into the procedures and practices, local and regional oversight for surgical and non-surgical processes and practices, infection prevention and control, quality and safety initiatives, resource utilization, and organizational culture.

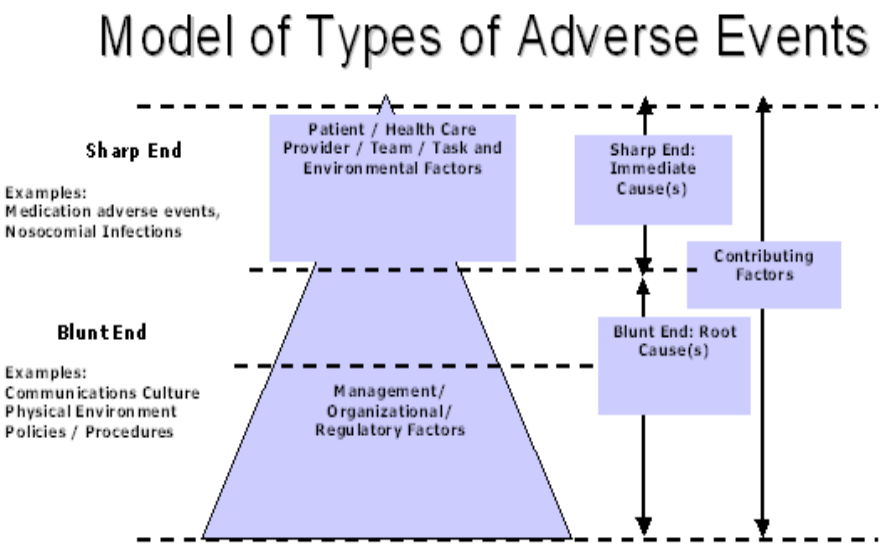
c) On-site review of operating room, endoscopy suite, and recovery room and re-enactment of syringe use

The Review Team examined the High Prairie Health Complex operating room, endoscopy suite, and recovery room noting that the endoscopy suite was not a separate functional area but a physical space within the operating room. While the recovery room was a separate entity, endoscopy patients were recovered in the Ambulatory Care area. To completely understand the practice of re-use of syringes, nursing staff were provided supplies they would have used in endoscopy and asked to re-create their processes.

d) RCA team meetings to validate facts, identify causes and contributing factors and concurrent information gathering

A root cause analysis was conducted with High Prairie Health Complex and AHS-PCH staff and management to identify root cause(s), contributing factors and recommendations; this group, added to the Review Team, formed the RCA team. Prior to embarking on the RCA process, the RCA facilitator provided just in time learning on a systems approach to investigation of adverse events, the elements of which are depicted in figure 2 below.

The point where healthcare services are provided to the patient, and the point where incidents are discovered, is referred to as the "sharp end" of the system. The "blunt end" of the system represents the broader management, organizational and regulatory factors involved in the system[6]. It includes such factors as policies and procedures, staffing patterns, physical plant, environmental structures, communication and culture. Figure 2 illustrates that it is not uncommon to find many root causes in the blunt end.



Adapted from: National Health Service, Department of Health & National Patient Safety Agency. (2001). *Doing Less Harm: improving the safety and quality of care through reporting, analysing and learning from adverse incidents involving NHS patients – key requirements for health care providers.* London: National Health Service.

Figure 2. Model of Types of Adverse Events

The systems approach, Swiss Cheese Model[6] was used to illustrate that adverse events rarely occur because of one failure, but occur because of multiple failures that are usually latent within the system[2]. In a well managed system, there are several layers of defense (quality and/or safety systems) represented by the slices of cheese. The holes in the cheese represent areas of weakness in the systems, some caused by active failure of individuals, others caused by latent conditions. These holes are continuously opening and closing and changing position. Serious danger occurs when a set of holes opens up briefly to allow a window of incident opportunity. The more protective the layers are, the safer is the system. The Swiss Cheese model has been used to explain how, despite quality and safety controls in place, errors occur resulting in adverse events (see Figure 3).

[6] Reason, J. Managing the Risks of Organizational Accidents, Aldershot: Ashgate; 1997

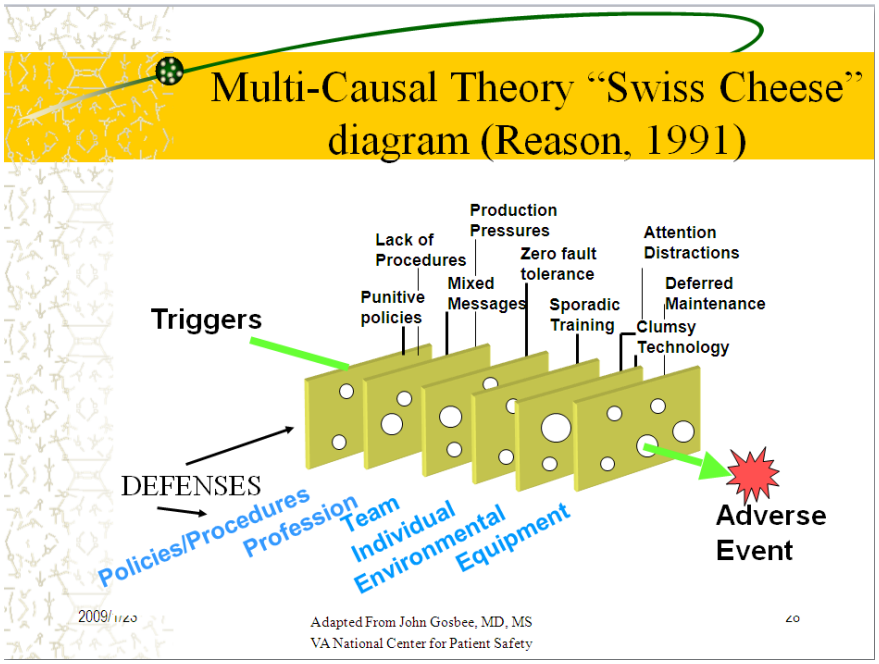


Figure 3 Swiss Cheese Model

The RCA team developed a flow chart of the events leading up to the incident, identified potential causes and fleshed out the supporting information around causes and contributing factors. Concurrently, the Review Team collaboratively identified and gathered information related to the activities of the RCA to depict a comprehensive understanding of the events, why they may have occurred and the significance of their impact. Where necessary and relevant, information from the individual interviews was shared with the RCA team and utilized appropriately. A series of cause and effect diagrams were developed by the RCA team to identify cause(s) and contributing factors.

e) Continued off-site information gathering and analysis of the RCA information

The Review Team developed causative statements based on the activities of the RCA team. Necessary clarifications were made using further interviews or reference to documentation. The information depicting history relevant to the practice of re-use of the single-use syringe, an understanding of endoscopy practices, a chronology of events leading up to identification of the practice as a deviation from an accepted standard, cause and effect diagrams, and causative statements were reviewed, verified and agreed to by the RCA team. At this point the quality assurance, protected process, ceased.

f) Development of recommendations

The Review Team drafted recommendations based on the information depicting history relevant to the practice of re-use of the single-use syringe, an understanding of endoscopy practices, a chronology of events leading up to identification of the practice as a deviation from an accepted standard, cause and effect diagrams, and causative statements.

g) RCA team review and sign off of report

At the last of three RCA meetings, the recommendations were reviewed, revised as necessary, and agreed to by the RCA team.

Causal statements in order of priority

Root Causes

I. Limited outside influences, external to the High Prairie Healthcare Complex, contributed to the continued practice of re-using the same single-use syringe for administering intravenous medications to multiple patients in the endoscopy suite.

II. The culture of autonomy present in the operating room, and in the endoscopy suite, isolated the operating room personnel and decreased the likelihood that the practice of re-using the same single-use syringe for administering intravenous medication to multiple patients would be recognized as being a departure from acceptable practice.

III. The culture of conformity in the operating room, supported by the value of conformity in surgical practices to ensure predictable outcomes, increased the likelihood that the practice of re-using the same single-use syringe for administering intravenous medication to multiple patients in the endoscopy suite would continue.

IV. The use of a single syringe for administering intravenous medication to multiple patients was practiced in anesthesia in the early 1990s and perceived to support a similar nursing practice. This increased the likelihood that the practice of re-using the same single-use syringe for administering intravenous medications to multiple patients would continue in the endoscopy suite.

Contributing Factors

1. The absence of clear authority and expectations for supervision of clinical practices in the endoscopy suite increased the likelihood that the practice of re-using the same single-use syringe for administering intravenous medication to multiple patients would continue.

2. Lack of a comprehensive nursing orientation and ongoing continuing education to endoscopy and operation room practices increased the likelihood that the practice of re-using the same single-use syringe for administering intravenous medications to multiple patients would occur.

3. The absence of a functional regional program that includes endoscopy, which might have generated audits of current practices and the development of standardized best practices, increased the likelihood that the practice of re-using the same single-use syringe for administering intravenous medications to multiple patients in the endoscopy suite would continue.

4. The strong influences present in the operating room, that continued to affect nursing practices in the endoscopy suite, increased the likelihood that any challenge to the practice of re-using the same single-use syringe for administering intravenous medications to multiple patients would be rejected.

5. The acceptance of the nursing practice of re-using the same single-use syringe for administering intravenous medications to multiple patients in the recovery room set a precedent for the acceptance of this same nursing practice in the endoscopy suite.

6. In the process of Regional Health Authority boundary changes in 2003, the lack of a coordinated transition process for the CLAVE® needlesafe system resulted in a local misunderstanding by some surgical nursing personnel that the CLAVE® system utilized a one-way valve and the risk of contamination was therefore minimized. This led to an increased likelihood that the practice of re-using the same single-use syringe for administering intravenous medications to multiple patients in the endoscopy suite would be considered acceptable.

7. Lack of a clear regional nursing education strategy led to an inconsistent approach to nursing education including but not limited to intravenous medication administration.

8. The lack of awareness and application (transfer of knowledge) of the Canadian Anesthesia Society Guidelines in 2007, coupled with the Guidelines' lack of specificity regarding reuse of syringes in anesthesia, increased the likelihood that the practice of re-using the same single-use syringe for administering intravenous medications to multiple patients in the endoscopy suite would go undetected.

9. The Alberta Health & Wellness *Standards for Single-use Devices (D2-2008)* referenced reprocessing of single-use devices as part of the directive not to re-use single use devices. This increased the potential that single-use syringes, (which are not intended to be reprocessed), would not be recognized as single-use devices and therefore not be subject to the standard.

10. Lack of structural integration of infection prevention and control, quality and safety and clinical risk management at the Regional level resulted in a fragmented approach to quality and safety that increased the likelihood that high risk activities would not be identified.

11. The historical practices of reprocessing and re-use of manufacturer labeled single-use devices (e.g. respiratory and anesthetic tubing) may have blunted the awareness of re-use of the syringe (as identified as a single-use device in the Alberta Health & Wellness directive) in multiple patients.

Root Causes, Contributing Factors and Recommended Actions

The recommended action statements, while aimed primarily at the High Prairie Healthcare Complex and the Alberta Health Services – Peace Country Health (AHS – PCH), may be applicable to other health care organizations. During the course of this review, a change in governance structure placed the former AHS – PCH into the North Zone, which included a larger geographical area and other health care facilities. The scope of the implementation of the recommendations will be determined by Alberta Health and Wellness and the Alberta Health Services (AHS).

The following systemic factors were considered in identification of the root causes:

HF-C = human factor, communication
HF – FS = human factor – fatigue, scheduling
HF-T = human factor, training
R = rules / policies / procedures
E = environment / equipment
B = barriers

Item #	Description	Category					
		HF-C	HF-T	HF-F/S	E	R	B
I	Limited outside influences, external to the High Prairie Healthcare Complex, contributed to the continued practice of reusing the same single-use syringe for administering intravenous medications to multiple patients in the endoscopy suite.	√	√		√	√	
II	The culture of autonomy present in the operating room, and in the endoscopy suite, isolated the operating room personnel and decreased the likelihood that the practice of reusing the same single-use syringe for administering intravenous medication to multiple patients would be recognized as being a departure from acceptable practice.	√	√		√	√	
III	The culture of conformity in the operating room, supported by the value of conformity in surgical practices to ensure predictable outcomes, increased the likelihood that the practice of reusing the same single-use syringe for administering intravenous medication to multiple patients in the endoscopy suite would continue.	√	√		√	√	
IV	The use of a single syringe for administering intravenous medication to multiple patients was practiced in anesthesia in the early 1990s and perceived to support a similar nursing practice. This increased the likelihood that the practice of reusing the same single-use syringe for administering intravenous medications to multiple patients would continue in the endoscopy suite.	√	√		√	√	

Root Cause #	Contributing Factor #	Action #	Causal Statements and Recommended Actions	Action E= eliminate C= control A= accept	Party Responsible	Timeline
I	Limited outside influences, external to High Prairie, contributed to the practice of reusing the same single-use syringe for administering intravenous medications to multiple patients in the endoscopy suite would continue.					
		IA	Nursing professionals undergo an annual review of intravenous medication preparation and delivery as part of a larger annual critical skills review program.	C		Long term
		IB	Persons working in the endoscopy suite and recovery room attend endoscopy CME activities on an annual basis.	C		Long term
II	The culture of autonomy present in the operating room, and in the endoscopy suite, isolated the operating room personnel and decreased the likelihood that the practice of reusing the same single-use syringe for administering intravenous medication to multiple patients would be recognized as being a departure from acceptable practice.					
		IIA	Implement a comprehensive, integrated regional program, responsive to the needs of patients and AHS – PCH, with a clearly defined structure, roles and responsibilities, authorities, reporting relationships and accountabilities for the clinical and administrative operations of the program.	**C**		Short Term
		IIB	Review the current clinical practices in AHS – PCH in endoscopy and recovery room and measure against "best practice" to identify opportunities for improvement.	C		Short term
		IIC	Incorporate appropriate "best practices" within the endoscopy suite and the recovery room at all sites.	C		Short term

Root Cause #	Contributing Factor #	Action #	Causal Statements and Recommended Actions	Action E= eliminate C= control A= accept	Party Responsible	Timeline
		IID	Regularly evaluate the clinical practices in the endoscopy suite and the recovery room against appropriate best practice indicators at all sites where relevant.	C		Long term
		IIE	Ensure timely availability of clinical expertise for endoscopy practices at each local site.	C		Long term
		IIF	Complete the revision and approval of the regional policy and procedure on single use devices to be consistent with the Alberta Health & Wellness directive for *Standards for Single-Use Devices (D2-2008)*. Policy to specify a clear definition of single-use devices that includes syringes.	C		Immediate
		IIG	Conduct an inventory of all critical, single-use devices (as per Alberta Health & Wellness definition) at all sites to clearly identify items subject to the single-use device policy.	C		Immediate
		IIH	Conduct an audit of the clinical practice use of all critical, single-use devices to ensure compliance to policy at all sites.	C		Short term
III	The culture of conformity in the operating room, supported by the value of conformity in surgical practices to ensure predictable outcomes, increased the likelihood that the practice of reusing the same single-use syringe for administering intravenous medication to multiple patients in the endoscopy suite would continue.					
		IIIA	Develop and implement a regional process to resolve practice discrepancies between professionals and professions as they relate to the provision of safe patient care.	C		Short Term

Root Cause #	Contributing Factor #	Action #	Causal Statements and Recommended Actions	Action E= eliminate C= control A= accept	Party Responsible	Timeline
		IIIB	See recommendations IIB- IIE.			
IV	The reuse of the same single-use syringe for administering intravenous medication to multiple patients was practiced in anesthesia in the early 1990s and perceived to support a similar nursing practice. This increased the likelihood that the practice of reusing the same single-use syringe for administering intravenous medications to multiple patients would continue in the endoscopy suite.					
		IVA	Alberta Health & Wellness (AHW), in collaboration with AHS, to consider the need to conduct a risk assessment of surgical and endoscopy cases dating back to the early 1990s and determine if a look back for Alberta patients is required based on risk assessment and likelihood that single-use syringes were used for administering intravenous medication to multiple patients.	C	AHW AHS	Immediate
	1	The absence of clear authority and expectations for supervision of clinical practices in the endoscopy suite increased the likelihood that the practice of reusing the same single-use syringe for administering intravenous medication to multiple patients would continue.				
		1a	Provide a comprehensive orientation including roles and responsibilities, accountabilities, and authority for clinical management of endoscopy service.	C		Long term
	2	Lack of a comprehensive nursing orientation and ongoing continuing education to endoscopy and operation room practices increased the likelihood that the practice of reusing the same single-use syringe for administering intravenous medications to multiple patients would occur.				
		2a	Develop and implement an educational strategy for nursing that supports front line nursing practice.			

Root Cause #	Contributing Factor #	Action #	Causal Statements and Recommended Actions	Action E= eliminate C= control A= accept	Party Responsible	Timeline
		2b	Ensure the development, implementation and evaluation of a comprehensive orientation strategy for nursing to support the needs of front line nurses and nurse managers in their area of practice.	C		Short term
		2c	Ensure each new employee has completed a comprehensive orientation program that includes but is not limited to an explanation of roles and responsibilities, requisite skills to deliver quality and safe patient care as well as good infection prevention and control practices.	C		Long term
	3	The absence of a functional regional program that includes endoscopy, which might have generated audits of current practices and the development of standardized best practices, increased the likelihood that the practice of reusing the same single-use syringe for administering intravenous medications to multiple patients in the endoscopy suite would continue.				
		3a	See recommendation IIA.			
		3b	Conduct an audit of endoscopy services in the region to assess adherence to current standards of infection prevention and control and address identified areas for improvement.	C		Short term
		3c	Strengthen the quality improvement focus of the clinical services teams (e.g. Regional Surgical Services Team and Regional Ambulatory Services Team) to support the rural needs of the Region.	C		Long term

Root Cause #	Contributing Factor #	Action #	Causal Statements and Recommended Actions	Action E= eliminate C= control A= accept	Party Responsible	Timeline
		3d	Ensure adequate representation and active participation from infection prevention and control, clinical risk management, quality and safety on the clinical services teams (e.g. Regional Surgical Services Team and Regional Ambulatory Services Team).	C		Long term
	4	The strong influences present in the operating room, that continued to affect nursing practices in the endoscopy suite, increased the likelihood that any challenge to the practice of reusing the same single-use syringe for administering intravenous medications to multiple patients would be rejected.				
		4a	See recommendation IIIA.			
		4b	See recommendations IIA – IIE.			
	5	The acceptance of the nursing practice of reusing the same single-use syringe for administering intravenous medications to multiple patients in the recovery room set a precedent for the acceptance of this same nursing practice in the endoscopy suite.				
		5a	See recommendations IIA – IIF inclusive.			
	6	In the process of Regional Health Authority boundary changes in 2003, the lack of a coordinated transition process for the CLAVE® needlesafe system resulted in a local misunderstanding by some surgical nursing personnel that the CLAVE® system utilized a one-way valve and the risk of contamination was therefore minimized. This led to an increased likelihood that the practice of reusing the same single-use syringe for administering intravenous medications to multiple patients in the endoscopy suite would be considered acceptable.				
		6a	Recognize the critical need and employ effective change strategies at the time of transition (e.g. boundary changes) to ensure continuous, safe and effective patient care.	C	AHS	Long term

Root Cause #	Contributing Factor #	Action #	Causal Statements and Recommended Actions	Action E= eliminate C= control A= accept	Party Responsible	Timeline
		6b	At the regional and site level, conduct a risk assessment and employ mitigation strategies to address the impact on quality and safety of patient care at times of major system changes.	C		Long term
		6c	Employ a coordinated approach to system changes that are implemented across AHS – PCH.	C		Long term
		6d	Provide coordinated education utilizing a standardized approach and materials in implementing system and product changes across AHS – PCH.	C		Long term
		6e	Develop a regional policy related to vendors' access to staff and patient care areas and identify criteria vendors must meet to conduct business within the organization.	C		Short term
	7	Lack of a clear Regional nursing education strategy led to an inconsistent approach to nursing education including but not limited to intravenous medication administration.				
		7a	See recommendation 2a.	C		Long term
		7b	Undertake a review of the adequacy of nursing educational resources and their effectiveness at all sites.	C		Long term
		7c	Based on the review of the current educational resources develop a strategy to provide appropriate educational resources for nursing.	C		Long term

Root Cause #	Contributing Factor #	Action #	Causal Statements and Recommended Actions	Action E= eliminate C= control A= accept	Party Responsible	Timeline
		7d	Conduct audits of compliance to the regional parenteral therapy guidelines for the administration of procedural sedation.	C		Short term
	8	The lack of awareness and application (transfer of knowledge) of the Canadian Anesthesia Society Guidelines in 2007, coupled with the Guidelines' lack of specificity regarding reuse of syringes in anesthesia, increased the likelihood that the practice of reusing the same single-use syringe for administering intravenous medications to multiple patients in the endoscopy suite would go undetected.				
		8a	Audit current practices of administration of intravenous medications in all sites to ensure that one single-use syringe is not used for the administration of medications to multiple patients.	C		Immediate
		8b	Professional colleges, professional regulatory bodies and professional associations to examine the effectiveness of the distribution of standards and guidelines to their membership and the impact on their practice.	C	CPSA CARNA ACP CLPN	Short term
		8c	Regional administration to determine and implement a robust and consistent process to ensure standards of practice are known and complied with within the appropriate clinical services.	C		Long term
	9	The Alberta Health & Wellness *Standards for Single-use Devices (D2-2008)* referenced reprocessing of single-use devices as part of the directive not to re-use single use devices. This increased the potential that single-use syringes, (which are not intended to be reprocessed), would not be recognized as single-use devices and therefore not be subject to the standard.				

Root Cause #	Contributing Factor #	Action #	Causal Statements and Recommended Actions	Action E= eliminate C= control A= accept	Party Responsible	Timeline
		9a	At the time of development of standards/directives, facilitate clarity and user comprehension by addressing one issue at a time.	C	AHW	Long term
		9b	Request that AHS conduct an inventory of critical, single-use devices to develop a provincial list that is not necessarily exhaustive but robust.	C	AHW	Short term
		9c	AHW to distribute the findings of the inventory to all hospitals and care facilities (public and private) within the province to ensure awareness of critical, single-use devices in use.	C	AHW	Short term
		9d	Request that AHS conduct an audit of all critical, single-use devices to ensure compliance with the directive and *Standards for Single-use Devices (D2-2008)*.	C	AHW	Short term
		9e	In standards/directives development, test drafts on user groups to ensure clear, consistent interpretation and understanding of the content before issuing final standard or directive.	C	AHW	Short term
	10	Lack of structural integration of infection prevention and control, quality and safety and clinical risk management at the regional level resulted in a fragmented approach to quality and safety that increased the likelihood that high risk activities would not be identified.				

Root Cause #	Contributing Factor #	Action #	Causal Statements and Recommended Actions	Action E= eliminate C= control A= accept	Party Responsible	Timeline
		10a	Incorporate quality safety, infection prevention control and clinical risk management into a reporting and accountability structure that is integrated, reports to a single senior manager or executive and has appropriate accountability and authority at the executive level of the AHS – PCH organization.	C		Short term
	11	The historical practices of reprocessing and re-use of manufacturer labeled single-use devices (e.g., respirator and anesthetic tubing) may have blunted the awareness of re-use of the syringe (as identified as a single-use device in the Alberta Health & Wellness directive) in multiple patients.				
		11a	See recommendations IIA – IID inclusive.			
		11b	See recommendations IIG and IIH.			

Summary

This review was conducted with full, transparent participation from the staff, physicians and management of the High Prairie Health Complex and Alberta Health Services – Peace Country Health (AHS-PCH) who consistently demonstrated a commitment to improve patient safety and healthcare quality. The findings and recommendations were collaboratively developed and validated with the Root Cause Analysis (RCA) Team consisting of High Prairie and AHS-PCH personnel and the Review Team.

It is hoped this report will inform the Alberta Health Ministry of the systemic factors that allowed an unacceptable practice to be integrated into patient care and the means to ensure discontinuation of the practice and monitoring of changed practice across the province. Optimistically this report will provide greater insight into practices regarding syringe use and others that can improve patient safety and health care quality.

Appendix – Glossary

ACP	Alberta College of Pharmacists
AHS	Alberta Health Services
AHW	Alberta Health and Wellness
Alberta Evidence Act	**(www.qp.gov.ab.ca/Documents/acts/A18.CFM)** Section 9 of the Alberta Evidence Act addresses situations involving "quality assurance activity". This activity means a planned or systematic activity the purpose of which is to study, assess or evaluate the provision of health services with a view to the continual improvement of the quality of health care or health services, or the level of skill, knowledge and competence of health service providers. Quality assurance committee means a committee, commission, council or other body that has as its primary purpose the carrying out of quality assurance activities and that is appointed by a number of named bodies, including as of July 1, 2006, the Health Quality Council of Alberta.
CARNA	College & Association Of Registered Nurses of Alberta
CLPNA	College of Licensed Practical Nurses of Alberta
Contributing factor	The reason(s), situational factor(s), or latent condition(s) that played a role in the genesis of an adverse outcome. From Royal College of Physicians and Surgeons, Canadian Patient Safety Dictionary, October 2003
CPSA	College of Physicians and Surgeons of Alberta
CSR	Central Sterilization Room
HQCA	Health Quality Council of Alberta
Incident	Events, processes, practices, or outcomes that are noteworthy by virtue of the hazards they create for, or the harms they cause, patients From Royal College of Physicians and Surgeons, Canadian Patient Safety Dictionary, October 2003
IPC	Infection Prevention and Control
IV	Intravenous Medications
Look back	When a risk of transmission of blood borne pathogens has been identified as a consequence of procedures, the organization having performed these procedures contacts the patients at risk to give advice about testing and potential treatment and to discuss methods of further transmission with those found to be infected
OR	Operating Room

Patient safety	The reduction and mitigation of unsafe acts within the health care system, as well as through the use of best practices shown to lead to optimal patient outcomes *From Royal College of Physicians and Surgeons, Canadian Patient Safety Dictionary, October 2003*
PCH	Peace Country Health Region
RHAs	Regional Health Authorities
Root cause analysis	An analytical tool that can be used to perform a comprehensive, system based review of critical incidents. It includes the identification of the root and contributory factors, determination of risk reduction strategies, and development of action plans along with measurement strategies to evaluate the effectiveness of the plan *From Canadian Root Cause Analysis Framework, Canadian Patient Safety Institute, 2006*
Safety Culture	The product of individual and group values, attitudes, perceptions, competencies, and patterns of behaviour that determine the commitment to, and the style and proficiency of an organization's health and safety management. Organizations with a positive safety culture are characterized by communications founded on mutual trust, by shared perceptions of the importance of safety and the efficacy of preventative measures. From Advisory Committee on the Safety of Nuclear Installments 1993:23 published in: Fleming, M. Patient Safety Culture Measurement and Improvement a "How To" Guide. *Healthcare Quarterly* Vol. 8, Special Issue, October 2005.

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