July 2007

HQCA
Health Quality Council of Alberta

REVIEW

of the Infection Prevention and Control and CSR Sterilization Issues in East Central Health Region

A Message to East Central Health, including all the Voluntary facilities

The Investigative Team would like to thank all the individual staff, managers, administrators and physicians from East Central Health Region (ECH), including St. Joseph's General Hospital (SJGH), who gave of their time to meet with us and share their perspectives on the focus of this particular report, that of looking at the events leading up to the MOH Order of March 16 resulting in the closure of admissions to SJGH. Of special note, the Root Cause Analysis (RCA) Team members committed several days from busy schedules to complete that part of the review, and their honesty, active participation, and desire to make the process work was very much appreciated.

It is not easy to have the microscope of patient safety focused on one's activities and even harder to pay particular attention to those areas requiring improvement. Your compassion for the patients you serve and desire to provide the best care possible have not gone unnoticed. Hopefully this report will be a constructive tool to provide a catalyst for discussion, about how you, and others, can find ways to improve the services you provide. It is the shared desire of wanting to continually make the health care system, and certainly safer, ultimately providing better care for the patients and families being served, that drives all of us to participate in reviews such as this.

Thank you for your involvement, and may the report serve to further heighten the importance of patient safety as a shared goal and your role in achieving that goal.

Sincerely,

John Cowell, MD
Chief Executive Officer, HQCA

Linda Poloway, Project Lead

Arlene Weidner, Team Member

David S. Matheson, MD, Team Member

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Review of the Factors that Led to the Enactment of the Medical Officer of Health Order of March 16, 2007

1. Executive Summary

On March 16, 2007 the East Central Health (ECH) Region Medical Officer of Health issued an Order affecting St. Joseph's General Hospital (SJGH), Vegreville, which closed the Central Sterilization Room (CSR) and ordered that admissions of inpatients cease. The action was based on a) evidence of inadequately sterilized medical equipment and b) an inability to contain the ongoing spread of Methicillin Resistant *Staphylococcus aureus* (MRSA). Immediate action was taken that included closure of the CSR, enhanced containment strategies to manage the MRSA, establishment of criteria to be complied with before re-admissions could occur, a look back process to determine if any patients who had undergone surgery or other procedures had been infected with Hepatitis B, Hepatitis C and/or Human Immunodeficiency Virus (HIV), and initiation of a chart audit to assess evidence of adverse events in patients linked with CSR sterilization or MRSA transmission.

Alberta Health and Wellness (AHW) requested that the Health Quality Council of Alberta (HQCA) conduct a review of the underlying causes and contributing factors of the SJGH closure, and further, to assess other East Central Health sites with respect to infection prevention and control (IPC) and CSR practices. In addition, AHW appointed an interim Board of Management to be responsible for the operation and administration of SJGH for at least a six month period.

An Investigative Team was struck by the HQCA, under the direction of Dr. John Cowell, CEO, consisting of three individuals experienced in the area of patient safety and quality and an Expert Advisory Panel with expertise in CSR and infectious diseases. All activities of the Investigative Team and Expert Advisory Panel were conducted under the auspices of the Quality Assurance Committee of the HQCA and were protected under Section 9 of the *Alberta Evidence Act*.

Part 1 of the investigation used interviews and a root cause analysis (RCA) process to identify the factors and root causes leading up to the MOH Order, and make relevant recommendations addressing the IPC and sterilization issues at SJGH, ECH and the provincial health system.

Part 2 assessed the adequacy and appropriateness of response to the Order by SJGH, ECH and AHW through interviews, observations and analysis of documentation. Part 3 of the final report and investigation reviewed all acute care facilities operated by ECH (both Voluntary and Non-Voluntary facilities) in terms of infection prevention and control procedures and practices and risk management, and was completed through visits to all 11 acute care facilities within ECH with a focus on the operation of the CSR. Recommendations relevant to ECH and the provincial health system are made.

The issuing of the MOH Order of March 16, 2007 was not the result of a single cause but a combination of factors, which together culminated in the Order. The root causes of both the CSR closure and the lack of containment of MRSA were found in legislation and Agreements that governed the operations of the ECH Region and SJGH. The primary cause originated in the Master Agreement and the Regional Health Authorities Act, which granted final authority to both the Voluntary facilities and the Regional Health Authority respectively. Remaining consistent with the HQCA mission 'to promote patient safety and health service quality on a provincewide basis', and using that as the lens to view the current situation, it is necessary to ensure appropriate authoritative leadership for patient safety. The current ambiguity related to final authority that exists within the Master Agreement and the RHA Act, has allowed unsafe practices to continue and **must be addressed immediately by AHW**.

Using a cause and effect diagramming process, the RCA team identified 19 additional contributing factors that contributed to the inappropriate sterilization of medical equipment in the CSR and inability to contain the MRSA transmission in SJGH. The following categories of causal factors are addressed:

- impact of relationships between ECH and SJGH on operations, quality and safety
- clarity of authority, accountability, and responsibility of each organization and its management

- organizational structure and processes to support safety and quality
- deeply engrained cultures that affect current operations and relationships
- communication within the region and its communities
- patient safety culture and impact on planning, operations, decision-making
- application and implementation of best practices, standards, policies and procedures and mechanisms to ensure compliance of same
- processes to define expectations and evaluate knowledge, competency and skills
- support of continuing education, training and professional development
- engagement of physicians in safety and quality
- duty to act on knowledge and appreciation for the significance of deficiencies in infection prevention and control and sterilization
- equipment and physical plant limitations
- human resource requirements for effective infection prevention and control
- provincial leadership for infection prevention and control
- role of and educational requirements for the board members especially in patient safety and quality leadership

A total of 76 recommendations are made that impact SJGH, ECH, AHW and Alberta Catholic Health Corporation. The recommendations identify broad scope opportunities for improvement in system safety and quality with a focus on infection prevention and control throughout the health care system. Specific operational changes are directed at SJGH and ECH to ensure safeguards and safety enhancements. Two associated findings that do not carry a causal link to the MOH Order are presented.

It is critical that ECH and SJGH collaborate to develop a structure and process to oversee the implementation of these recommendations, use outcome measurements to monitor progress, and implement an audit process to ensure continued compliance to new practices and processes.

2. Introduction and Context

On March 16, 2007 the East Central Health Region Medical Officer of Health issued an Order affecting SJGH, Vegreville, which closed the Central Sterilization Room (CSR) and ordered that admissions of inpatients cease. The Order was issued based on reason to believe that "inadequately sterilized medical equipment has been and continues to be used in SJGH, thereby potentially exposing patients to blood-borne pathogens", and that there were concerns that "measures required to control the ongoing spread of Methicillin Resistant *Staphylococcus aureus* (MRSA) in acute care patients in care at St. Joseph's General Hospital have not been implemented effectively", and that "inadequate supervision of staff and processes related to communicable disease control may have resulted in an increased risk to patients of contracting infectious diseases while in care at St. Joseph's General Hospital".

The Order of March 16, 2007 mandated that:
With regard to the Central Sterilization Room (CSR) at St. Joseph's General Hospital:

- The CSR was to be shut down until further notice.
- All equipment and instruments previously processed in the CSR from use in the hospital or elsewhere were to be removed.
- No further admissions of patients were to be accepted until it could be verified that adequate infection prevention control measures were being maintained consistently.
- Full co-operation with the East Central Health Authority Medical Officer of Health or designate(s) was to be demonstrated in the investigation to identify hazards, identify persons who are or have been potentially affected and to implement interventions required to minimize harm to patients.

With regard to the ongoing spread of Methicillin Resistant *Staphylococcus aureus* (MRSA) at St. Joseph's General Hospital:

- Control measures to limit MRSA transmission were to be implemented. Measures were to be defined after an on-site assessment by the Medical Officer of Health or designate(s).
- No further admissions of patients were to be accepted until it could be verified that adequate infection prevention control measures were being maintained consistently.

- Surveillance measures were to be implemented to confirm the effectiveness of the interventions.

On March 22, 2007 the Minister of Health, Alberta Health and Wellness requested the Health Quality Council of Alberta (HQCA), an independent organization legislated under the Regional Health Authorities Act and whose mission is to promote patient safety and health service quality on a provincewide basis, to investigate the situation. The HQCA was charged with identifying issues and concerns related to infection prevention and control (IPC) as stated in the Medical Officer of Health (MOH) Order of March 16, 2007 and to make recommendations for their resolution in the context of the dimensions of quality identified in the Alberta Quality Matrix for Health. Acceptability, accessibility, appropriateness, effectiveness, efficiency and safety make up the Alberta Quality Matrix providing a common language, understanding and approach for discussing quality among health care organizations, professionals, and other stakeholders.

An Investigative Team, under the direction of Dr. John Cowell, CEO, was struck by the HQCA consisting of Project Lead, Linda Poloway, BScPharm, FCSHP, Patient Safety Co-ordinator in the David Thompson Health Region, Arlene Weidner, RN, M.Sc., CHE, a nurse consultant in health care and health systems, and David Matheson B.Sc., M.Math, MD, FRCP(P), a physician consultant in patient safety and quality, and with access to an Expert Advisory Panel as required. All activity of the Investigative Team and Expert Advisory Panel was conducted under the auspices of the Quality Assurance Committee of the HQCA and was protected under Section 9 of the *Alberta Evidence Act*.

The following objectives for the Investigative Team were identified by Alberta Health and Wellness:

a) Identify the factors impacting IPC at St. Joseph's Hospital that led up to the Medical Officer of Health Order to St. Joseph's Hospital dated March 16, 2007.

b) Assess the adequacy and appropriateness of the response by St. Joseph's Hospital, East Central Health Region and Alberta Health and Wellness to the identified infection prevention and control issues outlined in the MOH Order.

c) Make recommendations to ensure the contributing factors and root cause(s) of infection control practices identified, including transmission of MRSA, are addressed within the St. Joseph's General Hospital, the East Central Health Region and the provincial health system.

d) Review all facilities operated under contract (Voluntaries) within the East Central Health Region, as well as facilities operated by East Central Health, in terms of infection prevention and control procedures, practices and risk management.

Using individual and small group interviews and a root cause analysis (RCA) process, the team addressed objectives a) and c) (with emphasis on St. Joseph's General Hospital); this part of the findings will be presented in Part 1 of the final report. Objective b) is presented in Part 2 and was developed through the use of interviews, observations and analysis of documentation. Part 3 of the report also addresses objective c) with emphasis on the East Central Health Region, as well as objective d) through visits to all 11 acute care facilities within East Central Health with a focus on the operation of the CSR and review of infection prevention and control activities in a patient care area. Findings and recommendations were made on the basis of observation, and information provided verbally and in written form and are presented in Part 3 of the final report.

This section of the report summarizes the results of the root cause analysis, a structured process for performing a comprehensive, system based review of an event with the goals of determining what happened, why it happened and what can be done to reduce the likelihood of that event occurring again.

3. Objectives of the Root Cause Analysis (RCA)

The objectives of the RCA were to:

a) Identify the factors and root cause(s) that led to the Medical Officer of Health Order to close the CSR, remove all equipment and instruments previously processed by the CSR, and accept no further admissions of patients until adequate infection prevention control measures could be demonstrated.

b) Make recommendations to ensure the contributing factors and root cause(s) of infection control practices identified, including transmission of MRSA, are addressed within the St. Joseph's General Hospital, the East Central Health Region and the provincial health system.

4. Root Cause Analysis – An Overview of the Process

As defined in the Canadian Root Cause Analysis Framework[1], root cause analysis is "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 plans."

A multi-disciplinary root cause analysis team is established involving individuals with first hand 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 RCA team first blueprints the events in chronological order to establish facts surrounding the issue. Throughout this process, the team repeatedly asks "why" or "what is the significance" of the event, resulting in a series of cause and effect diagrams that identify numerous causes and contributing factors. Those contributing factors and causes are prioritized and 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. Recommendations for action evolve from the causative statements and attempt to incorporate strategies that include strong interventions. Actions that would eliminate the event from recurring include forcing functions with physical plant changes or changing legislation that governs practice. Changing, for example, organizational structure would constitute an action of control that would reduce the likelihood of recurrence of the event but not eliminate it. On rare occasion, recommendations may accept the deficiencies that exist and agree to accept the risk knowing that they exist.

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

5. Methodology

The review was conducted in five phases:

a) Off-site preparation and information gathering

b) Individual interviews

c) RCA team meetings and concurrent information gathering

d) Continued off-site information gathering applied in the analysis of the RCA information and development of recommendations and actions

e) RCA team review and sign off on report

a) Off-site preparation and information gathering

Relevant documents were provided by East Central Health (ECH) and St. Joseph's General Hospital (SJGH) for review by the Investigative Team. These included but were not limited to:

- legislative and contractual agreements governing the operation of health care facilities within ECH*
- documentation describing the MRSA issues and attempts to contain its transmission in SJGH
- documentation describing the operation of the CSR at SJGH, its deficiencies and actions to improve quality
- documents addressing quality and safety activities, with focus on infection prevention and control in ECH*

*Includes Voluntary facilities within ECH

b) Individual interviews

Interviews were conducted with individuals in the following positions:

Position	ECH	SJGH	ACHC
Chief Executive Officer	●		
Medical Officer of Health	●		
Director Health Services*	●		
Vice President Operations	●		
Board Member	●		
Infection Prevention Control Co-ordinator	●		
Chief Corporate Services Officer	●		
Chief Nursing Officer	●		
Vice President Medicine	●		
Surgical Program Lead	●		

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

Position	ECH	SJGH	ACHC
Regional Manager, Materiel Management	●		
Interim Director of Nursing		●	
Board Chair		●	
Board Member		●	
Co-CEOs		●	
Retired CEO		●	
Previous Director of Nursing**		●	
Staff Nurse and IPC Site Investigator		●	
Charge Nurse		●	
Interim Management Board Members		●	
Materiel Manager		●	
CSR Processor		●	
Pharmacy Manager		●	
Chief of Medical Staff		●	
Interim Chief Executive Officer		●	
Chief Executive Officer			●
Board Chair			●

ECH – East Central Health
SJGH – St. Joseph's General Hospital
ACHC – Alberta Catholic Health Corporation

* Director Health Services – new position of May 7, 2007 held by previous Director, Acute Care (ECH)

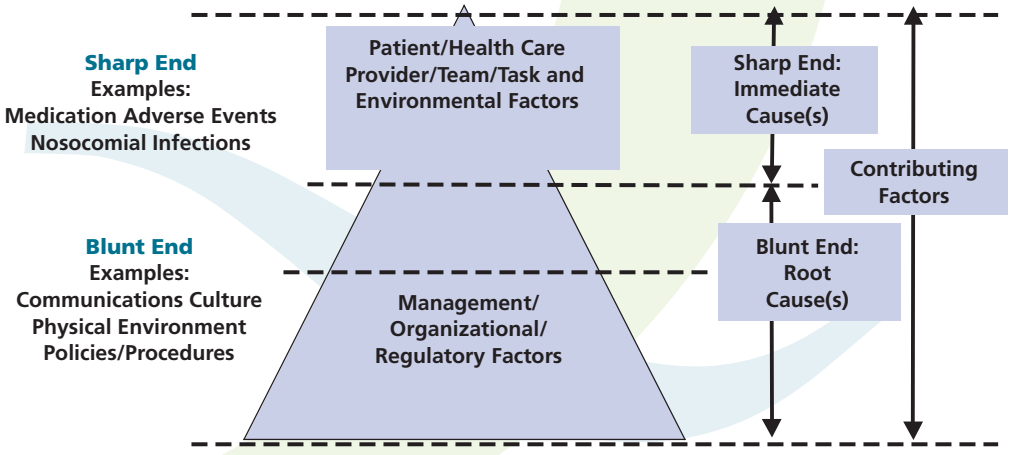
** SJGH previous Director of Nursing also served as co-CEO

c) RCA team meetings and concurrent information gathering

To ensure optimum input of the experience and expertise of local staff, a root cause analysis (RCA) was conducted with SJGH and ECH staff and management to identify root cause(s), contributing factors and recommendations; this group formed the RCA team. Prior to embarking on the RCA process, the RCA facilitator provided fundamental information on a systems approach to investigation of adverse events, the elements of which are depicted in the diagram below.

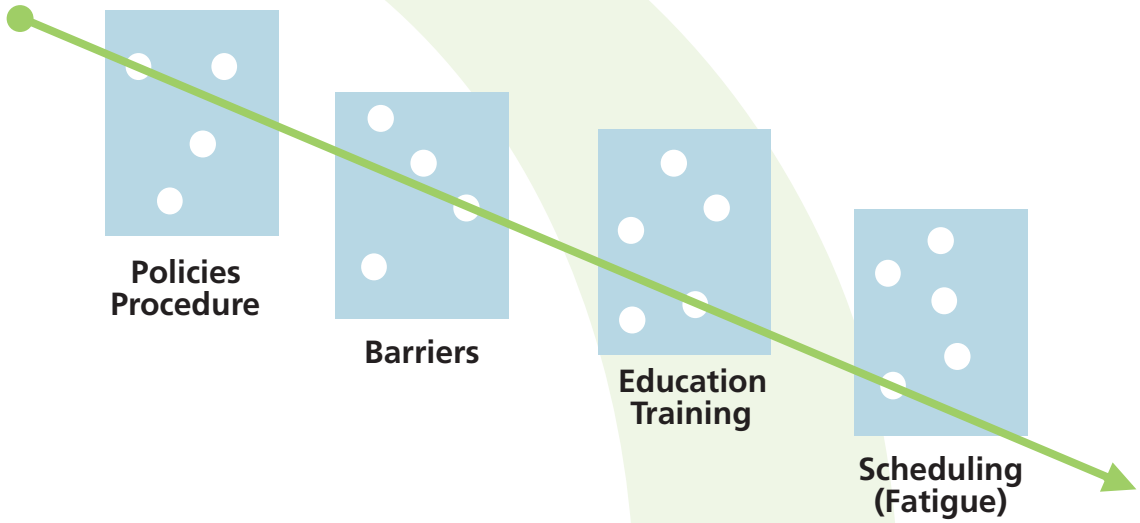
The point where health care services are provided to the patient, and the point where incidents are discovered, is referred to as the "sharp end" of the system. The "blunt end" of the system represents the broader management, organizational and regulatory factors involved in the system[1]. It includes such factors as policies and procedures, staffing patterns, physical plant, environmental structures, communication and culture. The diagram illustrates that it is not uncommon to find that many root causes are found in the blunt end.

Model of Types of Adverse Events



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.

The systems approach, Swiss Cheese Model 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 represented by the slices of cheese. In reality, there are holes in the layers, 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 the system.



[2] Reason, J. Managing the Risks of Organizational Accident, Aldershot: Ashgate 1997.

The RCA team was comprised of:

Name	Role	Position
Poloway, Linda	RCA Facilitator	HQCA Investigative Team Project Lead
Kraft, Evelyn	RCA Team Member	ECH Director Health Services
Johnson, Margaret	RCA Team Member	SJGH IPC Site Investigator, Staff Nurse
Matheson, Dr. David	RCA Team Member	HQCA Investigative Team
Melenka, Jo-Ann	RCA Team Member	SJGH Acute Care Nurse Manager
Olineck, Orest	RCA Team Member	ECH Board Member
Roach, Carole	RCA Team Support*	Executive Assistant to ECH CEO
Sorel, Denise	RCA Team Member	ECH Infection Prevention Control Co-ordinator
Stevenson, Brian	RCA Team Member	ECH Chief Corporate Services Officer
Weidner, Arlene	RCA Team Member	HQCA Investigative Team
Wilson, Ruby	RCA Team Member	SJGH Board Member
Wolbeck, Janet	RCA Team Member	ECH Surgical Program Lead

*Provided administrative support; did not actively participate in RCA.

The team met for three days to develop a flow chart of the events leading up to the MOH Order of March 16, 2007, identify potential causes and flesh out the supporting information around causes and contributing factors. Concurrently, the Investigative Team collaboratively identified and gathered information related to the activities of the RCA team 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.

d) Continued off-site information gathering and development of causes, contributing factors and recommendations

The Investigative Team developed draft root causes, causative statements and recommendations based on the activities of the RCA team. Necessary clarifications were made using further interviews or reference to previous documentation collected. Additional documentation from ECH and SJGH was obtained to support and complement the findings.

e) RCA team review and sign off of report

A draft flow chart, cause and effect diagrams, causes, causative statements and recommendations were reviewed and revised as necessary by the RCA team during a face to face meeting. At a subsequent meeting, the full report with updated versions of the above was reviewed, verified and agreed to by the RCA team.

6. Understanding of Events

a) Initial understanding

On March 16, 2007 the East Central Health Region Medical Officer of Health issued an Order affecting St. Joseph's Hospital, Vegreville, which closed the Central Sterilization Room (CSR) and ordered that admissions of inpatients cease. The Order stated that there was reason to believe that "inadequately sterilized medical equipment has been and continues to be used in St. Joseph's General Hospital, thereby potentially exposing patients to blood-borne pathogens", and that there were concerns that "measures required to control the ongoing spread of Methicillin Resistant *Staphylococcus aureus* (MRSA) in acute care patients in care at St. Joseph's General Hospital have not been implemented effectively", and that "inadequate supervision of staff and processes related to communicable disease control may have resulted in an increased risk to patients of contracting infectious diseases while in care at St. Joseph's General Hospital".

b) Final understanding

The final understanding of the events that led to enactment of the MOH Order is depicted in Appendix 1, Figure 1, pages 1-3, "Flow Chart of the Infection Prevention and Control Issues That Led to the East Central Health Authority Medical Officer of Health Order Dated March 16, 2007".

Two streams of events, MRSA transmission and CSR sterilization issues, began at divergent times and in different circumstances. This report will first chronicle the **MRSA transmission**.

In April 2003, regional health authority boundaries changed and Vegreville, including St. Joseph's General Hospital, was transferred from the Lakeland Health Authority to East Central Health Region. A review of the MRSA surveillance data by Infection Prevention Control staff revealed MRSA infection cases in Vegreville patients who received health care services to be higher than the regional norm. A notable factor was that standard surveillance practices for MRSA in Acute Care (AC) and Continuing Care (CC) conducted in Lakeland did not match practice in ECH. ECH conducted both laboratory based clinical culture surveillance and admission screening. Admission screening involved asking all new admissions (in AC, CC and Home Care) questions to identify if they were at risk of acquiring MRSA in another facility in the past six to12 months. If answers identified potential risk, there were directions to take skin and nares cultures and, in some cases, place the person on contact precautions until the results come back. It was felt by ECH that ECH's procedures of screening high risk patients for MRSA would have produced a better benchmark of MRSA colonization rate and improved identification of an outbreak when it occurred[3]. Information was collected on the number and type of MRSA cases in Vegreville. Simultaneously, the ECH IPCC provided the ECH Infection Control Manual to SJGH and conducted staff education on IPC.

By September 2003, an outbreak of MRSA was suspected based on the 13 cases chronicled from April to September 2003. A chart review was conducted on the MRSA positive patients and Infection Prevention Control personnel presented a summary report on the status of MRSA in Vegreville to the SJGH administration identifying the chronology and number of cases in acute care, continuing care, home care and the community with regard to patients

[3] MRSA "infection" refers to patients who have clinical conditions that are caused by MRSA as opposed to "colonization" in which a patient may have MRSA on his/her skin or nares but not have any signs or symptoms related to infection.

who had had medical services provided from the Vegreville health care facilities. An outbreak management plan was shared as part of this report, which would identify the number of MRSA positive cases (colonized or infected) and prevent transmission through specific IPC measures for SJGH and Vegreville Continuing Care. A baseline prevalence screening in September 2003 confirmed the presence of an outbreak with 40 cases in all of AC and CC. As part of the outbreak strategy, MRSA screening (taking clinical cultures and placing high risk persons on contact precautions) was commenced in *all* acute care and continuing care admissions. During the course of this screening, a safety threshold was established and communicated: MRSA screening involving clinical cultures for all admissions would be *reduced to high risk patients only* if there were two or fewer cases of MRSA due to transmissions within the facility for six months. Simultaneously, an evidence-based plan for control of MRSA was recommended and implemented, which included:

- staff educational presentations on the MRSA and its spread
- posters depicting the need for hand washing and reminders for same
- introduction of the use of contact precautions for positive MRSA cases (previously not required as per direction by Lakeland RHA)
- de-colonization of colonized cases with follow up screening
- referral of infected cases to infectious diseases consultants
- voluntary staff screening
- installation of wall mounted hand gels on the entrance to each patient room
- enhanced environmental cleaning

Hand gel stations were wall mounted immediately in Vegreville Continuing Care but did not get installed until November 2004 in SJGH. Recommendations for increased frequency of cleaning of showers, sinks, and toilets were not implemented at SJGH until 2006 and a permanent change to an IPCC recommended surface disinfectant was not made.

The screening of all admissions continued in acute care and is still in place at the time of writing this report (June 2007) as the safety threshold has to date never been reached, despite a drop in the number of MRSA cases identified in SJGH between January and June 2004. Evidence of MRSA transmission was not restricted to within Acute Care as Vegreville CC had evidence of new transmission within their care environment throughout 2005 and 2006 with new cases. Therefore, admission screening with clinical culturing of all admissions in Vegreville CC continued without exception until November 2006 when admissions stopped to that facility due to its impending closure.

The scope of the MRSA outbreak in Vegreville was much larger than other outbreaks that had occurred within ECH since 1999. IPC staff presented a number of reports regarding the status of MRSA at SJGH and requesting direction:

- November 2004 (13 months after the outbreak was identified) - an outbreak summary to Senior Managers in ECH providing the outbreak findings and activities to date and outlining areas that required further direction such as specific allocation of fiscal and human resources to detect and control MRSA for the SJGH site.
- March 2005 - another outbreak summary was presented to the Medical Site Chiefs.
- April 2005 - a similar presentation as that made to the Medical Site Chiefs was made to the ECH Board.
- April 2006 - a presentation to the ECH Regional Ethics Committee requested advice on:
  - the feasibility and ethics of beginning admission screening of new residents to Vegreville CC with physical states (e.g., open chronic wounds, chronic indwelling urinary catheters) that would put them at higher risk for MRSA acquisition in a care setting with known, high endemic rates.
  - disclosure of this information to the potential resident.

Several months later the Ethics Committee provided their support of disclosure regarding MRSA to potential residents and their families and requested that the IPC staff take that initiative forward.

Direction on allocation of fiscal and human resources was not provided from the Senior Managers, Board or Physicians to IPC personnel to contain the MRSA and so the current approach to monitoring and managing cases linked to the outbreak continued:

- admission screening to promptly identify new cases
- placement of new and previously positive case on contact precautions
- consideration of the feasibility for de-colonization
- referral of infected cases to infectious disease consultants
- contact screening and individual care plan development

No additional IPC resources were approved by ECH when

requested nor did SJGH assign dedicated staff to assist with IPC activities at that site to assist with management of cases and compliance monitoring.

January 29, 2007 marked a meeting of the IPC staff, Medical Officer of Health, SJGH administration, nursing and laboratory to develop a plan for enhanced surveillance of MRSA as periodic cases with suspected transmission in the Acute Care facility continued. Screening for MRSA was to be done on admission, prevalence cultures conducted every seven days for patients in extended admission, and discharge cultures done to determine potential exposure during that specific admission. On identification of further new cases, directions were given to the SJGH nursing administration by the IPC personnel on February 15, 2007 to conduct chart audits of these new MRSA patients for the purpose of determining compliance with infection prevention control directives.

At the March 15, 2007 Implementation Team meeting consisting of SJGH and ECH Boards and Senior Management (developed to implement the recommendations from the Blackwell Operational Review – January 2007) the issue of MRSA was added to the agenda; the Team was advised that MRSA was a continuing problem. The next day the IPC Co-ordinator and Medical Officer of Health were requested by ECH to visit SJGH on a fact finding mission to confirm that the following infection prevention control recommendations were implemented and if not, why not:

i. to confirm that housecleaning solutions were changed to the agent of choice as recommended by IPCC

ii. that contact precautions were being applied for all new MRSA and previously positive MRSA patients

iii. that the CSR had been closed (see CSR section below)

It was confirmed that no change in housecleaning solutions had been made and the consistent use of contact precautions was not being applied.

On March 16, 2007 at 18:00 the MOH Order was enacted as a result of the inability of SJGH to contain MRSA transmission and the fact that inadequately sterilized equipment, had been and continued to be used. At the time of the MOH Order, seven new cases were suspected to be linked to an admission at SJGH within the previous two months, indicating a sharp rise in expected cases.

The first insight into issues surrounding the **CSR stream** of events began with an acknowledgement in November 2003 by ECH that SJGH did not have a scope washer-sterilizer and was using immersion in Cidex® for 20 minutes to provide disinfection of scopes followed by autoclaving. This practice did not align with ECH procedures of disinfection with Cidex® for 45 minutes, followed by autoclaving or use of the scope washer-sterilizer. CSR was under the management and supervision of ECH Materiel Management. In March 2004, a report from ECH IPC staff to ECH Senior Management provided a report from an Ad Hoc Sterilization Committee summarizing the status of sterilization processes and infection prevention and control in ECH with regard to best practice standards. The following finding and corresponding recommendation were provided in the report:

- Finding: "Identified that endoscope reprocessing practices (manual cleaning and disinfection) were not meeting best practices in one affiliate hospital." *(The affiliate hospital was subsequently identified as SJGH)*.
- Recommendation: "That "endoscopic" practices at each facility be reviewed by the facility staff (nurse manager and all physicians performing endoscopies) and be compliant with the ECH CSR Manual policies."

No evidence was provided to demonstrate follow up action by ECH on the finding and recommendation.

SJGH first identified a washer-disinfector and a flash sterilizer as capital equipment requests, priority number 10 and 8, respectively in February 2005. In January 2006 a scope washer-sterilizer was identified as priority number 2 on the capital equipment request list; that piece of equipment was approved by ECH in August 2006 but a requisition for same was not completed by SJGH. It was realized in January 2007 by the SJGH administration that the February 2005 request for the washer-disinfector did not consider the need for renovations and a new request was submitted with these costs included. A hiatus of activity around the capital equipment continued until February 16, 2007 when a request for a washer-disinfector and scope washer-sterilizer was submitted to ECH; the request was approved immediately with a recommendation for full assessment of the CSR to determine the need for renovations or major upgrades.

In August, 2006, audits of all the CSRs commenced and were part of the activities of the new Surgical Program Lead appointed to her position in April 2006. The audits were to increase the exposure of the new Surgical Program Lead position, ensure standards were being met, educate the staff on CSR requirements and address the lack of standardization in the peri-operative program. An audit tool developed by SPS Medical®, a surgical processing

company, was selected as a credible tool based on the Surgical Program Lead's knowledge and the awareness that this tool was used in other surgical centres. Visitation criteria included the presence of a regularly operating OR, available CSR and dedicated staff, availability of Obstetrics and an operational Emergency Department. The order of visitation was based on geographical logistics and activities of the CSR occurring on the intended day of visitation.

On January 22, 2007 the last of the CSR audits in ECH was completed in SJGH. Significant deficiencies were identified and included:

- no division between the decontamination and sterile processing areas
- lack of decontamination equipment of a washer-disinfector and scope washer-sterilizer
- scopes were not disassembled prior to sterilization
- manual cleaning of the rigid scopes using brushes was not observed and confirmed not to be a regular practice
- brushes for cleaning lumens of scopes required replacement
- evidence of sterilization of the brushes was not found
- a 20 minute cycle of sterilization, apparently based on information initially provided by the manufacturer at the time of original purchase, was used instead of the required 45 minutes
- there was no traceable record matching the patient to the scope and to sterilization load of scopes

The inadequacy of the physical layout conducive for proper sterilization procedures, and the recommendation to purchase a washer-disinfector was communicated by the auditor to the SJGH nursing administration, Materiel Management personnel and CSR staff. Concerns with these deficient CSR findings were raised by the ECH nursing administration and reported to the ECH senior management who then discussed the findings with SJGH nursing administration.

Recognizing there may be a risk of transmission of blood borne pathogens, immediate action was taken on January 25, 2007 to cancel scope procedures for the next scheduled date of February 19 and consultation with an infectious disease specialist conducted. A meeting later in February was scheduled to discuss the CSR deficiencies. On February 13, 2007 the SJGH CSR audit was reviewed by ECH administration and IPC. It was decided the CSR should be closed. Consequently, ECH nursing and medical administration communicated verbally, through telephone dialogue, with SJGH nursing administration to close the CSR, directing that scopes were no longer to be sterilized at SJGH and were to be sent elsewhere. Discussion about future renovations to the CSR was also conducted at this time. No written directive to close the CSR was issued.

Evidence of continuing discussion between the ECH and SJGH nursing administration took place February 28, 2007 whereby the logistics of transporting CSR equipment and instruments to an alternate site for sterilization were reviewed. Further communication that day clarified that a locum dentist would not be allowed to perform procedures in the hospital with his own sterilized instruments.

On March 15, ECH nursing administration became aware that the surgical instruments from SJGH were not being sent elsewhere for sterilization. The Implementation Team, struck to implement the recommendations from the Blackwell Operational Review, was meeting the afternoon of March 15 and the results of the SJGH CSR audit and status of MRSA were added to the agenda. The Team, consisting of ECH and SJGH Board and senior management members, heard that the scopes had been ineffectively manually cleaned and sterilized. The consultant report of the infectious disease specialist indicated a low risk of blood borne pathogens that could cause infection but recommended a chart audit of a subset of patients who had cystoscopy with biopsy as the risk of infection may have been higher in this group. The Implementation Team left the meeting with the understanding that the CSR was closed and that instruments and equipment were being prepared for transport to an alternative site for sterilization. No approved minutes of the Team meeting were available for review. In hindsight, one member of that team recalled hearing a side bar conversation that would have provided insight that the CSR was still processing non-scope pieces of equipment but that information remained unknown to the Implementation Team at large.

The next morning of March 16 it was verbally confirmed that the CSR had not been closed and equipment was still being processed at SJGH. The IPCC and MOH were asked to conduct a site visit to validate that the CSR had not been closed and to determine whether there existed a risk to public safety. Upon inspection of the CSR, the MOH determined a sufficient risk to public safety existed and the MOH Order was declared for SJGH effective immediately.

c) Flow chart of final understanding

See Figure 1, Appendix 1 for flow chart of final understanding.

7. Cause and Effect Analysis

a) Description of causes and effects

After completion of the flow chart depicting events leading up to the MOH Order, a series of questions of "why" or "what caused this event" are asked moving from the "sharp end" of the incident (actions of individuals) to the "blunt end" where underlying systemic deficiencies generally reside. This results in identification of multiple causes and causal chains that more clearly elucidate the events leading up to the major incident. The causal chains are illustrated through cause and effect diagrams that pictorially identify root and contributing causes, found at the end of a causal chain.

See pages 1-7 of Appendix 2 for clarification of the above. The issuing of the MOH Order of March 16, 2007 was not the result of a single cause but a combination of factors, which together, culminated in the Order.

The **root causes** of both the CSR closure and the lack of containment of MRSA were found in legislation and Agreements that governed the operations of the East Central Health Region and St. Joseph's General Hospital. The Master Agreement (1994) had given the Voluntary facilities autonomy in the arena of regionalization and "full authority" for matters relating to the "…directing all programs and services offered by the voluntary health facility…". Similar language is found in the *Regional Health Authorities Act* (1994) granting "final authority in respect of the matters referred to in clause (5a)" to the regions. Lack of agreement on who would have working and governing authority for all matters and each component part of matters pertaining to the operation of SJGH, and unclear authority of the ECH led to lack of accountabilities and responsibilities for infection control and prevention, quality improvement, patient safety, risk management and utilization management. The current ambiguity related to final authority, that exists within the Master Agreement and the RHA Act, has allowed unsafe practices to continue, and **must be addressed immediately by AHW**. Until full authority resides in one organization, it is unlikely that progress will be made in many of the recommendations made in this report and the safety of the patient will be jeopardized.

Without a firm directive from legislated agreements, SJGH and ECH were required to develop a working relationship that should have allowed a collaborative approach to provisions of health programs and services. A Service Agreement between ECH and SJGH was never developed to define the working relationship and to identify programs and services to be provided by SJGH. A lack of agreement on the definition of the relationship with specific reference to "partnership" versus "contracted provider" and the resulting implications of how the relationship was to be managed resulted in a strained working relationship between the two organizations. The working interpretation was that ECH had to be 'invited in' to work with SJGH and that SJGH had the 'option' of following ECH direction, programs or services. Whether the lack of clarity of the legislation and SJGH's status to consider ECH advice as optional were real or legitimate, ECH chose not to act when they knew that sterilizing procedures for scopes were sub-optimal.

To add to the complexity of the relationship between ECH and SJGH, a long standing culture of autonomy of SJGH initially cultivated over decades by Sisters who independently and successfully created SJGH from its infancy continued to exist. This culture continues with SJGH board, administration, and staff, and combined with the lack of clarity for authority from the major agreements resulted in a working relationship, which accepted that policies, programs and services offered by East Central Health Region were optional for SJGH. Autonomy eventually resulted in isolation of SJGH and decisions were sometimes made with insufficient support to patient safety issues.

To address the **CSR closure**, four causal chains were identified:

Lack of equipment

The SJGH CSR did not have a washer-disinfector or a scope washer-sterilizer, which are standard pieces of equipment in a current CSR. A long standing culture of frugality, cultivated by the Sisters of Charity in the formative years of creating SJGH, continued and was pervasive among the staff and management. Staff were expected to "make do" with what was available. The CSR Processor, early in her assignment to the CSR in 1992, identified deficiencies in the CSR, such as lack of hospital scrubs,

lack of separation of decontamination from sterilization process areas, and a need to restrict traffic through the CSR; however, no changes resulted from these suggestions. This was one example of several that provided insight into a lack of participatory management. In addition, the CSR Processor lacked any process to regularly provide feedback to her supervisor on the resources needed to do her job.

The CSR Processor was quite isolated in performance of her duties; that isolation was congruent with the strong desire for autonomy of SJGH. Not until two years after boundary changes that placed SJGH in the East Central Health Region (2005) did she join regional CSR meetings where operational issues were discussed. It was there that she learned of the missing pieces of equipment in her CSR. This knowledge was shared with the ECH CSR Supervisor but no action was taken, possibly due to the previously discussed working understanding of the relationship between ECH and the Voluntary facilities such as SJGH. Hence lack of clear authority, responsibility, and accountability of the ECH CSR Supervisor resulted in no action to facilitate SJGH purchasing the necessary equipment or discussion of the inadequacies of the SJGH CSR with the site CSR Supervisor.

ECH had developed a comprehensive capital equipment process but, once again, the process had not been formally adopted at SJGH. Lack of clear authority described above coupled with the working understanding of programs and services of ECH being optional at Voluntary sites may have contributed to the deviation from the ECH capital equipment process. Lack of a formalized process at SJGH for identifying and prioritizing capital equipment in SJGH did not allow for staff to identify necessary items to do their job in a safe and effective manner, for management and staff to assess the priority of that need and to submit the highest priority needs to the capital equipment decision making body in ECH.

Failure to act on knowledge that SJGH scope practices deviated from the ECH standard

It was known by ECH in 2003 that SJGH did not have a scope washer-sterilizer and that high level disinfection was being achieved using immersion in Cidex® (glutaraldehyde) for 20 minutes. ECH advocated 45 minutes but did not take action to intercede or change practice noting only that the practice at SJGH did not meet ECH standards. It is acknowledged that safe disinfection could have occurred using glutaraldehye for 20 minutes if the lumens had been appropriately manually cleaned with brushes designated for that purpose. That manual cleaning was not the practice in SJGH as identified by the CSR audit in January 2007. Furthermore it was discovered in March 2007 that no fume hood was available to support safe use of glutaraldehyde, and, hence, a staff safety issue had gone unrecognized for some time by SJGH and ECH. However, had the recommendation made in March 2004 by ECH IPC to ECH senior management to review all endoscopic practices been implemented, the deficiencies in manually cleaning the scopes in SJGH could have been identified earlier and the MOH Order of 2007 potentially averted. Staff and management of SJGH and ECH had a duty to act when potentially unsafe patient safety issues were known.

Best practices for peri-operative processes were not consistently applied across the region

ECH policies and procedures for CSR sterilization processes were developed in 2002 but not made available to the SJGH CSR Processor until 2005. There was no consistent process to communicate and implement new or revised policy and procedures and the arrival of ECH policies in 2003 at SJGH, viewed as optional for use at that site, were not given to the CSR staff. Furthermore, no site based Peri-Operative Team was in place in SJGH to develop, monitor and continuously evaluate the practice in the CSR and to share issues with a regional peri-operative structure. Infection prevention and control had not been involved in the CSR operations or development of best practices and the impact of inappropriate decontamination or sterilization was not clearly identified to the staff at SJGH. CSR practices were discussed at ECH Regional CSR meetings but there was no concerted effort to ensure that best practices were in place at all sites, including those offered by the Voluntary facilities.

The opportunity to keep current with CSR practices was not available to the CSR Processor, potentially influenced by the frugal culture of SJGH. The lack of regular performance appraisals resulted in a missed opportunity to assess her knowledge, competency and skills to reveal strengths and areas for improvement as well as resources needed to do the job. Coupled with this was an assumption that her supervisor would have all the knowledge of CSR requirements without any additional training or

education in the CSR field. No attempt to access external resources to educate staff and management on CSR requirements and standards was evident. Rather, the desire to remain autonomous and utilize available expertise at SJGH reduced the likelihood for external influence. As a result, the lack of informed and adequate supervision led to the failure to observe that cleaning of the rigid cystoscopes for disinfection and sterilization was not adequate in that manual cleaning of the lumens with brushes did not occur. The SJGH CSR Supervisor was subject to the same system failings of lack of clear expectations to do the job, no specialized training and no systematic evaluation of her performance.

Lastly, workload in the CSR was dependent on one person to complete the tasks with a limited and insufficient number of instruments, which required rapid turnaround for the surgical cases, and which may have contributed to the deviation of decontamination and sterilization procedures from standards.

CSR was not closed February 14, 2007 as intended by ECH

On review of the results of the SJGH CSR audit, the ECH nursing administration telephoned SJGH nursing administration and stated that the CSR must be closed immediately. A written directive providing rationale for that action was not provided, nor were clearly defined expectations and instructions to operationalize that directive. The reliance on verbal direction without written documentation led to an altered interpretation of what was meant by "the CSR must be closed immediately". Renovation estimates and layout planning in the CSR department at SJGH to accommodate new equipment were occurring simultaneously and may have clouded the clarity of what was meant by "closure" or the reason for the closure. The use and cleaning of scopes ceased, but other medical equipment continued to be processed in the department. The lack of response to the verbal direction to close the CSR was seen by ECH as SJGH exercising their "option", as a Voluntary facility, to accept direction from ECH. As this response had been experienced numerous times in the past, ECH interpreted the lack of CSR closure as defiance by SJGH.

Nine causal chains were identified for the ongoing and unchecked **MRSA transmission.**

Lack of standardized MRSA benchmark data

A difference in the surveillance for MRSA existed between Lakeland Health Authority and East Central Health Region. It was felt that ECH's procedures of screening high risk patients for MRSA would have produced a better benchmark of MRSA cases and improved identification of an outbreak when it occurred. The lack of standardization of surveillance at the provincial level opens the door for divergent practices.

Lack of implementation of new screening procedures at SJGH

When a higher than regional norm of infectious MRSA cases was discovered in Vegreville patients who received health care services and an outbreak was confirmed in September 2003, SJGH staff were requested to implement MRSA screening on all acute care and continuing care admissions. Screening would be reduced to high risk patients only if the IPCC was unable to link two cases of MRSA to transmissions within the facility for six months; this was an empiric safety threshold created in the absence of provincial standards providing direction. Despite education on MRSA, SJGH staff lacked conviction for the heightened screening noting that MRSA seemed endemic in other health care facilities and those others were screening only high risk patients. Further resistance to the new screening procedures was fuelled by the thought that more cases of MRSA detected in SJGH would be a product of increased screening and that if other sites screened all admissions, SJGH might not look unique. As a result, SJGH staff felt they were being "picked on". At this time, other circumstances contributed to build a "victim syndrome" within SJGH. Their operating budget had been reduced by $500,000 and staff generally were not aware of the rationale. SJGH felt dictated to by the new health authority that they had recently become a part of and the historical desire to remain autonomous, coupled with lack of clear authority, perpetuated SJGH's position of optionally accepting ECH direction.

Precautionary measures were not applied in SJGH until positive MRSA status was confirmed in high risk patients

Included in the protocol for MRSA screening were directives for contact precautions to be implemented with high risk patients before confirmation of MRSA. However, due to a lack of consistent processes to implement new directives, policies and procedures, the staff remained unaware of this screening tool and did not implement contact precautions on high risk patients.

Delayed implementation of hand gel stations outside of every patient room in SJGH

Despite a recommendation to install wall mounted hand gel stations outside of every patient room in September 2003, no action was taken until December 2004. Lack of a detailed plan and consistent approach to implementing new practices or procedures in SJGH and a view that the directives were optional to accept led to a significant delay in response.

Some patient bathrooms did not have sinks or hand gels in SJGH

Over a year after the confirmation of an MRSA outbreak, it was realized that patient bathrooms did not have a sink or hand gel to allow hand cleansing. Contamination of the door knob to exit the bathroom and use the sink in the patient room was highly probable and would have perpetuated transmission. Staff had become accustomed to the lack of sinks within the bathroom and had not recognized this as a patient safety issue. There existed no forum for the staff at SJGH to regularly discuss issues of quality or safety and no risk management system in the site or the region to assess risk and safety. The long standing frugal culture may have contributed to the avoidance of expense of new sinks and installation costs. As with other directives, the hand gel stations were not responded to immediately, related to a lack of a detailed plan and inconsistent approach to implementing new practices or procedures in SJGH.

Housecleaning solutions were not upgraded to meet requirements of IPC

A recommendation to change housecleaning solutions made in September 2003 was briefly complied with and then abandoned. The culture of frugality likely influenced the decision not to use the more expensive recommended product. Direction was taken from the vendor rather than the IPCC and reflected the dysfunctional relationship between SJGH and ECH. Inadequate housekeeping resources were identified as a reason for non-compliance with the request to increase the frequency of cleaning. SJGH demonstrated lack of ownership of the problem by not considering realignment of dollars from their global budget, fuelled by a poor relationship with ECH stemming from the historic proposed budget cut. Safety was not identified as a criterion for setting priorities in decision-making and there was clearly a lack of a process within ECH to review incidents and issues that required immediate attention and co-operation between the region and a Voluntary facility.

No dedicated IPC resources to get SJGH MRSA issues under control

It is questionable whether ECH has sufficient IPC resources to manage the IPC issues within the region, and provincial or national staffing benchmarks are not available to assist in the assessment. Nonetheless, the profile of infection control is not elevated at the ECH senior management table and the lack of alignment in the reporting structure or integrating mechanisms among infection control, CSR and the Medical Officer of Health reflects a deeper discord in the structure and connectivity of risk management, safety, quality and infection prevention control.

MRSA situation not taken seriously by SJGH and to a lesser extent ECH

In addition to the dysfunctional relationship between the two organizations, the Boards did not demonstrate a clear understanding of the seriousness of the MRSA situation and did not take action to improve the situation. Their role and responsibilities in quality and safety are not well articulated and are rooted in lack of clear orientation, including job descriptions and ongoing education. A catalyst to demonstrate the criticality of the MRSA situation and commit resources to contain the MRSA was absent. While chart reviews are currently being conducted to determine any linkages between MRSA and deaths, no routine morbidity and mortality chart reviews are regularly conducted in SJGH or ECH. Medical by-laws and regulations do not provide direction at SJGH for such reviews. Boards in ECH and SJGH do not regularly address safety and quality as standing agenda items and have no markers of risks outside of the incident management process. Physicians were not engaged in communicating the seriousness of the MRSA situation or taking leadership to improve the situation.

b) Causes and effects diagrams

Diagrams showing the cause and effect relationships are found in Appendix 2, pages 1-7.

c) Description of associated findings

Use of Public Health Act to mobilize action against infection prevention and control issues in hospital including inadequate sterilization in the CSR

It was obvious that ECH IPC staff attempted to address the ongoing MRSA transmission on multiple levels without adequate response. SJGH did not implement IPC recommendations in whole or part and ECH did not develop a process to address this issue earlier with the urgency required but without the dramatic act of hospital closure made possible by invoking the *Public Health Act*. Infection prevention and control had limited influence without a strong voice at the decision-making table within ECH. Lack of co-operation between the regional health authority and Voluntary facility limited the effectiveness of the IPC recommendations and may have triggered the *Public Health Act* intervention. However, CSR operations are not typically in the domain managed by the Medical Officer of Health although it could be rationalized that inadequate sterilization of instruments and equipment could result in a threat to public safety. However, a whole spectrum of inappropriate patient care practices could threaten patient safety but are traditionally dealt with by facility management. Why was it necessary to involve the MOH in reviewing the safety of the SJGH CSR? Was the application of the *Public Health Act* the only means to change practices at SJGH?

Lack of regulation of CSR practices and personnel

The Investigative Team suggests that the practices within the SJGH CSR could have been changed with a co-ordinated approach to review all endoscopic cleaning practices and procedures at all ECH sites by external expertise and a commitment to implement best practices at all CSRs including those of the Voluntary facilities. It became apparent that practices in CSR should be standardized but a provincial or national model is lacking. Furthermore, CSR personnel are not regulated, nor are requirements for specialized training and education in the field of decontamination and sterilization mandatory. This deficiency may be setting other surgical processes or procedures up for failure if internal expertise to assess the appropriateness, effectiveness and safety of CSR operations is not available within each regional health authority. Are the deficiencies in standardization of CSR processes and personnel appropriate to be addressed provincially or nationally to ensure safety in decontamination and sterilization?

8. Root Cause Analysis Findings

a) Causal statements of root causes and contributing factors

Root causes

1. Lack of clarity and granting of final authority to both the Regional Health Authorities and Voluntary facilities from the *Regional Health Authorities Act* and Master Agreement respectively, and lack of consensus between East Central Health Authority and St. Joseph's Hospital, Vegreville, on who (Voluntary facilities or RHA) has final authority for all matters and each component part of matters pertaining to the operation of the hospital supported autonomy of St. Joseph's General Hospital and unclear authority of the East Central Health Region leading to lack of accountabilities and responsibilities for infection control and prevention, quality improvement, patient safety, risk management and utilization management.

2. Lack of agreement on definition of the relationship between St. Joseph's General Hospital and East Central Health Region with specific reference to "partnership" versus "contracted provider" and the resulting implications of how the relationship was to be managed resulted in a strained working relationship between the two organizations as well as an interpretation that ECH had to be 'invited in' to work with SJGH and that SJGH had the 'option' of following ECH direction, programs or services.

3. Long standing culture of autonomy of SJGH cultivated over decades by Sisters whose initiative, independently and successfully, created SJGH from its infancy. This culture continues with SJGH board, administration, and staff. This, combined with the lack of clarity for authority from the major agreements, resulted in a working relationship, which accepted that policies, programs and services offered by East Central Health Region were optional for SJGH. Autonomy eventually resulted in isolation of SJGH and decisions were sometimes made with insufficient support to patient safety issues.

Contributing factors

4. Lack of empowerment of staff to influence quality and safety improvements at SJGH resulted in critical equipment not being available for cleaning, decontamination and sterilization.

5. Lack of a requirement and process to develop and implement best practices for infection prevention and control at all sites resulted in inconsistent compliance with standards across the region.
6. Lack of clear authority of ECH CSR Supervisor to recommend proper CSR equipment for purchase for SJGH resulted in lack of a necessary piece of decontamination equipment, which ultimately placed the patients or others having procedures at risk of infection.
7. Lack of application of a minimum set of standards and criteria to determine where and how services are provided throughout the Region to ensure efficiency, effectiveness and safety, resulted in local services provided at SJGH that were not supported by on-site expertise or infrastructure.
8. Lack of consistent process to communicate and operationalize policies, procedures, and directives, resulted in lack of change in procedures and practices to contain MRSA infection and comply with standards of cleaning, decontamination and sterilization and to completely close the CSR on first notice of same.
9. Lack of formalized process for identifying and prioritizing capital equipment in SJGH resulted in absence of a necessary piece of equipment in CSR.
10. Lack of process in SJGH to evaluate knowledge, competency and skills of staff and management and lack of engagement of physicians, resulted in deficiencies in infection prevention and control or decontamination and sterilization processes that remained undetected.
11. Culture of frugality cultivated historically continues to exist among SJGH board, administration and staff, resulting in real or perceived constraints, which limited their compliance with directives that may or may not have resulted in increased costs but would have improved patient safety.
12. Lack of process to standardize equipment and supplies in the Region resulted in unique practice for cleaning and sterilizing instruments that was not readily identifiable as a deviation from standard practice.
13. Lack of provincial standards and guidelines for MRSA screening and surveillance and consequent different practices in different RHAs resulted in incongruence of determining benchmark data of MRSA cases in Vegreville and an inability to detect an impending outbreak of MRSA when SJGH first joined the ECH region.
14. Presence of a sense of being "victimized" and "picked on" by SJGH personnel caused resistance to suggested measures made by Infection Prevention and Control Co-ordinator.
15. Lack of support by ECH for requested increase in infection prevention and control staffing and lack of dedicated infection prevention and control resources to get SJGH MRSA situation under control resulted in ongoing transmission of MRSA.
16. Lack of patient safety advocacy, as exemplified by infection prevention and control, patient safety and quality improvement issues, at ECH senior management decision table resulted in lack of appreciation of the importance for the requested increase in infection prevention and control staffing and lack of approval for the recommended dedicated infection prevention and control resources to get SJGH MRSA situation under control.
17. Lack of functional ECH structure aligning patient safety, quality, risk management, and IPC resulted in inefficient and ineffective communication about the need to urgently address the SJGH MRSA situation.
18. Inability of the SJGH Board, and to a lesser extent, the ECH Board, to understand the seriousness of the ongoing MRSA situation and take action to resolve ongoing high levels of transmission resulted in continuation of MRSA transmission.
19. Lack of a trigger process (e.g., morbidity and mortality review of MRSA cases by SJGH medical staff) to demonstrate the scope and seriousness of the MRSA situation allowed the continuation of MRSA transmission practices without heightened concern and an urgent need to act.
20. Lack of engagement of SJGH physicians to communicate and reinforce the seriousness of sterilization breaches and continued MRSA transmission perpetuated a lack of heightened concern and diminished the sense of urgency to address the problems.
21. Lack of an explicit and evident patient safety culture in SJGH and ECH did not support the development of quality and safety markers and performance measurements to monitor compliance with expectations for provision of safe and quality care.
22. Knowledge and appreciation of significance of deficiencies in infection prevention and control and sterilization within SJGH was not acted on by either SJGH or ECH, resulting in continuation of unsafe practices.

9. Root Cause, Contributing Factors and Recommended Actions

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

Item #	Description	Category					
		HF-C	HF-T	HF-F/S	E	R	B
1	Lack of clarity and granting of final authority to both the Regional Health Authorities and Voluntary facilities from the *Regional Health Authorities Act* and Master Agreement respectively, and lack of consensus between East Central Health Authority and St. Joseph's Hospital, Vegreville, on who (Voluntary facilities or RHA) has final authority for all matters and each component part of matters pertaining to the operation of the hospital supported autonomy of St. Joseph's General Hospital and unclear authority of the East Central Health Region leading to lack of accountabilities and responsibilities for infection control and prevention, quality improvement, patient safety, risk management and utilization management.	●			●	●	●
2	Lack of agreement on definition of relationship between St. Joseph's General Hospital and East Central Health Region with specific reference to "partnership" versus "contracted provider" and the resulting implications of how the relationship was to be managed resulted in a strained working relationship between the two organizations as well as an interpretation that ECH had to be 'invited in' to work with SJGH and that SJGH had the 'option' of following ECH direction, programs or services.	●			●	●	●
3	Long standing culture of autonomy of SJGH initially cultivated over decades by Sisters who independently and successfully created SJGH from its infancy continues with SJGH board, administration, and staff; this, combined with the lack of clarity for authority from the major agreements resulted in a working relationship, which accepted that programs and services offered by East Central Health Region were optional for SJGH. Autonomy eventually resulted in isolation of SJGH and decisions were sometimes made with insufficient support to patient safety issues.	●			●	●	●

Root Cause #	Contri-buting Factor	Causal State-ments	Item #	Description of Action	Action E = eliminate C = control A = accept	Recommended Party Responsible	Outcome Measure	Measure Date (M/D/Y)
		The SJGH Board or interim Management Board of SJGH have been identified interchangeably as the party responsible for governance of SJGH dependent upon the time anticipated to implement the recommendation. Should Board authority change at the actual time of implementation of these recommendations, that Board with authority shall be the party responsible and the name shall change.						
1		Lack of clarity and granting of final authority to both the Regional Health Authorities and Voluntary facilities from the *Regional Health Authorities Act* and Master Agreement respectively, and lack of consensus between East Central Health Authority and St. Joseph's Hospital, Vegreville, on who (Voluntary facilities or RHA) has final authority for all matters and each component part of matters pertaining to the operation of the hospital supported autonomy of St. Joseph's General Hospital and unclear authority of the East Central Health Region leading to lack of accountabilities and responsibilities for infection control and prevention, quality improvement, patient safety, risk management and utilization management.						
			1A	Immediately review and clarify the Master Agreement and *Regional Health Authorities Act* to identify ONE organization to have final authority for all matters and each component part of matters pertaining to the operation of the health care facilities in a regional health authority.	E	AHW		
			1B	If it is determined that a Master Agreement is to be in place, identify in that Agreement the ethical principles and guidelines of Voluntary facilities and describe their impact on agreement of services to be provided.	C	AHW		
			1C	Develop Service Agreements with the Voluntary facilities identifying the specific clinical and support services offered at each site reflecting the health needs of the local community and overall service needs of the Region while ensuring optimal use of resources.	C	RHAs, ACHC and Voluntary Facilities		
			1D	Provide clarity in the Service Agreements on how the Voluntary facilities' ethical principles and guidelines are unique and how they are to be protected in the delivery of programs and services within the regional health authority.	C	RHAs, ACHC and Voluntary Facilities		
			1E	Develop clear structures and processes to review incidents and issues requiring immediate attention and co-operation in all facilities in the Region.	C	ECH and Voluntary Facilities		

Root Cause #	Contri-buting Factor	Causal State-ments	Item #	Description of Action	Action E = eliminate C = control A = accept	Recommended Party Responsible	Outcome Measure	Measure Date (M/D/Y)
			1F	Clearly define authority, accountability and responsibility of regional managers overseeing regional programs and their relationship to site managers, staff and physicians for all sites in the Region.	C	ECH and Voluntary Facilities		
			1G	Clearly define authority, reporting, accountability and responsibility of site managers and physicians relative to regional programs and program leads.	C	ECH and Voluntary Facilities		
			1H	Ensure that the review and identification of equipment and supplies required for SJGH is conducted by ECH Surgical Program Lead in collaboration with the Regional Surgical QI Team.	C	ECH Surgical Program Lead		
2		Lack of agreement on definition of relationship between St. Joseph's General Hospital and East Central Health Region with specific reference to "partnership" versus "contracted provider" and the resulting implications of how the relationship was to be managed resulted in a strained working relationship between the two organizations as well as an interpretation that ECH had to be 'invited in' to work with SJGH and that SJGH had the 'option' of following ECH direction, programs or services.						
			2A	Determine the relationship between ECH and SJGH, and define, in the Service Agreement, the full spectrum of implications for this relationship including planning, management, accountabilities and authorities of each.	C	ECH and SJGH		
			2B	Develop a population based strategic plan for the Region and all sites within ECH that identifies service expectations of the ECH and Voluntary facilities and that provides a structure and processes to develop, maintain and monitor such services.	C	ECH and Voluntary Facilities		
			2C	Develop minimum set of standards and criteria applicable to all facilities in the Region (Voluntary and regional facilities) to determine where and how services are provided to ensure acceptability, accessibility, appropriateness, efficiency, effectiveness, safety and quality.	C	ECH and Voluntary Facilities		
			2D	Develop an Agreement to replace the existing and proposed Service Agreement(s) with one that identifies clear roles, responsibilities, services and programs delivered in the Region, and specifies the particular services offered at each site.	C	ECH and SJGH		

Root Cause #	Contri-buting Factor	Causal State-ments	Item #	Description of Action	Action E = eliminate C = control A = accept	Recommended Party Responsible	Outcome Measure	Measure Date (M/D/Y)
	3	Long standing culture of autonomy of SJGH initially cultivated over decades by Sisters who independently and successfully created SJGH from its infancy continues with SJGH board, administration, and staff; this, combined with the lack of clarity for authority from the major agreements resulted in a working relationship, which accepted that programs and services offered by East Central Health Region were optional for SJGH. Autonomy eventually resulted in isolation of SJGH and decisions were sometimes made with insufficient support to patient safety issues.						
			3A	Develop and implement a process to resolve disagreements as they relate to alignment of regional processes with Voluntary ethical principles and guidelines.	C	ECH and Voluntary Facilities		
			3B	Develop a structure, reporting and accountability process that supports co-operative leadership at the regional and site level.	C	ECH and Voluntary Facilities		
	4	Lack of empowerment of staff to influence quality and safety improvements at SJGH resulted in necessary equipment not being available for cleaning, decontamination and sterilization.						
			4A	Actively define and create a culture of safety that empowers all staff, managers, administrators, Board members and physicians to improve patient related care using strategies such as regular safety culture surveys of staff, regular quality/ safety rounds, regular (transparent) performance indicator reports, administrative walkabouts, routine addition of patient safety and quality topics to all meeting agendas, and any other patient safety initiatives which would be appropriate.	C	SJGH Board and CEO		
	5	Lack of a requirement and process to develop and implement best practices for infection prevention and control at all sites resulted in inconsistent compliance with standards across the Region.						
			5A	Inter-disciplinary Regional Surgical QI Team to include physician(s) and Infection Prevention Control representative(s) as well as representatives from sites performing surgery.	C	ECH Surgical Program Lead		
			5B	Terms of Reference for Regional Surgical QI Team to define roles and responsibilities of team that reflect the mandate and expertise of the full team.	C	ECH Surgical Program Lead		
			5C	Regional Surgical QI Team to develop best practice guidelines including minimum volumes, monitoring, and continuous evaluation of their continuum of practice that includes performance indicators for all phases of care and all sites.	C	ECH Surgical Program Lead		

Root Cause #	Contri-buting Factor	Causal State-ments	Item #	Description of Action	Action E = eliminate C = control A = accept	Recommended Party Responsible	Outcome Measure	Measure Date (M/D/Y)
			5D	Regional Surgical QI Team to develop and implement criteria to determine which sites should have a Site Surgical Team that ensures safe, efficient and effective practices.	C	ECH Surgical Program Lead		
			5E	Regional Surgical QI Team to develop performance indicators for quality and safety that the Site Surgical Team reports on regularly to the Regional Surgical QI Team.	C	ECH Surgical Program Lead		
	6	Lack of clear authority of ECH CSR Supervisor to recommend proper CSR equipment for purchase for SJGH resulted in lack of necessary piece of decontamination equipment, which placed the surgical patients or others having procedures at risk of infection.						
			6A	Clearly define authority, accountability and responsibility of managers overseeing regional programs and their relationship to site managers, staff and physicians. (See also 1F)	C	ECH and Voluntary Facilities		
			6B	Clearly define authority, reporting, accountability and responsibility of site managers. (See also 1G)	C	ECH and Voluntary Facilities		
	7	Lack of application of minimum set of standards and criteria to determine where and how services are provided throughout the Region to ensure efficiency, effectiveness and safety resulted in local services provided at SJGH that were not supported by on-site expertise or infrastructure.						
			7A	ECH and Voluntaries to review compliance of CSRs at each site with CSA standards, using a comprehensive, contemporary CSR audit tool, determine ability to meet workload demands and conduct risk benefit analysis to determine number and scope of service of all CSRs.	C	ECH Surgical Program Lead		
			7B	Use information about the needs of the population to identify location and scope of services across the region, and review the resources required to provide site specific services while ensuring compliance with best practices and standards. See also 2B. *(Specific example: If cystoscopy procedures are identified as a required service for SJGH, and the service is supported by SJGH, it must provide the appropriate number of skilled staff, and an appropriate physical plant to support the procedure experience, including an adequate supply of required instruments and supplies.)*	C	ECH and Voluntary Facilities CEO		

Root Cause #	Contri-buting Factor	Causal State-ments	Item #	Description of Action	Action E = eliminate C = control A = accept	Recommended Party Responsible	Outcome Measure	Measure Date (M/D/Y)
	8	Lack of consistent process to communicate and operationalize policies, procedures and directives resulted in lack of change in procedures and practices to contain MRSA infection and comply with standards of cleaning, decontamination and sterilization and to completely close the CSR on first notice of same.						
			8A	Develop processes and procedures that utilize checklists and feedback mechanisms to communicate and implement new and revised policies, procedures and directives and ensure compliance to same.	C	ECH and Voluntary Facilities CEOs		
			8B	Ensure orientation of new employees includes instruction on dissemination of and compliance with policies, procedures, and directives.	C	ECH Human Resources Manager		
			8C	Provide written directive with clearly defined expectations and instructions to communicate critical actions required, supportive rationale and a feedback mechanism to ensure a common understanding has been achieved and follow up action occurs.	C	ECH and Voluntary Facilities CEOs		
	9	Lack of formalized process for identifying and prioritizing capital equipment in SJGH resulted in absence of necessary equipment in CSR.						
			9A	Provide orientation to SJGH Department Heads of ECH Capital Equipment Planning process that addresses assessment of need, prioritization, purchase and development of strategic and comprehensive plan for replacement, expectations and responsibilities for participation, and the need to involve front line staff.	C	SJGH CEO		
			9B	Conduct full assessment of quantity and quality of capital equipment inventory at Voluntary facilities and provide support for objective prioritization of requirements across the Region.	C	ECH – Chief Corporate Services Officer		
	10	Lack of process in SJGH to evaluate knowledge, competency and skills of staff and management, and lack of engagement of physicians, resulted in deficiencies in infection prevention control or decontamination and sterilization processes that remained undetected.						
			10A	Ensure regular and comprehensive performance appraisals be conducted for all physicians, staff and management (including CEO) using 360 degree feedback for management.	C	SJGH CEO and Board		

Root Cause #	Contri-buting Factor	Causal State-ments	Item #	Description of Action	Action E = eliminate C = control A = accept	Recommended Party Responsible	Outcome Measure	Measure Date (M/D/Y)
			10B	Develop or refine performance management process to ensure regular written assessment of knowledge, competencies and skills and remedies to address areas requiring improvement.	C	SJGH CEO		
			10C	Develop or update job descriptions for all staff, managers (including the CEO), and physicians with input from same that provides clear direction on purpose, responsibilities, accountabilities, qualifications, competencies and expectations for performance and maintenance of skills and competencies.	C	SJGH CEO and Board		
			10D	Incorporate professional development and continuing education plans for all staff as part of the performance appraisal process and reflect planning for development needs in the budget process.	C	SJGH CEO		
			10E	Provide forum for staff and management to routinely share learnings from continuing education with immediate supervisor and co-workers.	C	SJGH CEO		
	11	Culture of frugality cultivated historically continues to exist among SJGH board, administration and staff, resulting in real or perceived constraints which limited their compliance with directives that may or may not have resulted in increased costs but improved patient safety.						
			11A	Management to involve staff in budget and capital equipment planning and allocation.	C	SJGH CEO		
			11B	Staff to be advised of capital equipment approvals and timelines for purchase and commencement of use.	C	SJGH CEO		
			11C	Directives for new procedures or processes to identify use of specific supplies and equipment to be routinely utilized.	C	SJGH CEO		
			11D	Resources required for services should be based on population needs assessment (see 2B) and staff must demonstrate requisite competencies to care for the populations being served.	C	SJGH CEO		
	12	Lack of process to standardize equipment and supplies in the Region resulted in unique practice for cleaning and sterilizing instruments that was not readily identifiable as a deviation from standard practice.						

Root Cause #	Contri-buting Factor	Causal State-ments	Item #	Description of Action	Action E = eliminate C = control A = accept	Recommended Party Responsible	Outcome Measure	Measure Date (M/D/Y)
			12A	Integrated Regional Standards Committee to conduct inventory of CSR supplies and equipment, identify approved standards of same and communicate outcome to all sites.	C	ECH Regional MM Manager		
			12B	CSR supplies and equipment at all sites to be updated to reflect regional standards.	C	ECH Surgical Program Lead		
	13	Lack of provincial standards and guidelines for MRSA screening and surveillance and consequent different practices in different RHAs resulted in incongruence of determining benchmark data of MRSA cases in Vegreville and an inability to detect an impending outbreak of MRSA when SJGH first joined the ECH region.						
			13A	Develop provincial standards for MRSA screening and surveillance so all RHAs have consistent practice.	C	AHW		
			13B	Develop a provincial group responsible for leadership in determining provincial standards with respect to infection control.	C	AHW		
	14	Presence of a sense of being "victimized" and "picked on" by SJGH caused resistance to suggested measures by Infection Prevention and Control Co-ordinator.						
			14A	Use information from the Blackwell Operational Review for SJGH (2007) to demonstrate that SJGH is not under resourced compared to other ECH facilities.	C	SJGH CEO		
			14B	Re-address equity of funding to SJGH based on clearly identified expectations of programs and services determined collaboratively with ECH (see recommendations 2B and 2C for reference).	C	SJGH CEO ECH CEO		
			14C	Develop communication strategies to regain public and staff confidence of safety and quality with respect to infection prevention and control within SJGH.	C	ECH MOH SJGH CEO AHW		
			14D	Hold forum for interim Management Board to clarify myths and misconceptions of commonality of MRSA within health care facilities and describe unique situation of MRSA cases in Vegreville.	C	ECH MOH		
			14E	Hold staff and physician forum to clarify myths and misconceptions of commonality of MRSA within health care facilities and describe unique situation of MRSA cases in Vegreville.	C	ECH MOH		

Root Cause #	Contri-buting Factor	Causal State-ments	Item #	Description of Action	Action E = eliminate C = control A = accept	Recommended Party Responsible	Outcome Measure	Measure Date (M/D/Y)
			14F	Develop pictorial representation of current MRSA cases and threshold required to decrease frequency and type of screening processes. Depict progress and comparison with other facilities in pictorial story.	C	ECH IPCC		
	15	Lack of appreciation by ECH for requested increase in infection prevention and control staffing and lack of dedicated infection prevention control resources to get SJGH MRSA situation under control resulted in ongoing transmission of MRSA.						
			15A	Develop provincial benchmarks for infection prevention control resources required.	C	AHW		
			15B	Consider mechanisms for provincial and/or regional support for a flexible and co-ordinated response to outbreaks.	C	AHW		
	16	Lack of patient safety advocacy, as exemplified by infection prevention and control, patient safety and quality improvement issues, at ECH senior management decision table resulted in lack of appreciation of the importance for the requested increase in infection prevention control staffing and lack of approval for the recommended dedicated infection prevention control resources to get SJGH MRSA situation under control.						
			16A	Develop clear strategies that explicitly define how quality improvement, patient safety, risk management and infection control will be led regionally, and how input, advice, actions and accountabilities will occur among all sites and within the Region.	C	ECH and Voluntary Facilities CEOs		
			16B	Communicate safety and quality strategies developed and/or implemented to the previous Board of SJGH.	C	SJGH interim Management Board		
			16C	Develop and implement a corporate policy requiring that decisions for situations requiring immediate attention must consider patient safety as a criteria.	C	ECH and Voluntary Facilities CEOs		
	17	Lack of functional ECH structure aligning patient safety, quality, risk management and IPC resulted in inefficient and ineffective communication about the need to urgently address the SJGH MRSA situation.						
			17A	Develop optimal senior reporting structure for patient safety, quality improvement, risk management and IPC to ensure adequate representation at decision-making table of ECH and appropriate integration of these overlapping and mutually supportive functions and develop other structures to ensure integration of these issues.	C	ECH and Voluntary Facilities CEOs		

Root Cause #	Contri-buting Factor	Causal State-ments	Item #	Description of Action	Action E = eliminate C = control A = accept	Recommended Party Responsible	Outcome Measure	Measure Date (M/D/Y)
	18	Inability of the SJGH Board, and to a lesser extent, the ECH Board, to understand the seriousness of the MRSA situation and take directives to resolve ongoing high levels of transmission resulted in continuation of MRSA transmission.						
			18A	Develop key performance indicators of safety and quality in organizational and departmental planning that are reported regularly to the Board.	C	ACHC CEO and SJGH CEO		
			18B	Develop clear roles and responsibilities for the Boards that include clarity of their role in ensuring quality and patient safety.	C	ACHC ECH & interim Management Board & AHW		
			18C	Develop an orientation process for Board members that addresses the purpose of Board, roles, responsibilities and expectations of Board members, reporting and structure of the organization.	C	ACHC ECH & interim Management Board & AHW		
			18D	Identify a mechanism to ensure ongoing education of current best practices for all Board members, especially with respect to their leadership responsibilities in patient safety and quality improvement.	C	HQCA, ACHC ECH & interim Management Board & AHW		
			18E	Develop a provincial strategy to educate Board members as to their role with respect to patient safety, IPC, quality improvement, clinical risk management and other such clinical care quality leadership matters.	C	HQCA		
			18F	Develop a succession plan for SJGH Board members.	C	ACHC SJGH Board		
			18G	Develop criteria and a process that identifies the leadership, safety and quality requirements of the Chief Executive Officer and supports the optimal selection and ongoing performance assessment of this position.	C	ECH & SJGH Boards		
			18H	Ensure compensation is adequate to support appropriate recruitment and retention of Board members and ensure alignment with RHA regulations and equity with other Voluntaries.	C	ACHC		

Root Cause #	Contri-buting Factor	Causal State-ments	Item #	Description of Action	Action E = eliminate C = control A = accept	Recommended Party Responsible	Outcome Measure	Measure Date (M/D/Y)
			18I	Ensure all boards understand their role and responsibilities in ensuring quality and patient safety.	C	ACHC, ECH & Voluntary Boards		
	19	Lack of a trigger process (e.g. morbidity and mortality review of MRSA cases by SJGH medical staff) to demonstrate the scope and seriousness of the MRSA situation allowed the continuation of MRSA transmission practices without heightened concern and an urgent need to act.						
			19A	Complete morbidity and mortality chart reviews of SJGH patients to determine potential link of death to MRSA infections.	C	ECH VP Medicine		
	20	Lack of engagement of SJGH physicians to communicate and reinforce the seriousness of sterilization breaches and continued MRSA transmission perpetuated a lack of heightened concern and diminished the sense of urgency to address the problems.						
			20A	Review SJGH Medical Staff By-Laws and Medical Staff Rules to reinforce the responsibilities of physicians in quality and safety reviews.	C	SJGH Chief of staff		
			20B	Initiate regular morbidity and mortality chart audits and other such quality assessment processes, and report the results to SJGH Medical Advisory Committee, Site Chiefs Meetings and ECH Quality Council.	C	ECH VP Medicine		
			20C	Working with knowledgeable partners such as the College of Physicians and Surgeons of Alberta, develop key performance indicators to be reported to the Boards that demonstrate the ongoing efforts of medical staff contributions to quality and safety.	C	ECH VP Medicine CPSA[4] HQCA		
			20D	Develop a process to demonstrate compliance of physicians with Medical Staff By-Laws and Medical Staff Rules.	C	ECH VP Medicine		
			20E	Develop a strategy and curriculum to assist physician leaders such as department heads and chiefs of staff to better fulfill their roles in quality and patient safety leadership.	C	ECH VP Medicine CPSA, HQCA		
	21	Lack of explicit and evident patient safety culture in SJGH and ECH did not support development of quality and safety markers and performance measurements to monitor compliance with expectations for provision of safe and quality care.						
			21A	Conduct a safety culture survey to determine the baseline culture related to safety in ECH.	C	ECH and Voluntary Facilities CEOs		

[4] CPSA – College of Physicians & Surgeons of Alberta

Root Cause #	Contri-buting Factor	Causal State-ments	Item #	Description of Action	Action E = eliminate C = control A = accept	Recommended Party Responsible	Outcome Measure	Measure Date (M/D/Y)
			21B	Determine the top patient safety concerns through a culture survey, administrative walkabouts, and feedback from program managers etc. and develop strategies to improve safety that include performance indicators.	C	ECH and Voluntary Facilities CEOs		
			21C	Assess the organization's performance relative to the CCHSA Required Organizational Practices that support patient safety and include a process to oversee progress and ensure ongoing compliance on a quarterly basis.	C	ECH and Voluntary Facilities Boards & CEOs		
	22	Knowledge and appreciation of significance of deficiencies in infection prevention and control and sterilization within SJGH was not acted on, resulting in continuation of unsafe practices.						
			22A	Oversee that any professional who becomes aware of a potential safety hazard or probable risk to patient safety is duty bound to take appropriate and timely action such as reporting the situation to their supervisor or taking appropriate action to resolve the situation.	C	ECH and Voluntary Facilities Boards & CEOs		
			22B	Enhance the importance of patient safety and quality of care at ECH and SJGH by including safety as a standing agenda item at all meetings.	C	ECH & SJGH Boards and CEOs		
			22C	Patient safety is to be a criteria used in decision-making by all staff and management. (See also 16C)	C	ECH and Voluntary Facilities Boards & CEOs		
			22D	Identify a senior level administrator who has access to Board decisions and participates in senior management planning and decision-making as a 'safety champion'.	C	ECH and Voluntary Facilities CEOs		

10. Glossary of Terms

ACHC: Alberta Catholic Health Corporation

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.

Capital equipment: Equipment assessed a cost in excess of $5000

CCHSA: Canadian Council on Health Services Accreditation

CEO: Chief Executive Officer

Colonization (of MRSA): Patient may have MRSA on body surface but does not have any signs or symptoms of infection

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

Cystoscope: An instrument for examining and treating lesions of the urinary bladder, ureter, and kidney; consists of an outer sheath with a lighting system, a viewing obturator, and a passage for catheters and operative devices
From Mosby's Medical, Nursing, & Allied Health Dictionary Fourth Edition, 1994

Disinfection: The process of killing pathogenic organisms or of rendering them inert
From Mosby's Medical, Nursing, & Allied Health Dictionary Fourth Edition, 1994

ECH: East Central Health Region

Endoscope: An instrument for visualization of the interior of organs and cavities of the body with an endoscope
From Mosby's Medical, Nursing, & Allied Health Dictionary Fourth Edition, 1994

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 Control

IPCC: Infection Prevention Control Co-ordinator

Latent: Structural flaws in the system, or 'resident pathogens', that predispose to adverse outcomes
From Royal College of Physicians and Surgeons, Canadian Patient Safety Dictionary, October 2003

Lumen: A cavity or the channel within any organ or structure of the body
From Mosby's Medical, Nursing, & Allied Health Dictionary Fourth Edition, 1994

Master Agreement: Agreement between the Minister of Health and the Catholic Health Association of Alberta that identifies the fundamental principles that govern the relationship between the Regional Health Authorities and the Voluntary health facilities in their region. Also referred to as "Umbrella Agreement".
From Agreement relation to principles of continuing ownership/ operation of voluntary health facilities and programs in the regional health care system, December 1994

MOH: Medical Officer of Health

Morbidity and mortality reviews: A specific audit that targets negative conditions or outcomes. It is a quality assurance/quality improvement audit methodology including in depth physician peer review of individual clinical cases to identify reasons for clinical outcomes.

MRSA: Methicillin Resistant *Staphylococcus aureus*

Nares: Pertaining to the nostrils

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

Peri-Operative: Pertaining to events, activities before, during or after surgical procedures

Prevalence screening: Taking of blood cultures to determine the presence of MRSA within a specific population

Public Health Act: (www.canlii.org/ab/laws/sta/p-37/20070515/whole.html
Legislation passed in 2000, with appropriate versions developed subsequent to the original act, specifying structures, personnel, and processes for ensuring the health of the public.

Regional Health Authorities Act:
(www.qp.gov.ab.ca/Documents/acts/R10.CFM)
Legislation passed in 1994 at the time of regionalization in Alberta, specifying responsibilities, powers of authority, bylaws, and other requirements of any regional health authority

Risk management: Organizational activities designed to prevent patient injury or moderate the actual financial losses following an adverse outcome
From Royal College of Physicians and Surgeons, Canadian Patient Safety Dictionary, October 2003

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. Health care Quarterly Vol. 8, Special Issue, October 2005.

Scope: A suffix meaning an 'instrument for observation or visual examination'
From Mosby's Medical, Nursing, & Allied Health Dictionary Fourth Edition, 1994

Service Agreement: Agreement between the Regional Health Authority and Voluntary facility setting out the terms and conditions respecting the provision and funding for services and programs to be provided by the Voluntary facility

SJGH: St. Joseph's General Hospital in Vegreville, Alberta

Sterilization: A technique for destroying microorganisms using heat, water, chemicals, or gases
From Mosby's Medical, Nursing, & Allied Health Dictionary Fourth Edition, 1994

System: Describes the entirety of health care and is defined as a set of interdependent components interacting to achieve a common aim
From Royal College of Physicians and Surgeons, Canadian Patient Safety Dictionary, October 2003

Voluntary Facility: Catholic and other Christian denominations and non-denominational owners or operators of hospitals and long term care facilities in Alberta
From Agreement relation to principles of continuing ownership/operation of voluntary health facilities and programs in the regional health care system, December 1994

PART 2: Evaluation of Follow Up Action

Evaluation of Follow Up Action by St. Joseph's General Hospital, East Central Health Region and Alberta Health and Wellness

1. Introduction

The following objectives were identified by Alberta Health and Wellness (AHW) for the Health Quality Council of Alberta (HQCA) review:

1. Identify the factors and root cause(s) that led to the Medical Officer of Health Order to close the Central Sterilization Room (CSR), remove all equipment and instruments previously processed by the CSR, and accept no further admissions of patients until adequate infection prevention control measures could be demonstrated.
2. Assess the adequacy and appropriateness of the response by St. Joseph's Hospital, East Central Health (ECH) Region and Alberta Health and Wellness to the identified infection prevention and control (IPC) issues outlined in the MOH Order.
3. Make recommendations to ensure the contributing factors and root cause(s) of infection control practices, including transmission of MRSA, identified are addressed within St. Joseph's General Hospital (SJGH), East Central Health Region and the provincial health system.
4. Review all facilities operated under contract (Voluntaries) within East Central Health Region, as well as facilities operated by East Central Health, in terms of infection prevention and control procedures, practices and risk management.

Part 1 of the report describes the outcome of the root cause analysis, which focused on objectives 1 and 3. Part 3 of the report addresses objective 4. This section, Part 2 of the report, pertains to objective 2.

The order from the Medical Officer of Health (MOH) on March 16, 2007 to stop admissions to St. Joseph's General Hospital (SJGH) and to close the Central Sterilization Room (CSR) was based on two main factors:

- ongoing and unresolved concerns regarding containment of Methicillin Resistant *Staphylococcus aureus* (MRSA) spread; and
- concerns with central sterilization processing of equipment.

Three main organizations responded to the Medical Officer of Health Order and took the following actions:

a. St. Joseph's General Hospital (SJGH)
   i. Closed the CSR.
   ii. Enhanced containment strategies to manage the MRSA, including implementation of enhanced environmental cleaning for the facility.

b. East Central Health (ECH)
   i. Provided ECH senior nurse to oversee immediate implementation of strategies to contain MRSA.
   ii. Developed a "report card" of criteria that would need to be met to have the Order gradually reversed.
   iii. Held regular on-site inspections of SJGH using that report card to ensure required changes were being implemented expeditiously.
   iv. Ensured that Employee Assistance was offered to staff stressed by the closure.
   v. Initiated a look back to determine if any patients had been infected with Hepatitis B, Hepatitis C and/or Human Immunodeficiency Virus (HIV).
   vi. Initiated chart audits to assess:
      1. any evidence of infections or other adverse events for patients receiving invasive procedures dependent on CSR sterilization.
      2. any evidence for MRSA as a cause of death of patients in SJGH or ECH.

c. Alberta Health and Wellness (AHW)
   i. The Department of Public Health provided additional resources to the ECH Medical Officer of Health for a brief period immediately after the Order was released to aid in the look back strategy.
   ii. Requested the HQCA to conduct a review of the underlying causes and contributing factors of the SJGH closure, and further to assess other ECH sites with respect to infection prevention control (IPC) and CSR practices.
   iii. Appointed an interim Board of Management to be responsible for the operation and administration of SJGH for at least a six month period.

2. Discussion, Findings and Recommendations

The appropriateness of each of these responses is discussed, significant findings identified and recommendations made where opportunities exist to improve. The discussion of the responses is based on information available in late June 2007 and many assessments are subjective in nature.

Response from St. Joseph's General Hospital

The impact of hospital closure on the staff of SJGH, the residents of Vegreville, ECH and possibly for all of Alberta cannot be minimized. The community was shaken by the action and looked for restoration of their confidence in their local health system. Many SJGH staff members were hurt personally and professionally by the closure, were chastised in their own community and immediately had to begin a new and different approach to their clinical care. These stressors were felt acutely by the staff, many of whom were angry and frustrated but also hopeful that the future would be better. While visiting SJGH in May and June, it was clear to the Investigative Team that not all the personal issues had been resolved. Because of concerns that the SJGH staff was not adequately informed and supported, the Investigative Team believe that the Employee Assistance Program (EAP), which was well received, could have been made available for a longer time with more one-to-one therapy sessions offered. In addition, the public had not been adequately informed by knowledgeable individuals local to the community as to the cause of the closure, actions taken immediately in response to the closure, and the ongoing progress after closure. Frequent regular communications with the community may have helped both local residents and staff. Recommendations relevant to this have been made in Part 1 of this report[5].

Finding: Several staff members remarked that the EAP was too short and more individual time would have allowed them to personally deal more fully with the impact of the closure.

Recommendation: See third recommendation on page 34 re: Responses by ECH.

At SJGH, there were major changes that occurred immediately. The CSR was fully closed and equipment disinfected and/or sterilized. SJGH began an enhanced environmental cleaning of the facility. This has proceeded well, although somewhat slower than desirable related to a delay in hiring additional staff. This is a problem that ECH helped solve. The staff received additional education and support to better understand the issues of infection containment and the importance of their practices on the spread of MRSA. All clinical areas were reviewed on site by nursing leaders and others from ECH and SJGH, protocols assessed, and equipment and supplies scrutinized. It was identified that some clinical practices such as non-stress testing for fetal distress required reassessment based on contemporary protocols. Concerns exist that the processes and equipment in use may present a patient safety risk; however, these aspects were beyond the scope of this review on infection control and CSR. It is anticipated that this concern will be addressed by ECH and SJGH in a collaborative and timely manner.

Finding: The CSR was closed immediately. Environmental cleaning and staff education proceeded well within the ability of available resources.

Recommendation: ECH and SJGH should work collaboratively to evaluate clinical protocols other than the IPC, CSR or unit-based ones to ensure that services are provided safely.

A plan to re-open the hospital was developed in co-operation with the MOH. A report card audit system identifying criteria that must be met would be used weekly and would provide the evidence required in determining when the hospital could re-open. Using this report card, the ECH nurse leaders toured the facility with SJGH nursing leaders on an unscheduled but weekly basis to assess how much of the plan had been completed and, if there were problems, helped to resolve them. On June 18, 2007 the eighth of these unannounced on-site reviews was done and the results demonstrated that the majority of the planned tasks have been completed. Still outstanding are terminal cleaning of non-clinical areas and expansion of housekeeping services to provide 24/7 coverage.

Finding: SJGH responses to the directions of ECH to contain MRSA were appropriate with some exceptions of delayed commencement.

[5] See also RCA recommendations 14C, 14D and 14E from Part 1 of the report.

Recommendations: SJGH and ECH should continue to perform report card audits intermittently to sustain the gains achieved in containing MRSA in SJGH.

Updating and/or conversion of policy and procedures to ECH standards is ongoing and affecting numerous inpatient and outpatient settings in SJGH. Generally, the ECH nurse leaders appear comfortable that SJGH has responded to the challenges and required upgrades. Some changes, like revising cleaning schedules or removing unnecessary equipment, seemed to take a long time before being completed. It is noted that the one negative aspect of this strategy was that SJGH staff commented that the manner in which these on-site reviews were initially conducted was perceived as derogatory and contributed further to their level of stress. The Investigative Team has reviewed the documentation of the on-site reviews done since the closure and is comfortable that adequate progress is being made.

Finding: IPC and unit based policies and procedures are being updated and standardized by ECH.

Recommendation: Conduct audits to ensure compliance to updated policies and procedures.

Finding: The changes should be sustainable since many procedures like cleaning and stocking carts or cupboards in clinical areas have now been made routine, check lists have been developed and a compliance sign off sheet established and used. It will be important, however, for the current and future leadership of the site to continue to focus on these issues to maintain the gains that have been achieved.

Recommendation: Audits to ensure compliance to new procedures should continue.

SJGH began taking patients again April 17, 2007. The decision by the MOH to begin to allow SJGH to admit patients was based on the ongoing closure of the CSR, the fact that all surgery had been postponed indefinitely, and ongoing progress was being made according to the weekly report cards and visits of ECH nursing leaders. The bed capacity is being increased gradually (on June 18, SJGH's 20 beds were open out of the usual 25 bed capacity) to allow for required staff recruitment, as well as for staff to update protocols and become accustomed to the new ones. There was also a need to ensure that MRSA spread within the hospital did not occur.

Finding: Routines that provide a safe environment have been established and continue to support SJGH's ability to admit patients.

Recommendation: SJGH and ECH continue to collaborate to conduct comprehensive audits of the clinical care environment to ensure a safe environment continues, and to do so until SJGH has achieved an agreed upon threshold of sustainability.

Since the MOH Order was implemented, screening of all admissions and discharges for MRSA continues at SJGH[6]. There has been one previously known MRSA positive case admitted to the hospital and early results do not show any spread within the facility, suggesting the containment practices have been effective. The staff of SJGH and ECH should be proud of this and continue to work to maintain these results. They will continue to have positive cases admitted intermittently given the pool of colonized individuals that live in the Vegreville community.

Finding: One MRSA patient has been admitted since the MOH Order and no spread of the infection has been detected.

Recommendation: SJGH and ECH should reinforce that good infection control strategies do work by demonstrating the results and congratulate the staff on their short-term success. Their diligence in maintaining the IPC strategies to ultimately reach the target threshold and eliminate the need for screening on all patients should be actively encouraged.

Other significant changes that SJGH had to contend with included the departure of the two interim CEOs and the recruitment of an interim Director of Nursing and a new interim CEO. These changes were required to provide the necessary leadership to the organization during this stressful time. Despite the general support of these changes, they contributed to continued staff stress in dealing with yet more change. The future challenge of recruiting people into these positions on a permanent basis is significant for the interim Board of Management and/or the existing SJGH

[6] A target threshold has been set for SJGH to continue screening all admissions until they can demonstrate two or less cases spread within the institution over six consecutive months. Once this target is reached, only high risk patients need be screened.

Board once the interim Board's term is completed. Those positions will be extremely important to lead the cultural change required, to provide leadership and support for the staff as well as the patients and the Vegreville community, to actively work on improving the relationship with ECH, and to continue to focus on clinical practice issues.

Finding: Senior level vacancies have occurred since the MOH Order.

Recommendation: SJGH interim and existing Boards need to pay heed to appropriate recruitment of senior administrators for organizational and clinical leadership critical to the future of SJGH. Explicit description of the attributes required must be defined to guide recruitment.

Responses by ECH

The regular on-site inspections, which focused on specific criteria, were generally effective and timely. Current report cards demonstrate adequate progress with the majority of tasks completed. Some tasks of the plan and the report card were structure and process strategies such as "implement Infection Control Rounds" or "implement Nursing Practice Committee". In the future, these activities must be evaluated for effectiveness.

Finding: The process of conducting unscheduled audits measuring against established criteria has worked well and has demonstrated regular progress at SJGH.

Recommendation: ECH and SJGH must evolve from process-oriented measures of progress to outcome-oriented performance indicators to measure success in achieving the outlined plan.

It is the opinion of the Investigative Team that the Employee Assistance offered to the staff in SJGH was not offered as soon as necessary for full benefit of the staff or for a long enough time to support their level of stress at work and in the community. Feedback indicated that the service provided had been very helpful and it is acknowledged that SJGH did commit to bring the EAP services back for repeat offerings of support as required.

Finding: EAP was insufficient to meet the needs of individual SJGH staff.

Recommendation: In crises situations it is critical for organizations (such as ECH and SJGH in this case) to provide adequate EAP support to staff to ensure they can capably participate in future changes in the organization.

From the clinical perspective, there was a risk that the invasive procedures done at SJGH put patients at risk for infections such as Hepatitis B and C and HIV. A plan for a look back[7] was initiated to determine if any infections had occurred as a result of interventions in SJGH. The Medical Officer of Health began the look back promptly by sending registered letters or phoning approximately 3000 at-risk individuals. The infectious status of about 1600 of the 3000 individuals has been completed. Individuals with results requiring additional investigation are being referred to Infectious Disease specialists in Edmonton. The main challenge now for the ECH Medical Officer of Health is to find those individuals who have not yet been contacted. A second attempt to contact the remaining individuals is underway. The proposed plan to locate these people has been reviewed by the Investigative Team and an Infectious Disease (ID) specialist member of the Expert Advisory Panel; the strategy seems well designed (i.e. timely, appropriate and adequate). Continued attention to this project will be required to ensure all the people who can be found are contacted. However, the project is generally proceeding well and should be able to identify individuals who may have been infected through SJGH interventions.[8]

Finding: The first phase of the look back was able to contact more than 50% of the patients and the plan for the second attempt to contact the remainder is well designed. Patients identified to have some communicable disease potential are being referred to ID specialists in Capital Health.

Recommendation: The second attempt to contact the remaining patients should proceed as outlined and expeditiously as is feasible.

[7] A look back is a strategy that identifies a group of people that may be at risk for a particular infection and contacts them to have additional blood work to assess if they have been infected. Some people may be infected with the organisms of concern either from the intervention itself or from other causes such as needle sharing or sexual contacts. Not all individuals who are found to be positive will be infected by the interventions that occurred in SJGH and therefore additional specialist investigation and therapy is required.

[8] Finding individuals who are positive from other causes but are unaware of their condition can assist them as some therapies and/or counseling are appropriate and would not have been done.

Recommendation: ECH and the specialist consultant must determine how ongoing care will be provided to the patients identified as having communicable diseases. The plan must include educating local family physicians who may have an ongoing role to play in managing the patients' relevant chronic conditions.

ECH has initiated two chart audits:

- One audit is of patients that may have suffered other infections or untoward events subsequent to the surgical interventions or other procedures at SJGH involving instruments that were not appropriately cleaned and sterilized.
- The second audit is for those who may have had MRSA that contributed to any morbidity or possibly mortality.

Although the goals of each of these studies are different as shown in the bullets above, the approach is the same. The studies involve chart reviews that have the potential to identify cases and clinical practices of concern at SJGH. Unlike the look back patients, however, where identified individuals will require different treatment in the future and their personal communicable disease status must be managed, the vast majority of the sequelae of the patients identified in the chart audits will have resolved by now or a few patients may have died of related or unrelated causes. The future care of those identified in the chart audits may not be much different from what is being provided to each individual patient. The goal is to understand the full impact of the clinical care surrounding SJGH so that SJGH, ECH and others may learn from these findings and demonstrate to the public the conscientious efforts of the Region in providing adequate follow up and care to affected patients.

The chart audits are proceeding but at a much slower rate than the look back. Three physician reviewers have been identified who will review all the charts and an Infectious Disease specialist in Edmonton has agreed to review any charts identified by the initial three reviewers to comment on the infection issues inherent by each case. A draft plan to identify the charts to be reviewed has been created but needs greater clarity. Final numbers of which and how many charts must be audited remains to be determined. The Investigative Team and the Infectious Diseases expert of the Expert Advisory Panel feel that the general principles of the audits are appropriate and adequate as are the choices of the physicians to do the reviews. However, there is concern among the Team that the clarity of the approach needs to be improved and action to review the charts needs to begin immediately.

An additional point is the availability of funds required to address these necessary but extraordinary responses. While funds were made available, finding qualified individuals locally was a challenge. Acquiring external expertise resulted in delays and likely increased costs due to travel and other expenses of the external consultants. Mechanisms to assist sites without in-depth expertise in chart audit could be designed.

Finding: More clarity is required regarding the chart audit plan. The chart audits to assess the morbidity and mortality that may have occurred at SJGH are appropriate but are moving too slowly.

Recommendation: ECH should move this initiative forward faster and with a greater sense of urgency.

Recommendation: Under ECH's leadership, ECH and SJGH must work collaboratively to clarify the existing plan and explain how they will manage: disclosing findings to affected patients or families;[9] the medical legal implications of finding affected patients; and finding clinical care processes in the chart audits that may reflect less than adequate medical or nursing standards of the SJGH staff.

Finding: Finding qualified staff to perform key additional, sometimes complex, functions is extremely difficult in small communities.

Recommendation: See next recommendation below.

Responses by Alberta Health and Wellness (AHW)

AHW provided support for the ECH Medical Officer of Health prior to his issuing the Order via consultation with the Provincial Medical Officer of Health and immediately following the Order, as did Capital Health. This support consisted of providing two infection control practitioners, one from AHW and the other from Capital Health, and two communicable disease nurses from Capital Health, all of whom were available for 11 days each. An epidemiologist from AHW was available to provide advice. SJGH also provided Health Records staff support to the look back

[9] See www.hqca.ca website for important documentation regarding disclosure.

initiative. In and of itself, the support was good, helpful and appreciated, but it may have been inadequate. ECH did contract the services of a nurse experienced in communicable diseases for approximately three months to assist in the look back although commencement of this support was delayed due to recruitment difficulties. The Investigative Team is aware that staffing issues, such as in finding nursing support for the look back project and clerical, nursing and physician support for chart audits, did cause some delay.

One suggestion supported by the Investigative Team and a member of the Expert Advisory Panel was that consideration could be given to developing surge capacity in the Department of Public Health or in AHW itself to assist when significant events arise. This may be especially relevant in the smaller regions as the depth of in-house expertise can be limited and requisite skills are often not available in the local community even on a contract basis. Efforts to consider how this in-depth expertise can and should be made available throughout the province need to be explored, and is integral to creating equitable access and quality of care for the residents of Alberta.

Finding: Short-term support was made available to ECH but was of insufficient duration to optimally manage the complex follow up of the look back and chart audits. Support from Capital Health was noteworthy and important.

Recommendation: AHW and/or the Department of Public Health create a surge capacity strategy designed to provide access for centres that require additional expertise necessary to resolve major critical incidents such as occurred at SJGH.

Recommendation: The metropolitan regions, with assistance from AHW, acknowledge that the presence of highly skilled clinical, scientific or administrative specialists is associated with a responsibility to provide leadership in these areas to the smaller regions and local centres. They must recognize a leadership and capacity building responsibility beyond their own boundaries.

An interim Management Board was appointed for SJGH for addressing patient safety, operational and management issues at SJGH and more closely integrating the hospital services at SJGH with those of other hospitals, health plans and services in the East Central Health Region. The Investigative Team met with some members of the interim Board and the previous/existing Board of SJGH. The existing Board stated (as in the RCA, Part 1 of the report) that they did not have full knowledge of what was happening in SJGH, did not fully appreciate the severity of the MRSA spread, and were not well versed in their role as a board with respect to patient safety and quality leadership. Putting an interim Management Board in place was probably required to provide the leadership necessary to support the changes needed, to work with ECH, to implement the recommendations of the Blackwell operational review and of this HQCA review, and to provide a transition plan to the existing Board at the end of the term. Careful transition planning is required before the appointment of the interim Board comes to an end as members of the previous Board have not been involved in many activities since the enactment of the MOH Order and may be harbouring anxieties and frustrations in being released of their governance responsibilities. It is too early to assess fully the progress for all these responsibilities so the Investigative Team cannot fully comment on the progress to date. The interim Board has appointed an acting CEO for SJGH, which is an important early step. The acting CEO has started a search for a Director of Nursing.

Finding: The interim Board of Management has many significant responsibilities. The appointment of an acting CEO for SJGH was an appropriate and important decision.

Recommendation: Support for the interim Board to provide continued leadership with respect to the management of SJGH, provide regular updates to AHW and ECH, develop a clear and considerate transition plan for transferring authority over to a well prepared existing SJGH Board and identify clearly the characteristics required of a new CEO before progressing with recruitment.

Evaluation of Responses by SJGH, ECH and AHW

	Response	Evaluation of Response[10]	Comments
SJGH	Closed CSR	Appropriate, effective, safe	Completed immediately
	Enhanced MRSA containment strategies including enhanced environmental cleaning	Appropriate, effective, safe	Initial MRSA containment data shows no hospital spread – will need to continue vigilance; approximately 95% facility cleaning completed according to new requirements; some delays due to inability to recruit human resources
ECH	Provided ECH senior nurse to oversee immediate implementation of strategies to contain MRSA	Effective, safe	Quick progress was made in complying with MRSA containment strategies; a more sensitive approach in dealing with SJGH stressed staff could have been used
	Regular inspections at SJGH	Appropriate, effective, safe	Generally believe progress is being made; qualitative outcome indicators should be included in report card
	Provided employee assistance program (EAP)	Not offered in timely manner nor sufficiently extensive	Initial contact with EAP was inadequate to address concerns of many staff; additional EAP and/or individual counselling would be helpful
	Initiated look back	Appropriate, effective, safe	Next challenge is to identify as many of the remaining at-risk individuals as possible; plan for this phase is appropriate
	Initiated chart audit	Slow to initiate	Clinical staff have now been found to perform the review; additional clarity in process to follow is required
AHW	Support from Department of Public Health[11]	Effective, efficient and appropriate but brief	Opportunity to consider how in-depth expertise can be provided to small regions during crises
	Requested HQCA to conduct review	Acceptable, appropriate, effective, efficient, safe	Significant underlying issues have been identified
	Appointed an interim Board of Management	Appropriate, safe	Need to ensure sound action plan and transition to previous Board; progress to date not evaluated

[10] Reference is made to the HQCA Quality Matrix – acceptability, accessibility, appropriateness, effectiveness, efficiency and safety.

[11] Plus support from Capital Health.

Tour of East Central Health Sites June 13-15, 2007 and Incidental Findings

1. Executive Summary

The Scope of Work identified by Alberta Health & Wellness (AHW) included a specific objective to "review all facilities operated under contract (Voluntaries) within the East Central Health (ECH) Region, as well as facilities operated by ECH, in terms of infection prevention and control procedures, practices and risk management." Information from the root cause analysis (RCA) process, individual interviews, documentation review, the development and use of a semi-structured interview, and site tours to all acute care sites over a three day period were used by the Investigative Team to develop contextual observations and analysis of the findings. During the site tours, the Investigative Team was accompanied by a nurse consultant with expertise in CSR issues.

Many of the observations noted during the site tours validated the root causes and contributing factors identified during the root cause analysis process (see Part 1 of this report), including concerns and opportunities related to the relationship between the ECH Region and the Voluntary facilities, patient safety, regionalization, regional development of programs and services, management style of ECH, infection prevention and control (IPC) policies and practices, and the status of CSRs. There were 31 recommendations identified, in addition to general and site specific recommendations for CSRs. The majority of these recommendations (11) related to IPC issues.

Other recently completed reviews, including the Health Facilities Review Committee (reports from site visits 2002 and 2004), Canadian Council on Health Services Accreditation (CCHSA) from 2005, and the Operational Review conducted by Denise Blackwell and Associates (2007) were examined to identify areas of congruence or divergence with the findings of the Investigative Team. This analysis identified the importance of reviewing evidence relevant to self reports, and the concern that the positive (although in hindsight, they could be interpreted as false positive) comments may have contributed to the sense of complacency in attending to patient safety issues in a more timely manner. Many of the observations and recommendations in the Operational Review were congruent with the findings of this review.

Many of the findings during the site tours validated the issues that were identified during the root cause analysis. In general, the Investigative Team found the staff to be committed and dedicated to providing the best care possible to the residents in their communities. With timely resolution of the issue as to which one organization has final authority over patient care matters, the Region would be positioned to move forward more readily on implementing the recommendations from this report as well as other reports and operational reviews. While most of the recommendations could be acted on without that clarity, there is historical evidence that without that clarity, potential safety hazards will continue to exist.

2. Review of the Infection Prevention and Control Procedures, Practices and Risk Management

Introduction

The Scope of Work identified by Alberta Health & Wellness (AHW) included a specific objective to "review all facilities operated under contract (Voluntaries) within the ECH Region, as well as facilities operated by ECH, in terms of infection prevention and control procedures, practices and risk management." Information from the root cause analysis (RCA) process, individual interviews, documentation review, the development and use of a semi-structured interview, and site tours to all acute care sites were used by the Investigative Team to develop contextual observations and analysis of the findings.

The focus of the site tours was on infection prevention and control procedures, practices, and risk management. The objective of the tours was to determine if any of the key contributing factors or concerns found in the in-depth review of SJGH by the root cause analysis were present in other acute care sites of ECH.

Methodology

Site visits of all of the other 11 acute care sites (three operated by Voluntary facilities; eight by ECH) were conducted June 13-15, 2007.

Acute care sites were selected to provide the context for the findings at SJGH, which was an acute care hospital, and the focus of an in-depth RCA review subsequent to the

MOH Order of March 16, 2007. Given the geographical distance, the time available to conduct this part of the review, and the number of sites requiring visitation, it was determined to spend 1.5 hours at those sites that had a CSR but did no surgery, and two hours for those sites that had a CSR and performed surgery.

To assess this objective, the HQCA Investigative Team constructed a semi-structured interview based on the findings at SJGH. The Investigative Team was accompanied by a member of the Expert Advisory Panel, a nursing consultant with expertise in CSR standards. At each site, interviews using the semi-structured questionnaire were held with the site lead administrator, the Nursing Care Co-ordinator, the CSR processor and the IPC Site Investigator. In addition and concurrent with the interviews, the CSR expert and a member of the Investigative Team toured the CSR; at least one member of the team toured one or more acute care units to make direct observations.

3. Relationship between ECH and Voluntary Facilities: Interpretation of the Master Agreement and the RHA Act

In visiting the three Voluntary acute care sites, three interpretations of which organization, the Voluntary facility or ECH Region, had final authority for the quality of care were given. The following were identified as having final authority:

- the Voluntary facility
- the Region
- a joint responsibility between the Region and the Voluntary facility

From the RCA process, it was determined that the root cause of the events leading to the issuing of the MOH Order at SJGH was related to the lack of clarity as to which organization, the Voluntary facility or ECH, had final authority on matters related to patient care. These three interpretations are evidence that clarity is required on authority and accountability, as the lack of clarity did create a potential for conflict.

Regions were created to improve efficiency and effectiveness of providing services across the continuum of care and to enable better access to regional expertise, especially the expertise that may not be available in smaller facilities.

ECH is a unique region in that 58% of the acute care services and 52% of the continuing care beds are provided by the Voluntary facilities. In today's dynamic, complex, and specialized health care environment, the available time and attention needs to be spent on identifying and creating the optimal environment for quality and safe patient care, and energy spent on debating who is in charge is counter-productive. Ethical principles and guidelines need to guide both Voluntary facilities and regional services. In no way should the Voluntary facilities be expected to provide services that threaten their principles and guidelines, but the same could be said for regional facilities as well. However, the focus must remain on the patient, and what is best for patient care!

The Investigative Team did not analyze in depth the Master Agreement and the *Regional Health Authorities Act* and hence this review did not assess the political or legal implications of changing current legislation. Remaining consistent with the HQCA mission "to promote patient safety and health service quality on a provincewide basis', and using that as the lens to view the current situation, the current ambiguity related to final authority that exists within the Master Agreement and the RHA Act has allowed unsafe practices to continue, and must be addressed by AHW.

It is recommended that:

AHW determine one organization to have full and final authority for the quality of care, including IPC, quality improvement, patient safety, utilization management and clinical risk management.[12] Given the length of time this issue has been unable to be resolved within the ECH Region and the risk it caused as evidenced in the analysis of events at SJGH, AHW is urged to move forward to rectify this as soon as possible.

4. Observations Related to Patient Safety

The Investigative Team identified several issues pertaining to the management of patient safety, quality of care, risk management and infection prevention and control.

In order to assess how these responsibilities (patient safety, quality improvement, risk management and infection control) are aligned structurally within the organization, the Investigative Team reviewed the organizational chart for ECH and asked relevant questions during the site interviews.

[12] See also recommendation 1A in the RCA document.

An organizational chart is intended to identify specific roles and responsibilities, and assist in identifying whom to contact for specific concerns. Some would argue that organizational charts clearly reflect major organizational philosophies. The following issues arose in reviewing the ECH organizational charts and in conversation with the site staff:

- Given the significant role that the Voluntary facilities play in the delivery of care (58% of acute care beds and 52% of continuing care beds), the organizational charts do not recognize the services provided by the Voluntary facilities or their role with respect to many aspects such as planning, operations or quality of care within ECH.[13] The only places the Voluntary facilities (CEOs/ Administrators) appear on the organizational charts are in a dotted line relationship to the Chief Corporate Services Officer and VP Medical Services.
- Site staff from both ECH and Voluntary facilities stated that it is not clear whom to call for quality of care issues because often it is not clear who has responsibility for patient safety, quality improvement, or risk management.
- The current organizational chart indicates that the patient safety, quality improvement, and IPC report to different senior administrators when these "domains" of quality are so intertwined that separation can jeopardize collaboration. While it may be preferable, it is not essential that these positions all report to the same senior administrator. There does, however, need to be some structure in place to ensure that collaboration and co-ordination of these important functions occurs so their individual efforts can be aligned and leveraged.
- In the organization structure, there is no obvious recognition of clinical risk management and utilization management as particular domains of quality improvement, and a position title reflecting a focus on "patient safety" is absent.
- A new and vacant position known as the Director of Quality was described to the Investigative Team by a senior administrator in ECH but other senior administrators or directors were either unaware of the position or unclear as to its purpose and responsibilities. A position of this nature requires collaborative planning and strategic placement in the organizational chart to achieve optimal outcomes.
- ECH has no involvement in any of the *Safer Healthcare Now!* initiatives. Most staff interviewed were not aware of these quality improvement activities demonstrated to improve safety and quality of care. However, one site was very familiar with the intervention related to prevention of surgical site infections, and had assessed their performance relative to the major components included in that initiative.
- There appears to be an over-reliance on the incident management system (SORS) as the primary indicator of risk in the system. "Voluntary reporting only identifies a small fraction of adverse drug events. Using incident reports for quality assurance/quality improvement will lead to significant bias when assessing quality of care."[14] Although the focus of that study was on adverse drug events, the principle can be generalized; the reliance of incident reports as the only measure of quality assurance identifies only a subset of the concerns that need to be addressed. Other indicators of risk must be identified and regularly reported.
- ECH has recently changed the reporting relationships of CSR processors from Materiel Management to nursing leadership. This was one of the outcomes of the CSR audit conducted from August 2006 to January 2007, as it was recognized as a risk that Materiel Management did not have the clinical expertise to adequately assess competence and standards in CSR. While under the direction of Materiel Management, however, CSR personnel from all sites were able to participate in regular region-wide meetings. Local sites were expected to comply with appropriate procedures in the ECH CSR manual but their isolation from external CSR practices limited their ability to identify internal clinical risks. While the change in reporting structure is important, it will be necessary to ensure that the nursing personnel assuming responsible for the supervision have the necessary knowledge and training to identify, understand and manage the clinical risks. Knowledge of CSR standards and best practices is a specialized expertise and not traditionally a significant part of basic nursing education.
- One potential risk management issue observed by the Investigative Team is that a significant proportion of the leadership groups in all facilities were in their positions for less than a year or so. The organization needs to ensure that they receive the necessary education, support, and mentoring to perform their duties at a high level. The Team was informed that discussions have occurred around the need and preliminary planning for a 'mentorship program', which would be supported. Without such support, it could be that they are "set up

[13] This latter deficiency might reflect lack of clarity about accountability for quality of care in the Master Agreement and the RHA Act as described in the RCA.

[14] Cullen DJ, et al. The incident reporting system does not detect adverse drug events: a problem for quality improvement. Jt Comm J Qual Improv. 1995, Oct, 21 (10); 549 –52.

to fail". This observation in no way implies any concern with competence of the new managers but rather the collective leadership experience available to new managers.

- There is no single senior executive who appears to be accountable for, and seen as, the 'champion' of quality of care issues in ECH, a strategy currently used by many regions. Such a position should have a high profile, and ideally be, or report to, a senior administrator. In addition, this position is best supported by equally high profile committees, such as the Quality Council in place in ECH. Unfortunately the Quality Council has not been meeting regularly, and has not had a history of dealing primarily with quality or safety issues.
- In reviewing documents submitted to the HQCA Investigative Team, there is evidence that some members of middle and senior management had been aware of quality and safety concerns in SJGH and other ECH facilities for several years. Nonetheless, there was inadequate evidence of follow up to the issues identified as well as inadequate leadership in the quality domain to ensure that these issues received attention, were investigated and resolved. A senior leader accountable for a "quality" portfolio could have been charged with ensuring resolution of the identified issues.

These collective observations reinforce a number of the contributing factors identified during the RCA process, namely that the profile of quality of care including quality improvement, patient safety, risk management, utilization management and IPC, does not appear to be a high priority for the Region. A notable exception is participation in the MOREob program, a quality improvement model proven to introduce and integrate best practices in obstetrical care. It is noted in the ECH Annual Report 2005-2006 that "Health care in the province has been focused on the electronic health record and therefore major patient safety initiative resources to move forward on other initiatives has been very scarce. This outcome has created delays in a multitude of safety projects not only in East Central Health but all RHAs" (p. 85). Making a conscious decision to delay safety projects needs to be done on the basis of a risk benefit analysis, which then allows the organization to consciously decide that they are accepting the risks associated with their decision to delay action. Observations such as these have led the Investigative Team to conclude that there was limited evidence that there was a strong pervasive culture of patient safety.

It is recommended that:

- ECH consciously increase the profile and priority of safety and quality of care in the organizational structure, operations and decision-making processes.
- ECH give serious consideration to identifying a position(s), which will be responsible and accountable as a leader and champion of the dimensions of quality of care inherent in the clinical realm, and further, clarify to site staff who this leader will be and how the sites' needs with respect to quality of care will be supported.[15] This leader must develop and implement plans that augment the quality profile at every site within ECH.
- ECH review its current organizational chart from the clinical risk management perspective to determine if other services or departments should be reassigned or if current supervisors require more training to supervise their areas of responsibility properly.
- ECH and Voluntary facilities recognize the role and contribution of all facilities within the ECH graphically in the organizational chart and functionally in the service agreements.[16] They are encouraged to continue to work on improving their relationship.
- ECH consider enrollment in some of the *Safer Healthcare Now!* initiatives to facilitate evidence-based practices in patient care and to enable networking with similar facilities across the country.[17]
- ECH conduct a patient safety survey to identify areas of patient safety strengths and areas for improvement.

5. Observations Related to Regionalization

Regionalization in Alberta has been in place for 13 years with restructuring occurring in 2003 when the number of regions was decreased from 17 to nine. ECH was affected by the realignment as "the counties of Lamont, Minburn, and Two Hills, and the town of Bashaw became part of East Central Health" including the facility of St. Joseph's Hospital in Vegreville. Others along the southern boundary were transferred to other regions. Consequently some facilities in ECH have a longer history as part of the ECH Region. The time taken for individual organizations to feel part of the larger region and for the regional practices to be

[15] See also similar but not identical recommendation 16A and 22D in the RCA report.

[16] See RCA recommendations 2A, 2D.

[17] See RCA recommendations 21A.

incorporated into their revised modus operandi can take years. It is important that efficiencies of centralization and regionalization be balanced with recognition and application of unique expertise and contributions of individual sites.

Strategic and service planning in the Region has appropriately been led by the corporate office. Recently, a consultant was retained to update the Health Plan in the Region. During the tours, comments were heard about this process that merit further consideration:

- Some site staff were concerned that they did not have an adequate opportunity for input into the creation of the plan although they do acknowledge there were opportunities to comment after it was relatively well developed. A plan was presented to them, with an expectation for them to react and comment on it, rather than creating the plan together. Providing an initial draft to stimulate discussion is a reasonable approach, but expectations for all participants to be able to influence that draft need to be emphasized.
- Some local leaders believe that emerging challenges within their community (e.g., changes in senior or pediatric population, new businesses in some communities, immigration of people with specific religious or language requirements, etc.) were not being adequately addressed within the central planning process, and they were not aware of a mechanism for ongoing planning to have these issues addressed in a prospective way.
- Some local leaders were not clear on what plans were in place to 'regionalize' (i.e. organize services across the Region) specific clinical or support services. The Investigative Team is aware that looking at opportunities for further regionalization of programs and services is part of the Regional strategic plan for 2007-2011.

The staff at the local sites must be, and must be perceived to be, integral parts of the regional ECH team. In that context, all sites need to be involved in developing regional perspectives of challenges, planning activities and improvement opportunities, even though their operating focus may be local. In fact, some interviewees commented on regional committees whose members were largely drawn from corporate offices or the regional leads. Committees are rarely structured to have staff representation from each and every site in ECH. Some regions have formed many if not most of their planning committees via representation of all local sites, to give regional perspectives and identify good ideas that can be brought forward. Such involvement assists in the ownership of proposed changes throughout the Region. It could be analogous for the local site leadership to "think regionally, act locally".

It is recommended that:

- ECH be clear about the role and input of local sites into regional planning, use and communicate a population based approach, and describe how allocation of services and the relevant resources are to be managed.[18]
- ECH consider strategies to increase the direct input of all local leaders, including Voluntary facilities, into all their regional committees.

In ECH, there are multiple small rural facilities and one medium size facility, St. Mary's Hospital in Camrose. It has the largest bed capacity and the greatest number of specialized staff and physicians. The regional role expected of St. Mary's Hospital related to the multiple rural facilities is not clear to either St. Mary's or to the smaller sites be they Voluntary or ECH facilities. Clarity on respective roles may facilitate patient referrals or identify where clinical assistance/advice could be sought. Such clarity on roles may improve patient safety.

It is recommended that:

- ECH clarify the role of St. Mary's Hospital with respect to clinical leadership and identify if this affects anticipated targets of internal patient referrals to Camrose or for repatriation of patients currently managed in other regions.

6. Regional Programs and Services

ECH has created some programs and services that are regional in nature such as IPC, Pharmacy, and Environmental Services. In addition, clinical programs like Medicine/Surgery or Maternal/Child care are becoming more formalized. The leads to these regional services and programs are expected to be responsible for providing leadership in their respective services or disciplines to the sites with regard to standards, allocation of services etc.

Acknowledging the regional services and programs are under development, the clarity of the roles of the program leads varies across the Region. For example, some site leaders seemed unclear as to what they could expect of the regional leads relative to the needs at the site and whether all operational issues within that program would

[18] See similar recommendation 2B, 7C in the RCA report.

be under the jurisdiction of a program lead. For example one site leader indicated she had not thought of requesting the regional person to come to her site to complete audits of their service, nor was she aware if that was an appropriate request of the regional program lead.

Of significant concern relative to patient safety, is the understanding of some regional service and program leads that they could not go into a Voluntary facility unless they had been specifically asked to do so. This did not seem to be as much of an issue with the IPC Co-ordinator and Practitioner, whose expertise was readily acknowledged, and who were consulted on a regular basis. Not accessing regional expertise could lead to variable standards of care and service across the Region, negating one of the advantages of having such positions.

It is recommended that:

- ECH clarify the role of the regional program and service leads, particularly in relation to the site administrators and managers, so that quality of care standards can be provided across the Region. This will also require clarification of their role with respect to Voluntary facilities and how their expertise should be accessed and used.[19]

Regional education resource requirements

There are three FTE educators in the Region. During the site interviews it was often mentioned that there was a lack of face-to-face education with appropriately qualified instructors, and instead, there was an over-reliance on self learning modules. Unlike SJGH where there seemed to be limited support for staff development opportunities, other sites commented that they had regular opportunities for development. Their major challenge was filling the shifts of direct care givers with replacement staff.

Given the dynamic environment of health care, and the rapid change in knowledge required, ongoing staff development is essential. Furthermore, opportunities for ongoing development are known to be an important factor in staff recruitment and retention.

It is recommended that:

- ECH review the adequacy of its educational resources, and the relative effectiveness of different educational strategies and methodologies. Alignment with other regions benefiting from more extensive educational services may be considered.

[19] See similar recommendations in the RCA 1G, 1H, 5C, 5E, 12A, 12B.

Number of key positions filled by inexperienced persons

Throughout the tours of ECH, it was observed that many of the individuals in positions such as the Health Services Co-ordinator or Nursing Care Co-ordinator were relatively new (often one year or less) in their positions. Individuals in these leadership positions will be responsible for supervising personnel in clinical areas for which they may not have the necessary expertise or clinical competence (e.g., CSR), which puts both them and the individuals they are supervising in a compromised position. It is acknowledged that this point was discussed under section 2.0 "Observations related to patient safety", but the critical nature of the concern warrants recognition in a separate section of this report.

It is recommended that:

- ECH and Voluntary facilities provide a comprehensive orientation program to these individuals so they are well informed of their responsibilities, and have the requisite skills to fulfill them. Other supports, such as linkages with individuals with appropriate clinical expertise, either internal or external to the Region, would be one option of providing them with the necessary mentoring.

7. Observations Pertaining to Management Style

It is perhaps presumptuous from this expedited review to comment on management style when it constitutes a small part of the main goals of the review related to IPC, CSR, patient safety and risk management. However the root cause analysis of the investigation and individual interviews did find some management style issues that did not facilitate prompt response to, and did not demonstrate appreciation for, the significance of IPC and CSR issues specifically and patient safety generally. After thoughtful consideration, it was decided to include these findings in this phase of the report so consideration may be given to improvement opportunities.

Some of the comments and concerns heard reflect:

Communication and information sharing

Communication in larger organizations is frequently a challenge, and in ECH it is compounded by the large geographical distances between many of the sites, creating challenges for frequent face-to-face meetings and personal contact with colleagues. Nevertheless, there were several

comments about the seeming lack of a clearly defined process for communicating across the Region.

The typical interaction for problem or issue resolution was described as follows. When a local problem is identified, it is communicated with the appropriate individual in the "Corporate" office who takes on the problem, resolves it often with limited local input, and informs the local site of what to do. The comment "it was taken out of my hands" exemplifies this approach, and while the issue may get resolved, an opportunity for learning by the site personnel, and building local capacity is not realized. In fact, it may increase dependence on (and workload for) the corporate/regional staff.

Information collected at the local sites and sent to the Region occurs (e.g., surgical site infections, medication incidents, falls), but limited response to the information is received back. Data collected is rarely compiled in a comparative fashion and sent back to the local sites so that local leaders can judge their performance compared to others. Wide variation exists as to the relative comfort with and use of data collected, but the desire to know how one was doing, not only in relation to changes on their site over time, but relative to the rest of the Region, was a situation most sites indicated they would be interested in. This process could identify which sites could serve as 'leaders' in different areas, and which sites may require additional support, and perhaps could encourage "healthy competition" to achieve higher levels of safety and quality.

One specific example highlights this practice. While some sites have established local/site QI teams, the predominant way of linking their work to the Regional QI team is by having an individual from the Regional Team provide a liaison function to the local team. That individual comes to the site and takes input from the team back to the regional discussions, and may come back to the site team with recommendations. However, the feedback is not always received, and such a structure and process does not provide direct involvement of the site team members into a regional process. Rather than increasing local capacity at the site, it tends to diminish the contribution of that site.

It is recommended that:

- ECH consider having direct participation and representation from the site QI teams at the Regional QI teams.

When a site is identified by the ECH corporate staff to be close to or at "best or leading practices", the knowledge is not consistently shared with other sites.

Comments were heard about a "lack of transparency" around the decision-making in ECH. This was associated with several sites identifying an issue of 'trust' with the Region.

It is recommended that:

- ECH provide comparative data to all site leaders (e.g., with the incident management system SORS), and other areas related to patient safety (e.g., surgical site infections).

Directive style of relating to sites

There was frustration expressed by local leaders at both the Voluntary facilities and the ECH sites concerning the appointment of one regional lead without open competition or local input. It must be stated that those expressing the concern understood clearly that appointment is an option, but would have preferred that input had been sought for selection and identification of responsibilities and that the position had been open to competition.

If a critical incident is identified, ECH has developed a response of sending in what they have called a SWAT team from the Region. This team interviews relevant people, analyzes the information, perhaps with an RCA approach, and makes recommendations for the site to implement. There is minimal to no input of the local staff into the process, or in analyzing the facts and identifying improvement opportunities. Alternatively, critical incidents, when managed most effectively, can be excellent opportunities to learn and improve. This observation in no way is a comment on the adequacy of the analysis by the regional team, but identifies that opportunities to learn by the local staff are not optimized and as mentioned previously, this approach does not build the local capacity and skills. Furthermore, inclusion of local staff involved in the incident to review the events and participate in the development of recommendations is a critical step to achieving ownership of the issues and need for resolution.

Many comments were made about the Integrated Regional Standards Committee (IRCS), established to facilitate standardization in equipment and supplies within ECH. Some local staff felt that IRCS did not solicit adequate local and/or clinical input into decision-making, resulting

in some decisions affecting the clinical staff adversely with respect to appropriateness and durability of the equipment or supplies, or the need for staff to "work around" equipment or supplies not optimally suited to their needs. Further, many were of the opinion that the decisions of IRCS seemed to be driven more by financial considerations than by clinical requirements.

Need for *"Closing the loop":* Staff members participating in the root cause analysis and others involved in the site tours described situations wherein the corporate office would issue a directive, often through sending an email, but did not follow up to assess if and how the directive was understood and what implementation was occurring. Whereas each site does have a responsibility to adhere to corporate policy, the strong culture in ECH of "sending an email" to instruct others to respond causes some recipients to question the decision and sometimes not implement the change requested without informing the sender. Examples of this were seen in CSR and IPC issues wherein a decision was made to remove all tabletop autoclaves from use in late 2003, early 2004 for all except dental use, but units were still in operation in some sites as late as 2007. Implementing change is complex and is based in large part on explaining the rationale for the change, getting input of those involved to implement it, and following up to ensure change has occurred. In essence, the responsibility of a senior executive or manager does not end with simply telling someone to do something. The rationale must be understood and communicated and compliance determined.

As mentioned above, the collection of data gathered from all sites to the corporate office, as well as the fact it is not routinely compiled comparatively and shared with the local sites, is another example of this one way communication and illustrative of not closing the loop.

It is recommended that:

- ECH consider these observations and assess if opportunities to improve communication style can be found. Some options deserving consideration:[20]
  i. create more planning structures that include local representatives on the regional planning and quality committees;
  ii. routinely provide feedback of site specific data in comparative format to all sites, and perhaps using external benchmarks, for their information;
  iii. use a change management strategy[21] that increases the probability that targeted changes will occur and be maintained;
  iv. analyze which decisions being made by senior management should and could be made by staff who report to them, determine which decisions must be made by senior level managers and executive, and consciously and appropriately delegate decision-making to individuals, representative groups or committees; and
  v. develop a robust system to manage recommendations from all sources such as external groups like CCHSA, HQCA, Institute for Safe Medication Practices (ISMP) or the Health Quality Network, or internal reviews like morbidity and mortality reviews, the Quality Council or regional directives.

8. Status of Infection Prevention and Control

Staffing requirements for IPC resources:

ECH has two infection prevention control practitioners who provide a consultation service to all sites within the Region. These individuals are widely acknowledged for their expertise, responsiveness, and commitment to ensure quality infection prevention and control practices. These individuals are not situated in a clinical site, but do conduct regular visits to all sites and provide additional time and attention when a situation warrants it such as when an outbreak is identified.

In the St. Mary's Operational Review (*Blackwell Management Group, March 2006*) there was a recommendation for a 0.5 FTE practitioner on site, with the rationale that the hospital size (76 beds and 400 staff) warranted it. While "the number of certified Infection Control Practitioners required for a comprehensive program has not been firmly established, the general guideline is 1 for every 150-175 acute care beds and 1 for every 150-250 residential care beds, taking into consideration the complexity of care. There are no clear guidelines to indicate the number of practitioners required to support other programs such as community mental health and home care programs. However there is a need for Infection Control Practitioner's knowledge and

[20] Many of these options align with recommendations derived from the RCA and are repeated here to indicate that they were also identified in sites beyond SJGH and to reinforce the ideas.

[21] Kotter, JP. Leading Change: Why Transformation Efforts Fail. Harvard Business Review, March/April 1995, page 59.

expertise in the community."[22] A Health Canada working group in 2004 identified 3.0 FTE for every 500 acute care beds, and 1.0 FTE for every 150-250 beds in long term care facilities.[23]

ECH has 300 acute care beds [includes 41 alternate level of care such as dialysis, coronary, sub-acute, and Stroke and Geriatric Empowerment Unit (SAGE), 890 long term care beds (including respite)]. In addition, the Region is the fifth largest in Alberta, and covers a large geographical area, with travel time impacting time spent with staff.

It is recommended that:

- ECH in concert with the Voluntary facilities identify the IPC needs for the Region, and review the adequacy of the current number and allocation of infection control practitioners within the Region to meet the needs of the Region.

Structure of IP&C

There is a Communicable Disease Committee-Infection Prevention Control (CDC-IPC) Working Group, but the focus of this group for the past several months has been on developing the Pandemic Flu Plan. Attendance at these meetings is described as unpredictable, meetings may be cancelled due to other priorities, and there is no established mechanism to obtain input from, and forward recommendations to, Voluntary facilities. While the Pandemic Flu Planning is clearly a priority for regions at this time, caution needs to be exercised to ensure that other key patient safety issues like IPC do not become overlooked.

The organization is to be commended for creating the position of a Site Infection Investigator, which was established in 2003 to ensure some site focus on IPC. This responsibility is however an "add on" to the person's primary role, and there is no FTE allotted in the IPC budget for these positions. A two day training session is provided to these individuals on an annual basis and teleconferences are held every three months with about 60% attendance. The individual volunteering for that role is responsible for conducting IPC audits twice a year, either by themselves or as a team with IPC practitioner involvement, submitting the results to the IPCC, and following up on recommendations that arise from the audit. The Site Infection Investigators were part of the team interviewed during the site visits.

It is recommended that:

- In order to gradually build IPC expertise and capacity on each of the sites, ECH IPC should encourage the site to develop their own recommendations based on their analysis of their audit. Those recommendations and audit analysis could be submitted to the IPCC for feedback and confirmation or clarification.
- Furthermore, ECH should consider 'formalizing' the role of the Site Infection Investigator by incorporating the expectations into the FTE position rather than it being an "add on".

IPC physician support

There is no dedicated physician support for IPC, and limited evidence of discussion with reference to IPC issues in the Medical Advisory Committee minutes, although the Team is aware that medical expertise in Infectious Diseases from Capital Health has been consulted on occasion. The MOH is accessed when advice in needed on outbreak management, input is required on policy development, when specific education is required on issues that involve public health, and rarely when such significant concern exists about a situation that the MOH is accessed in order to invoke the *Public Health Act*, such as occurred in the SJGH situation.

It is recommended that:

- ECH identify a physician either within the Region, or on a consulting basis external to the Region, as providing leadership in IPC issues and providing support to the IPC practitioners.

Involvement in CSR

There is no formal and ongoing involvement of IPC in CSR despite historic requests from this position to have regular involvement in CSR cleaning and sterilization issues. The IPCC had been requested to get involved in CSR issues on an ad hoc basis, such as occurred in 2004 when the IPCC was identified as the chair of an Ad Hoc Sterilization Committee. The IPCC had not been involved in any of the CSR audits conducted August 2006 to January 2007. After the unsafe practices were identified in the SJGH CSR, a special meeting was convened to inform the IPCC of the deficiencies at SJGH.

[22] Office of the Auditor General of British Columbia. Infection Control: Essential for a Healthy British Columbia, March 2007, p.36.

[23] Morrison, J. American Journal of Infection Control 2004 (32)2-6.

It is recommended that:

- ECH ensure there is a formalized ongoing relationship between IPCC and CSR, and that they collaboratively participate in key quality and safety structures.

Physical plant considerations

One of the observations at SJGH made by the IPCC was that there were some bathrooms with no sinks in them, requiring an individual to use the handle prior to cleaning their hands. A recommendation was made to ensure that hand gel dispensers were mounted inside each of those bathrooms in order to provide a mechanism for hand cleaning prior to leaving the bathroom. It was initially identified that this was a situation unique to SJGH. However, on several sites during the ECH tours, similar situations were found with bathrooms with no sinks and no hand gel dispensers mounted inside the room.

It is recommended that:

- ECH and Voluntary facilities review all sites to ensure that bathrooms with no sinks contained within the bathroom, must have hand gel mounted inside the room.
- Furthermore, it is recommended that observations made and interventions used at one site be communicated through the regular teleconferences or by some other more timely communication vehicle, in order to ensure learnings from one site are spread to the rest of the Region.
- Finally, in any future construction activities, IPCC needs to be involved to prospectively identify considerations relevant to IPC issues such as the requirement of sinks in all bathrooms.

Transport of soiled equipment in private vehicles

When the CSR was closed at SJGH, a plan was required to move the equipment from SJGH to another site (initially Two Hills and subsequently Viking). It became apparent that: there was no procedure in place for the safe movement of equipment; staff were requested to transport instruments and equipment in their personal vehicles; and a plan for the movement of this equipment needed to be quickly developed.

It is recommended that:

- The Region continue to develop a policy and procedure for the safe movement of soiled instruments that does not require the use of staff's private vehicles, does not require the lifting of heavy crates by staff, and that incorporates sound principles of IPC and Occupational Health & Safety.

Review of IPC Survey Submitted to AHW, April 2004

Partly in response to the IPC issues revealed at SJGH through the issuing of the MOH Order, AHW requested all regions in Alberta to complete an IPC survey. There are a number of areas in the survey submitted from ECH that warrant further review and response, including:

- It is commonly noted that policies are not reviewed or monitored for compliance, including contracted services.
- It is stated that IPC is "offered" to the Voluntary facilities. This places the patients and the Region at risk if IPC offerings are rejected and the Region accepts same. (The risk of this working agreement is discussed extensively in the root cause analysis report).
- The 'Reducing Surgical Site Infections' two year risk management initiative needs to be reviewed relative to the infection rates identified in the survey, which are consistently higher than the benchmarks identified in the initiative (data for 2005 and six months of 2006 provided). It is not clear what analysis or follow up has occurred in response to those rates. In addition, since the implementation of Meditech in March 2006, there is no electronic ability to collect the surgical infection rates, requiring manual collection of this data. Such collection is not being consistently obtained as indicated in the Table of Responses from Acute Care Sites (Appendix O-1). These deficiencies in reporting surgical site infections may be addressed, at least in part, by enrollment in the *Safer Healthcare Now!* initiative, "Prevention of Surgical Site Infections", where tools to collect and collate data are provided.
- The IPCC has indicated that they are not able to meet important objectives (e.g., urinary tract infection rates, blood culture surveillance) due to time constraints, again raising the issue of adequacy of resources for the Region.
- 2006 IPCC Annual Report specifically requests an increase of 1.0 FTE to meet growth demands – additional resources have not yet been approved, yet there has been a "285% increase in MRSA cases requiring management since the last non-outbreak year 2004; number of outbreaks requiring management have increased 60% from 2005 to 2006, and 100% from 2004-2006".
- There are surveys completed for acute care sites, long term care sites, and home care sites, but no evidence of any compilation or analysis of the data to identify areas that are managing well and areas that require follow up or improvement.

- In the home care surveys, there is little evidence that IPC is a high priority. It was noted that in the Vegreville Home Care survey there was no mention of MRSA surveillance, yet it is known that there is a high prevalence of MRSA in the Vegreville community.
- The surveys indicate that if the site does have an IPC committee, it is often inactive or meets sporadically. Furthermore, some committees make reference to a regional link while others appear to be "stand alone" committees. These committees do not have consistent objectives or regional oversight.
- The Regional CDC-IPC Working Group has been focused on pandemic flu planning for the past number of months.
- The 2006 Hand Hygiene Audits included identification of some findings of concern related to inconsistent practice. Given the length of time this has been a focus in the Region, consideration needs to be given for the use of different strategies to increase compliance with best practice.

It is recommended that:

- The Regional Quality Council review the ECH Survey submitted to AHW and analyze the report in order to develop an implementation plan for areas requiring follow up or further action. All sites within ECH, including the Voluntary facilities, must be subject to the plan to oversee and improve IPC.
- In addition, AHW is currently completing an Infection Prevention and Control Strategy Interview, which is expected to be completed no later than June 22, 2007. The submission completed by ECH should also be reviewed by the Operations Team and Quality Council to increase awareness of issues of IPC and possible recommendations to address. This may be an important venue to influence a provincial strategy for IPC.

9. CSR Issues

CSR Audits: August 2006–January 2007

The CSR audits were conducted by the Surgical Program Lead from August 2006 to January 2007, with the January 22, 2007 audit of SJGH being the final one. Several issues were identified related to the audit tool and process, including:

- The audit tool selected for use was the Sterility Assurance Checklist and Facility Audit developed by Sterile Processing Services/Keir Surgical, which the Surgical Program Lead had become aware of while attending a conference. It provided a high level overview of key areas to observe, but does not provide significant detail.
- Throughout the site interviews, concerns were raised about the audit process, with some sites noting that it was identified as a review or a visit, and in one case, specifically indicated it was not an audit.
- There was no consistent feedback at the time of the audit, a lag time between the audit and the document being sent to the site, incongruities noted between the narrative and the checklist, and inconsistent processes and practices were observed on different sites. For example, while scope cleaning was observed during the SJGH CSR site audit, scope cleaning was not consistently observed at the other sites. Consequently, there is significantly more detail required to be assured there is full awareness of the practice issues in all CSRs in the Region. Some sites prepared a written response to the audit, but it is not known at this time what will be done with that feedback.

10. CSR Issues Identified during Site Tours

During the three day site tours, Muriel Shewchuk, a nurse consultant with recognized expertise in the area of CSR accompanied the Investigative Team, and accompanied by one member of the team, toured each CSR. The purpose of the tours was to do a high level overview of each CSR in acute care except for SJGH, which was closed, in relation to:

- Obvious breaches in safe practice and non-compliance with standards with potential patient risk.
- Status of safe environmental controls in CSR.
- Status of equipment used in CSR.
- Level of knowledge and skill set among management supervising the CSR workers.
- Level of staff education, certification and compliance with policies and procedures.
- Staff confidence in job functions.
- Evidence of collaboration and participatory management to ensure best practices.
- Evidence of quality assurance, standardization and compliance.
- Barriers to good processes, quality and safety.
- Regional communication successes and deficiencies.

Process and information sources

The sources for this information included:

- Review of CSR Audits of each site completed by Surgical Program Lead.
- Interviews with teams of employees representing Acute Care Management, Central Service front line staff, Operating Room lead, and Site Investigator Infection Prevention and Control.
- Tour of the decontamination areas, sterile supply preparation area, operating theatres and review of mechanical equipment used in processes.

Limitation of observations

The observation was very short and in most places the areas were not working on specific supplies and soiled materials to be directly observed. Also, due to the short time and high level nature of the review, detailed discussion with staff was not appropriate.

Strengths

1. St. Mary's Hospital in Camrose has accessed a number of consultants, uses the Grey Nuns expertise as a resource, and has an experience and skill set level among their staff resulting in the required knowledge for safe central sterilization practices.
2. Vermilion has a high level of expertise, and has kept up with recent practice changes and requirements.
3. Everyone interviewed was very co-operative and forthcoming, and deserves and requires the appropriate ongoing Regional support.

Summary of observations and recommendations

The following table was prepared after visiting the decontamination and sterilization areas in all acute care sites in East Central Health Region, with the exception of SJGH in Vegreville, June 13–15 inclusive and is provided acknowledging the limitations of the observations described above.

Date/Site	Observations/Deviation from CSA Standard*	Action Required/Priority Ranking*	Action Taken	Date Resolved
ALL SITES	At most sites, supervisory responsibility was recently transferred from Materiel Management to Nursing. However, supervising nurses' lack of education about and in depth comprehension of the CS processes, puts them and those they supervise, who are doing the best they can with limited resources, at risk. More than two months have passed since they assumed this responsibility, but they have yet to receive the necessary comprehensive education	NCC's must receive the education they need to adequately supervise the CSR for patient safety and liability – HIGH		
	CSR audits began August 2006 but written reports were not distributed until April 2007; some staff are not addressing recommendations and others may not have even seen them	Provide results of audit to sites in timelier manner in future; provide opportunity for feedback from site – MEDIUM		
	Construction, repair and maintenance issues remain unaddressed in some sites after several years of requests (i.e. many since 2001)	Follow up to ensure all deficiencies identified in audits are addressed – HIGH		
	Uncertainty remains as to how each site cleans and sterilizes instruments with lumens	• Direct observation of cleaning and sterilizing technique used by the CSR processors for instruments with lumens should be completed by an knowledgeable person(s) – HIGH • If improper cleaning of lumen is observed, consult ID expert for assessment of risk and direction re: need for a look-back audit of patients exposed to scope procedures where improperly cleaned lumens were used		
	No standardization of scopes in ECH	Materiel Management, in collaboration with Surgical QI Team, to take the lead in standardization of scopes – HIGH		

Date/Site	Observations/Deviation from CSA Standard*	Action Required/Priority Ranking*	Action Taken	Date Resolved
	The existing staff are "doing the best they can" but there is a need for an organized program for ongoing education	Conduct a needs assessment of all CSR personnel, including casual staff, to determine ongoing education requirements and priorities and ensure requirements are met – HIGH		
June 13 – St. Mary's, Camrose (*Voluntary*)	Staff in the CSR wearing jewelry*	Remind staff to remove jewelry – HIGH		
	Sterile orthopedic instruments etc. on bottom rack of open wire storage carts need to be protected from housecleaning splatter of moisture and floor contaminants	Place items in solid bottom bins or obtain solid liner for bottom shelf – HIGH		
	Chemical indicators for sterilization not standardized in Region	Materiel Management to take lead in standardization of chemical and biologic sterilization indicators based on evidence and the input of relevant clinical and CSR staff – MEDIUM		
	Endoscopy Room on acute care nursing unit not under responsibility of CSR Supervisor • LPN (non-CSR certified) performs decontamination and sterilization • No separation of decontamination from sterilization area* • Sterilized products must pass through decontamination area to be stored for next use* • Link of patient, scope number and sterilization load number not traceable with permanent record	Reassign scope decontamination and sterilization to CSR Supervisor – Medium Link patient, scope number and sterilization load number in traceable, permanent record – HIGH		
June 13 – Tofield	Corrugated cardboard in sterilization room – contamination risk*	Remove cardboard – HIGH		
	No use of foot covers in decontamination room*	Apply foot covers in decontamination area – HIGH		
	Manipulation of specimens for inoculation of culture & sensitivity occurs in same room as decontamination	Segregate activities requiring aseptic or sterile environment from decontamination – HIGH		

Date/Site	Observations/Deviation from CSA Standard*	Action Required/Priority Ranking*	Action Taken	Date Resolved
June 13 – Lamont *(Voluntary)*	Link of patient, scope number and sterilization load number not traceable with permanent record	Link patient, scope number and sterilization load number in traceable, permanent record – HIGH		
	Corrugated cardboard in sterilization room – contamination risk*	Remove cardboard – HIGH		
	Computer keyboards not covered; keyboards may harbour pathogens	Purchase keyboard covers that are easy to clean – MEDIUM		
	Decontamination area open to sterilization area; door propped open; air from decontamination area equalizes with sterile supplies and sterile set up in eye operating room, five doors all open; positive pressure of OR disrupted with opening of doors into CSR, decontamination and public hallway*	• Close doors between decontamination and sterilization; install hands-free door opening device – HIGH • Educate all staff on air flow, microbial contamination and impact of risks to patients – HIGH		
	Inadequate cleaning from the previous patient in OR; horizontal surfaces in OR not wiped down between patients*	Review cleaning procedures to ensure appropriate cleaning between patients – HIGH		
	Nurses not wearing masks as the open sterile table is moved into the OR theatre through an open hallway; potential contamination of the edge of the table occurs as the open sterile table is pushed through a narrow door; basic infection control is not evident	Set up sterile table inside the OR – HIGH		
	3 sets of instruments used in cataract surgery are routinely flash sterilized to accommodate workload of 18 cases; 12 – 15 sets of instruments are required to handle that daily workload for appropriate cleaning and sterilization; endophthalmitis is a major risk for intraocular surgery and may result from 'short cut' cleaning*	• If flashing is necessary, flash packs should be used to transport instruments into the theatre; obtain necessary cataract instrument sets from Camrose – HIGH • Obtain microscope and instruments for cataract surgery from Camrose so second theatre can be set up in safe environment; instrument set up and cleaning is safe – HIGH		

Date/Site	Observations/Deviation from CSA Standard*	Action Required/Priority Ranking*	Action Taken	Date Resolved
	PPE clothing and eye shields not worn for washing cataract instruments; staff performing decontamination move freely into sterile area; understanding of risks and principles not evident	PPE and face shields to be worn consistently during decontamination – HIGH		
	PPE not routinely used by LPN for cleaning instruments from ER, OPD on nursing units; LPN performs direct patient care duties*			
June 13 – Two Hills	• Items for sterilization from Myrnam being transported in personal vehicles • Items for sterilization from Two Hills' physician office used to be transported in "wooden box covered with pillow case"; now items are wrapped and CSR "assumes" the clinic has done cleaning; CSR repeats cleaning	Develop policy for wrapping and transport of contaminated items; personal vehicles not to be used; designated couriers required – HIGH		
	Washer-sanitizer in place instead of washer-disinfector; decision made by ECH MM	Infection control personnel and nurses (not non-clinical staff) to make decisions on level of equipment required – LOW		
	Foam mats purchased at a public retail store used for fatigue mats in decontamination and sterilization rooms; cannot be adequately cleaned	Remove mats and purchase institution approved fatigue mats that can be cleaned – HIGH		
	Wooden ledge in decontamination cannot be cleaned adequately	Remove wooden ledge in decontamination – HIGH		
	Corrugated cardboard in sterilization room – risk of contamination*	Remove corrugated cardboard – HIGH		
June 14 – Viking	Decontamination area open to sterilization area through large hole in wall*	Close hole between decontamination and sterilization – HIGH		
	Door to decontamination room left open to hall to improve circulation of hot air	Ensure CSA standards of air exchange are met – HIGH		

Date/Site	Observations/Deviation from CSA Standard*	Action Required/Priority Ranking*	Action Taken	Date Resolved
	Wooden shelving in sterilization room cannot be adequately cleaned*	Remove wooden shelving – HIGH		
	Limited ability for staff to influence selection of CSR equipment	Staff to be consulted for input into equipment decisions – MEDIUM		
	No written procedures for cleaning and sterilizing*	Written procedures need to be developed, communicated, and implemented – HIGH		
	• Holes in ceiling identified as needing fixing several years ago* • Suspended ceiling of material that sheds cannot be adequately cleaned* • Multiple floor covering seams are not intact; baseboards cannot be adequately cleaned	Develop complete maintenance plan for all CSRs, including timeframes – HIGH		
	Sterilization indicators not standardized	Materiel Management, in collaboration with Surgical QI Team to select sterilization indicators to be used – MEDIUM		
	Personal vehicles are used to transport CSR instruments and equipment to Viking for sterilization	Develop policy for wrapping and transport of contaminated items; personal vehicles not to be used; designated couriers required– HIGH		
June 14 – Vermilion	Lumens of scopes are flushed with tap water instead of de-ionized water before sterilization	Use de-ionized water to flush lumens – HIGH		
	PPE and face shields not routinely worn in decontamination	PPE and face shields to be worn consistently in decontamination – HIGH		
	Corrugated cardboard in sterilization area – risk of contamination*	Remove corrugated cardboard – HIGH		

Date/Site	Observations/Deviation from CSA Standard*	Action Required/Priority Ranking*	Action Taken	Date Resolved
	Decontamination room is not a room but a counter in laundry sorting room; potential to spray laundry workers with contaminated material or directly contaminate unsuspecting laundry workers; no protection or barriers	Identify renovation requirements to separate decontamination room from laundry - HIGH		
	Link of patient, scope number and sterilization load number not traceable with permanent record	Link patient, scope number and sterilization load number in traceable, permanent record – HIGH		
June 14 – Wainwright	Suspended ceiling made of shedding material in decontamination and sterilization rooms cannot be adequately cleaned*	Replace ceiling material - HIGH		
	Washer-sanitizer in place instead of washer-disinfector	Infection control personnel and nurses (not non-clinical staff) to make decisions on level of equipment required – LOW		
	PPE not consistently used in decontamination*	PPE to be worn consistently in decontamination – HIGH		
	Unrestricted traffic through decontamination room through three doors; no locks on any doors*	Eliminate unrestricted traffic through decontamination room - HIGH		
	Corrugated cardboard in sterilization area – risk of contamination*	Remove corrugated cardboard – HIGH		
	Sterilization indicators not standardized	Materiel Management to take lead in standardization of chemical and biologic sterilization indicators based on evidence and the input of relevant clinical and CSR staff – MEDIUM		
	Door between decontamination and sterilization rooms kept open to avoid activating smoke alarm with steam build up from sterilizers (Maintenance aware); steam may be wetting and contaminating sterilized, wrapped items*	• CSA air exchange standards to be met – HIGH • Source of excessive steam to be fixed – HIGH		

Date/Site	Observations/Deviation from CSA Standard*	Action Required/Priority Ranking*	Action Taken	Date Resolved
		• Door between decontamination and sterilization to be closed – HIGH		
	Personal vehicles are used to transport CSR instruments and equipment for sterilization	Develop policy for wrapping and transport of contaminated items; personal vehicles not to be used; designated couriers required – HIGH		
June 15 – Provost	Decontamination room door left open to hall/dietary all the time	Close door between decontamination and hall/dietary – HIGH		
	Open air flow between decontamination area and sterilization room	Close hole between decontamination and sterilization – HIGH		
	Nail care supplies from community health have not been sterilized; only cleaned	Nail care supplies to be sterilized – HIGH		
	Washer-sanitizer in place instead of washer-disinfector	Infection control personnel and nurses (not non-clinical staff) to make decisions on level of equipment required – LOW		
	Waterproof re-usable gown used for decontamination; wiped with PerCept® between uses	Use disposable water-proof gowns for decontamination – HIGH		
	Corrugated cardboard in decontamination area – risk of contamination*	Remove corrugated cardboard – HIGH		
June 15 – Hardisty	Washer-sanitizer in place instead of washer-disinfector (No sterilizer on site; all items sent to Daysland for sterilization)	Infection control personnel and nurses (not non-clinical staff) to make decisions on level of equipment required – LOW		
June 15 – Killam *(Voluntary)*	Staff performing CSR activities lacks formal CSR training and education	Appropriately prepared personnel must be responsible for handling of contaminated and sterilizing materials.		

Date/Site	Observations/Deviation from CSA Standard*	Action Required/Priority Ranking*	Action Taken	Date Resolved
	CSR is not a room but an alcove with a counter open to the public corridor with no door; most items are washed, boxed and sent to Daysland; notable exception: foot care instruments, which are supposed to be sterilized for each patient. (Health Canada – Foot Care). Process for cleaning foot care instruments: • foot care instruments are placed in countertop autoclave • chemical strips designed for steam sterilizers are used to indicate "sterilization" is complete • once the pressure cycle is complete the instruments are taken out and dried with a towel by hand, which increases the risk of re-contaminating the instruments • multiple instruments are placed in a peel pouch (which is designed for the steam sterilization cycle), pouch is sealed and provided to health care providers for use in foot care • no records of "sterilization" activities kept	• Necessary to educate and change practice to meet the standards and patient safety - HIGH • Consult ID expert for assessment of risk and seek direction re: need for look-back audit of patients exposed to non-sterilized foot care instruments – HIGH • Review practice of sterilizing foot care products at SJGH, Vegreville and take action as above if improper sterilization identified – HIGH		
	January 4 audit revealed that single use cautery devices were being re-used after "wiping the tip and use(d) till cautery is empty"; cross contamination between patients identified as risk; practice discontinued in January 2007	Consult ID expert for assessment of risk and seek direction re: need for look-back audit of patients exposed to non-sterilized, single use cautery devices – HIGH		
June 15 – Daysland	Personal vehicles are used to transport CSR instruments and equipment for sterilization by Home Care	Develop policy for wrapping and transport of contaminated items; personal vehicles not to be used; designated couriers required – HIGH		
	Large open area with no closure allows air flow between decontamination and sterilization areas*	Stop air flow between decontamination and sterilization – HIGH		
	Inconsistent use of PPE in decontamination*	Use PPE consistently in decontamination – HIGH		

Date/Site	Observations/Deviation from CSA Standard*	Action Required/Priority Ranking*	Action Taken	Date Resolved
	Corrugated cardboard in decontamination area – risk of contamination*	Remove corrugated cardboard – HIGH		
	Making own sterile water for OR from de-ionized water; this practice was directed to be stopped in 2001; no QA for the de-ionized water for sterile use in OR	Purchase commercially available sterile water – HIGH		
	Delivery of supplies by Materiel Management for sterile room were left open in decontamination room; principle of separation of decontaminated and sterilized area not observed	Educate staff on separation of decontamination from sterilization areas - MEDIUM		
	Wrappers for OR supplies stored very near the floor – risk of contamination from floor or housekeeping water	Obtain safe, alternative location for storage of OR wrappers; consider mobile cart – HIGH		
	Making own custom packages of dressings	Purchase commercial packages of dressings – LOW		
	Link of patient, scope number and sterilization load number not traceable with permanent record	Link patient, scope number and sterilization load number in traceable, permanent record – HIGH		

*Ranking of action required:

HIGH – Can or needs to be addressed immediately MEDIUM - address in next three months LOW – address in next 12 months

It is recommended that:

- ECH follow through on the plan developed to contract external CSR expertise to spend time with the Surgical Program Lead, using a comprehensive audit tool, and intentionally observing cleaning processes. Essentially this will be a 'train the trainer' approach, and subsequent audits of all sites can be completed using a comprehensive tool.
- ECH complete the recommendations contained in the Site Visits of CSRs from June 13-15, 2007, and monitor for completion on a monthly basis. Focus on the HIGH urgency items as priorities.

Education, training, skills and supervision of CSR Processor

Currently, the CS processor role is an unregulated discipline in Alberta. A number of options are available for the education preparation of the CSR processor role. There is an international course, which can be taken through Purdue University for $600. This organization has the expertise to remain current, has a textbook they have authored, and is the only course with recertification (www.iahcsmm.org). SAIT offers a course for $5800, done by correspondence (uses the International Association of Health care Central Service Materiel Management (IAHCSMM) textbook), and Vancouver Community College provides a correspondence course for $600 with no recertification. Currently there is no standardized Canadian accredited program.

Apparently some discussion has already occurred in Alberta about starting a "Canadian chapter" of the IAHCSMM. There is a certified instructor in Alberta, and her expertise could be used to train additional Canadian instructors. Those instructors could teach workshops to assist individuals get through the course faster as part of their orientation, ensure certification occurs, and subsequently, recertification. These instructors could also audit central sterilization (CS) areas.

There is apparently an ECH policy recently developed, and pending (not observed) that requires individuals in these CS positions to complete one of the CSR processor courses. Individuals currently in those roles that do not meet this qualification will have 18 months to commence the course. While the intent of this policy is to be commended, there are limitations with this approach in that the length of time identified to achieve the necessary qualifications and the lack of an orientation system and educational plan in the interim, remains a concern.

It is recommended that:

- Given the critical nature of the work of the CS processor in the Central Processing Department, especially as it relates to patient safety, it is recommended that ECH review the timelines proposed for requiring all staff to complete a certification program, identify a plan for required education needs for the interim period, determine how ongoing educational needs will be met, and implement a strategy to address those education needs.

In the short term, it is recommended that the cleaning procedures and practices of the current CS processor staff be directly observed to ensure that the cleaning practices meet procedure standards. This work has already started in ECH with the contracting of a nursing individual with CSR expertise who will be reviewing the practice of cleaning of lumens with the Surgery Program Lead.

11. External Reviews

Since SJGH became part of the ECH Region in 2003, a number of other reviews though not solely related to quality and safety have occurred. The Health Facilities Review Committee made a visit to the site in November, 2004, the Canadian Council on Health Services Accreditation (CCHSA) Accreditation Survey was held in April 2005, and the Blackwell Operational Review was conducted from August 2006 to January 2007.

Health Facilities Review Committee Site Visits to SJGH (June 2002 and November 2004)

Background

The Health Facilities Review Committee Act was proclaimed in 1978. The Health Facilities Review Committee (the "Committee") has two main roles, one of which is to routinely review and inspect health care facilities and observe the manner in which they are operated. The Committee monitors the quality of care, treatment and standards of accommodation provided to patients and residents in health care facilities.

The Investigative Team reviewed two reports summarizing the visits of the Health Facilities Review Committee to SJGH: one report was from June 25, 2002 and the other from November 23, 2004.

June 25, 2002 report: (SJGH part of Lakeland Regional Health Authority)

Many of the comments were descriptive statements of facts, e.g., number of pharmacy staff, number of beds funded, etc. There were some concerns identified regarding the fact that there were no RNs for casual shifts, the staff had expressed concerns about the shortage of supplies and the age of the equipment throughout the facility (e.g., deteriorating blood pressure cuffs, shortages of wheelchairs and lifts). The report also identified that "staff have mentioned these issues at meetings but no follow up or solution has been addressed". This became the basis of their first recommendation.

Four recommendations were made from this visit, including three relevant to this investigation:

- The need to ensure that a review of the aging equipment was completed for the safety of patients and staff.
- Consider altering the schedule of the teleconference in-services to meet the needs of both patients and staff.
- Ensure that all food in the freezer and storage area be kept off the floor to ensure the safety of the patients and staff.

A response requested to these recommendations by November 30, 2002 was received on September 30, 2002 essentially saying all of the recommendations had been addressed. Specifically;

- "Review of aging minor equipment is completed on a regular basis. Items such as stethoscopes which appear to have been depleted in supply return to the facility on a regular basis."
- Educational responses were sent to Lakeland RHA for response and reflected that "various strategies have been implemented to increase opportunities for educational sessions to Lakeland clients. Telehealth technology has been crucial to keeping staff and clients well informed on a wide variety of issues. The utilization of Telehealth throughout the Lakeland Health Region has been measured at 97% utilization, the highest in the entire Province of Alberta."
- "Action was taken immediately. All food is kept on appropriate pallets off the floor."

The contents of SJGH's response to each of the recommendations are seen incorporated into the follow-up actions of the next visit.

Several observations were made about Infection Control, including "visiting members noted that patient and public areas appear well managed for infection control". It is not noted what evidence was provided for this conclusion, but is interesting given how events unfolded subsequent to this visit.

November 23, 2004 visit

There were no recommendations made from this visit and the covering letter indicated that the "…members were pleased that significant positive changes had been made and new initiatives had been implemented…"

The report indicated that in response to their recommendations from the previous visit, reviews of aging equipment are conducted on a regular basis, and routine servicing of equipment has been undertaken. There is no reference to any of this equipment being from the CSR.

A section on Infection Control included a comment that "the facility appeared to be well managed for infection control, including the handling, storage, and disposal of medical wastes." This is interesting as the site had been trying to get the MRSA transmission under control when the initial outbreak was first identified in September 2003 (five months after becoming part of the ECH Region). The Committee also observed that the "…staff appeared to be familiar with good infection control practices". No evidence was provided for either of these observations.

A further comment in the Housekeeping section reported that "staff advised that in June 2004, they performed a complete disinfection of the facility because of a MRSA outbreak. The infectious outbreak was successfully eradicated". This was not accurate, as the site has been continuously attempting to control the spread of MRSA in acute care patients from September 2003 to the present time, and indeed became one of the issues resulting in the March 2007 MOH Order to close the site to admissions. In September 2003, a number of recommendations were made by the IPCC to address the 'outbreak' including a thorough environmental cleaning. While Continuing Care did a prompt and thorough cleaning of their entire site, the response in acute care was incomplete and delayed.

Implications

Although this current report is written with the benefit of hindsight, one has to ask if there is there a possibility that such a positive report (which in hindsight could be considered a false positive report) could have contributed to the ongoing lack of sense of urgency in the site to actively and vigorously deal with the ongoing spread of MRSA at the site? This sense of "complacency" was identified as one of the contributing causes for the inability to contain the ongoing transmission of MRSA. It further reinforces the importance of observing supporting evidence to validate self report comments, as opposed to taking comments at face value. In light of the complex nature of health care and the usefulness of on-site reviews with appropriate time and relevant expertise to review specific aspects of quality of care, the question needs to be asked whether the Health Facilities Review Committee has the appropriate structure and processes to adequate perform quality (including safety) reviews.

CCHSA Accreditation (April 3-8, 2005)

For six days in April, 2005, a team of surveyors using the CCHSA Accreditation standards, interviewed 11 teams and conducted site tours throughout the ECH Region. This time frame was two years after the boundary realignment of 2003, and almost 20 months after the initial MRSA outbreak identified at SJGH with ongoing but unsuccessful attempts to stop the spread of MRSA at the site. CCHSA documents reviewed included the Final Report, the Self Assessment of the Leadership & Partnerships Team, and the Report of the Acute Care Surgical Team.

Observations of congruence with those of the Investigative Team

There were some overall challenges identified in the Accreditation Survey Report by the Survey Team that are congruent with the findings of the Investigative Team, including:

- The need to "…continue to work on collaboration between the regional board (ECH) and the associate partners' boards." It was acknowledged how challenging this can be for a region with eight associate partners who deliver over fifty percent of acute care and continuing care services." (p.4)
- Ensuring that ECH and associate partners work more closely together in developing a longer range regional plan for the delivery of services.
- The need for ECH to "identify and utilize the specific expertise and best practice activities of its associate partners". (p.8)

These observations did lead to specific recommendations, with a risk severity rating of high (and medium ratings for likelihood and urgency).

The survey report commented on the fact that participation in decision-making is the lowest rating descriptor of all 22 descriptors, and asks the organization to encourage and use staff input in decision-making. This sentiment was articulated as well during the staff focus group (participants were all from Camrose p.47).

The Survey Team also identified a couple of areas for improvement including:

- Develop a clear and formal quality reporting structure within ECH, including reporting to the Board.
- Improve the linkages with the quality improvement activities of associate partners and ECH and further integrate them into a regional process that is supported by all parties (p.37).
- The need to review opportunities for standardization, noting that the servicing of basic equipment appears to run contrary to the principles of centralization. The frequency that the associate partners may be outliers with respect to straightforward network and standardization opportunities is of concern (p.40).

The Investigative Team would concur with these suggestions.

In the section on Minimizing Adverse Events, the Survey Team did identify the "..recent increased reporting of outbreaks has caused some concern, however this may be viewed positively as more effective reporting. There has been a recorded 300% increase with 14 outbreaks in the last seven months increasing from four the previous seven months." While the comment was identified as a strength (i.e. better reporting), they did suggest the "organization needs to ensure protected time for infection control management, especially for those whose job this might be considered as an add on" (p.42).

While the Investigative Team would support the suggestion to ensure protected time for infection control management, there is no consensus that those recent outbreaks were the result of more effective reporting.

One insightful suggestion made related to the "need to conduct compulsory audits to ensure compliance by all institutions related to the new infection environmental scan. With infection control, it has been repeatedly demonstrated that there may be great costs to an institution that delay this initiative. The potential to gain from benchmarking information now will return huge dividends in the future and can show immediate improvements to current infection and control practices" (p.42). It is not known if the Region has followed up on this suggestion, but it is one the Investigative Team would support.

Areas of divergence

The survey identifies the following strength in the "Leadership and Partnerships" section relevant to standard 5.0 "The organization is effectively and efficiently governed":

> "The associate partner boards function on behalf of their facilities and connect with the ECH Board through the participation in joint planning, the operational committee, and special meetings. There is a good exchange of information at these meetings. There is an open relationship among the boards. The ECH board has a collaboration committee as well." (p 32)

The Investigative Team did not find this open sharing of information or collaborative planning. There was no regular forum for all the Voluntary facilities (associate partners) to sit at the same table as the ECH Board or Administration, and the Collaboration Committee never became a functional entity.

Overall, the survey results indicated that ECH was above the national average on the dimensions of Responsiveness, System Competency, Client/Community Focus, and only slightly (0.1) below the National Average on Worklife. Such a positive rating may provide an organization with a (false) sense that they have quality and safety issues well managed. In the descriptor of Safety, only one key recommendation was made related to the need for an infant abduction protocol. It is important to note that this survey (April 2005) was completed prior to the implementation of the CCHSA Required Organizational Practices related to patient safety that became mandatory on January 1, 2006.[24]

The analysis of the Patient Safety section in the Accreditation Survey Report is interesting, with 113 criteria identified as having a significant impact on patient safety. Ninety-two percent (92%) of the criteria received a rating of 5-6 (maximum 7), indicating areas of strength. While there were eight (7%) criteria that received a rating of 4, signaling an area of caution, neither area of equipment use nor infection control was included in those ratings. This could be considered an omission, given the comments in the narrative about the discussions that had been held with staff about IP&C issues, and reinforcing proper handwashing.

Strengths were identified as *"patient, client, resident, and visitor safety is very important to ECH and the associate partners and they endorse and promote the current national approach to patient safety"* (p.35). In addition, the surveyors identified that *"there has been major progress in risk management activities in the past two years."* Another strength identified is that *"all the associate partners are involved in risk management/patient safety activities."* Evidence of those activities at all sites, given the findings at SJGH, was not apparent in the investigation.

In the same section it is noted that ratings for contracted services delivered according to the terms set out in the contract were rated above average at 6's. Whether this was including clinical services (such as the associate facilities) in the response or not, is unknown.

In the section on achieving positive outcomes, a strength was noted to be the fact that there was *"total clarity with respect to compliance with safety issues. In matters of risk and patient safety, it is the expectation that all facilities regardless of affiliate status will implement changes or improvements from any central reviews and analysis that are conducted" (p.44)*. While it is not known what evidence was used to support this statement, comments heard during these recent interviews, tours, and RCA process would indicate otherwise. It is acknowledged that this report is written at a different time.

In response to minimizing adverse events, standard 4.0 "The organization prevents and controls infections" the survey ratings were all 6's and 5's. They comment that the "capital equipment policy is impressive" and while that may be so, it was not being actively implemented in SJGH. The statement, "The practice of infection screening is paying dividends in the prevention of the spread of many common

[24] RCA report Recommendation 21C.

but potentially expensive or lethal infections" is difficult to accept given that the outbreak, recognized in September 2003, continued actively during the time of the survey, and indeed to the present day. The later comments of increased cases perhaps due to increased reporting is not valid given the Team's knowledge of cases reported from 2003–2005. This is an issue and identifies the limitations of a regional accreditation survey where variable regional practices that deviate from the standard may not be revealed at any one specific site. When a general comment then is made, it may be inaccurate for a specific site(s).

Whereas the surveyors found that 60-70% of staff had a performance appraisal completed in the past 18 months, and was substantiated by random records review (p.50), that did not seem to be the situation at SJGH, where the lack of regular performance review was identified as a contributing factor to the patient safety concerns identified in the MOH Order.

Self assessment of the Leadership & Partnerships Team

In the self assessment of the Leadership& Partnerships, there are two comments (p.21) identified as 'Strengths' that would not be congruent with the findings of this review.

1. *SJGH Board and CEO evaluation completed every two years* was not congruent with the evidence found during the in depth review of SJGH, nor was the comment that
2. *There is a process for conflict resolution for ECH and for associate partners.* While such a clause may have existed in the Co-operation Agreement, and was used in a situation with Lamont, the absence of its consistent use to serve as an effective mechanism for the two organizations to address their differences at SJGH became a significant issue in coming to agreement on who had 'final authority' in matters of patient safety.

Another comment found on page 22, namely "Changes are made based on a culture of patient safety and quality rather than budget based…" The examples used were obstetrics and the lab. While those changes may have been made based on patient safety and quality criteria, there are others which came to the attention of the Investigative Team that were not; for example, purchase of CSR washer-sanitizers were selected over washer-disinfectors which are a preferred piece of equipment. This is not to imply that financial constraints do not need to be considered in decision-making, but the patient safety concerns need to be made explicit and prioritized in the decision-making process.

Around the same time frame, a related comment found in the ECH Annual Report 2005-2006 mentioned that *"Health care in the province has been focused on the electronic health record and therefore major patient safety initiative resources to move forward on other initiatives has been very scarce. This outcome has created delays in a multitude of safety projects not only in East Central Health but all RHAs"* (p. 85). Making a conscious decision to delay safety projects needs to be done on the basis of a risk benefit analysis, which then allows the organization to consciously decide that they are accepting the risks associated with their decision to delay action. Observations such as these have led to the Investigative Team concluding that there was limited evidence that a culture of patient safety was a high priority for either SJGH or ECH.

The Acute Care Surgical Team report

This team received no recommendations, and there was no reference to the issue of monitoring surgical site infection rates. The Accreditation visit occurred at the time when the Quality Improvement initiative had been started to focus on surgical site infection rates. That such a key issue for the Surgery team could be omitted, and not identified as an area for improvement, is of note. The only area identified for improvement in the section on delivery care was related to the need to address the tumor staging criteria (p.79).

Nor was there any mention of CSR issues, and it is not known if CSRs were part of any of the site tours. In addition to some of the inpatient areas, site tours are usually completed on the lab, DI, and pharmacy, but it may be worthwhile for CCHSA to consider including CSRs as part of the mandatory areas to be reviewed during the site tours.

Similarly, in the Maternal/Child Team Report, there was no mention of C-section infection rates.

Implications

The observations noted during this review of the Accreditation documents underscore the importance of confirming self report with evidence. This has been a major focus for the CCHSA in more recent years, with the AIM standards seeking to achieve improved measurement as one key strategy for providing evidence. Regardless, the insights obtained by the organization in completing the self-assessment, assuming they take action on important insights revealed through that process remains an appropriate and important

part of the Accreditation process. Having an opportunity to review one's comments made as part of a Survey Team in a retrospective manner would be a useful exercise for surveyors, as it would highlight the importance of ensuring that evidence is available for declarations made.

An associated finding relevant to the accreditation process was that there did not appear to be a clearly structured process in ECH to oversee the implementation of the CCHSA recommendations. As well, the next survey is scheduled for 2008 yet awareness of the 2006 patient safety goals and Required Organizational Practices (ROPs) was lacking by ECH or SJGH management and staff. Without a strategy to organize the readiness of ECH for the next survey, ECH could find itself unprepared for the next one in 2008. Lack of familiarity with the ROPs may delay the ability for ECH to consider initiatives that improve patient safety and demonstrate compliance with the ROPs before 2008. Regardless, the important issue is the organizational awareness of and use of these tools, and conscientious completion of the self assessment to identify areas of organizational strengths and areas for improvement, is one of the most valuable processes of Accreditation, not the preparation for the next survey on-site visit per se.

SJGH Operational Review (Blackwell Management Group, 2007)

While the original intent of this Operational Review was to determine if the funding provided from ECH to SJGH was equitable and adequate for the services they were providing, there were a number of recommendations that have relevance to the scope of work for the Investigative Team, many of which align with the contributing factors and consequent recommendations emerging from the root cause analysis of SJGH:

Operational Review Recommendation #	Issue	RCA Recommendation #
#2	Need for a new Program and Service Agreement that defines the business relationship between ECH & SJGH	1B, 1D, Root Cause #2
#4	Need for SJGH Board Development Program to improve governance efficacy; need to implement a monitoring and reporting system to ensure timely, comprehensive and appropriate information to assist in governance decision; regular evaluation of Board performance	10A, 10C Contributing Factor #18; 18A-18I 18A 18D
#5	Need for effective mechanism for evaluating the job performance of the person in the senior administrator (CEO) role	10C, 18G
#6	Develop a plan of services for SJGH that is responsive to the health needs of the community	7B
#9	Need for a Quality Improvement Program and Risk Management Program for SJGH	4A, 16A, 17A, 21B
#25	Determine surgical capacity at SJGH site	5C, 5D

In addition, a number of observations identified in the Operational Review were congruent with information obtained through individual interviews and the observations of the Investigative Team, or were raised during the RCA.

Operational Review Observation	RCA Investigative Team Observation
Service Agreement makes resolution of differences between the parties difficult; should be replaced with a new Program and Service Agreement that defines the business relationship (p.14)	• Lack of clarity as to which organization has final authority in Master Agreement and RHA Act identified as a root cause by the RCA team. • Also the lack of agreement on what kind of a relationship should exist resulted in a 'strained relationship'.
The SJGH Board operates with a high degree of autonomy and is held accountable by ACHC for its performance (p.16)	Recommendations from RCA to clarify the role of the ACHC.
Board committees largely inactive (p.17) Failure to create an appropriate basket of programs and services for SJGH	• RCA identified that Board was challenged in fulfilling its' responsibilities. • Role for SJGH changing since becoming part of ECH. • Services diminishing, e.g., pharmacy distribution. • Agreement that programs and services to be provided by SJGH has not been clearly outlined by ECH.
Outbreak of MRSA but remedial action was very slowly implemented (p.20)	One of the primary causes for MOH Order.
Inadequate service provision in management training and skill development, performance review (p.20)	Identified as contributing factors in RCA.
People often felt intimidated and that they had little control over their areas of responsibility (p.20)	RCA identified lack of participatory management and empowerment of staff, resulting in inability to create necessary changes.
Medical staff organization (p.23)	Need for increased engagement/integration of physicians.

Summary:

Both the CCHSA Accreditation process and the Health Facilities Review Committee unannounced visits could be identified as quality and safety monitors and processes. Both rely heavily on self assessment and self report, and in reviewing their reports, the need to supplement self reporting with evidence is highlighted. Health Facilities Review Committee findings are based on limited observation and may be considered superficial without evidence to support their conclusions.

In the RCA process, a recommendation (14A) was made to use the Operational Review to address the sense of "victimization" perceived by SJGH. The Investigative Team would support the ongoing activities of the Implementation Committee to use the Operational Review as a way of moving forward into the future.

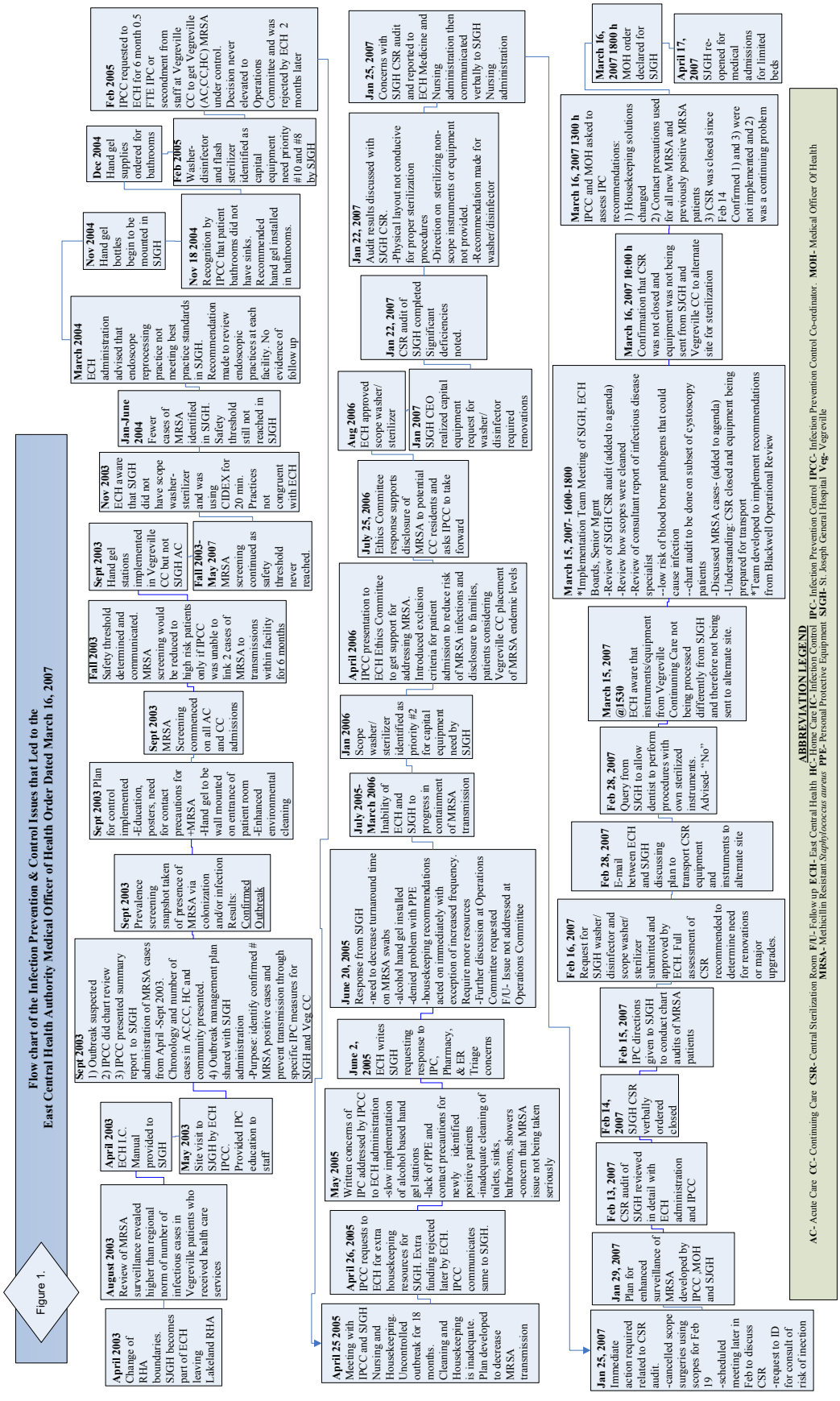
12. Role of the Medical Officer of Health

Given the way in which the MOH became involved in the safety concerns identified at SJGH, and the issuing of the MOH Order to close the hospital, a number of questions arose relating to the optimal role for the MOH in such a circumstance.

- As identified during the RCA process, the MOH was brought into the discussion regarding possible safety issues at the SJGH site relatively late in the process, primarily accessed because of his expertise and ability to invoke the *Public Health Act*. What the MOH brings is the legislated authority to deal with a public health risk or perceived risk. The question was raised if that was the only way to guarantee practice change at that site? (Final Report, Part 1, p.15)
- What is the optimal reporting structure for the MOH? The position needs to be able to act in an objective manner, but when commenting on the organization that is that position's employer, one may be perceived to be, and perhaps is in, a compromising position. Ideally, the MOH needs to have access to key information, especially for areas for which they have the legislated responsibilities. Having good information related to the decision-making processes would also be a benefit.
- What is the role of the MOH within a hospital site relative to identifying patient safety issues in a prospective manner? While this is a common role in the community, e.g., auditing food establishments, this is not as common within a hospital environment. Most often, the MOH is consulted when "something goes wrong".
- What is the working relationship between a regional MOH and the provincial MOH? Both need to be perceived as being at "arms length" from their "Employers", in order to be able to act objectively and independently and to be percieved in that manner. The principle of autonomy for individuals providing Public Health services was supported by the National Advisory Committee on SARS and Public Health in 2003, which recommended a new arm's length Canadian Agency of Public Health.[25]

[25] http://www.phac-aspc.gc.ca/publicat/sars-sras/naylor/ - accessed June 2007.

APPENDIX 1: 6. c. Flowchart of final understanding



APPENDIX 1:

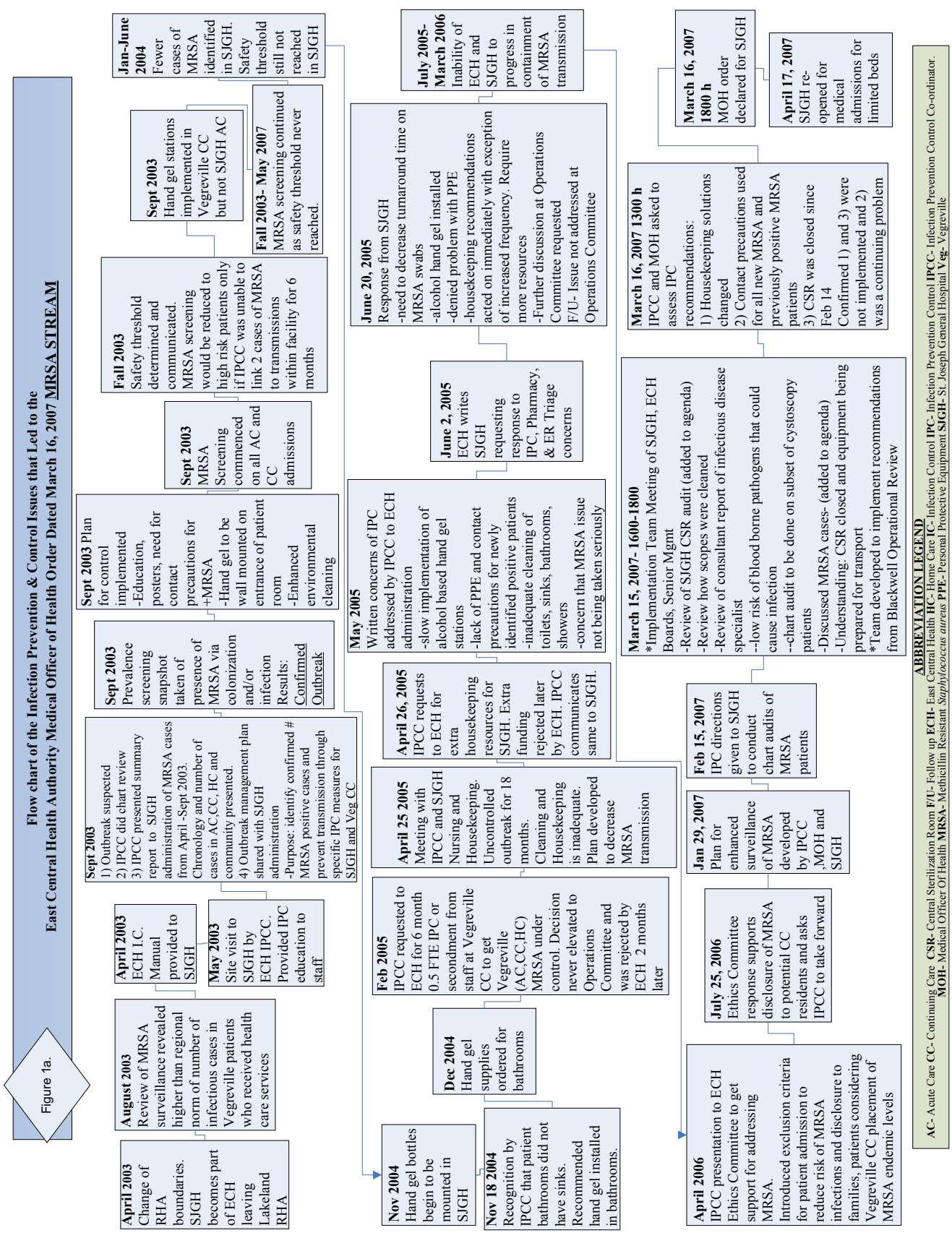


Figure 1a.
Flow chart of the Infection Prevention & Control Issues that Led to the East Central Health Authority Medical Officer of Health Order Dated March 16, 2007 MRSA STREAM
April 2003 Change of RHA boundaries. SJGH becomes part of ECH leaving Lakeland RHA
August 2003 Review of MRSA surveillance revealed higher than regional norm of number of infectious cases in Vegreville patients who received health care services
April 2003 ECH I.C. Manual provided to SJGH
May 2003 Site visit to SJGH by ECH IPCC. Provided IPC education to staff
Sept 2003 1) Outbreak suspected 2) IPCC did chart review 3) IPCC presented summary report to SJGH administration of MRSA cases from April -Sept 2003. Chronology and number of cases in AC,CC, HC and community presented. 4) Outbreak management plan shared with SJGH administration -Purpose: identify confirmed # MRSA positive cases and prevent transmission through specific IPC measures for SJGH and Veg CC
Sept 2003 Prevalence screening snapshot taken of presence of MRSA via colonization and/or infection Results: Confirmed Outbreak
Sept 2003 Plan for control implemented -Education, posters, need for contact precautions for +MRSA -Hand gel to be wall mounted on entrance of patient room -Enhanced environmental cleaning
Sept 2003 MRSA Screening commenced on all AC and CC admissions
Fall 2003 Safety threshold determined and communicated. MRSA screening would be reduced to high risk patients only if IPCC was unable to link 2 cases of MRSA to transmissions within facility for 6 months
Sept 2003 Hand gel stations implemented in Vegreville CC but not SJGH AC
Fall 2003- May 2007 MRSA screening continued as safety threshold never reached.
Jan-June 2004 Fewer cases of MRSA identified in SJGH. Safety threshold still not reached in SJGH
May 2005 Written concerns of IPC addressed by IPCC to ECH administration -slow implementation of alcohol based hand gel stations -lack of PPE and contact precautions for newly identified positive patients -inadequate cleaning of toilets, sinks, bathrooms, showers -concern that MRSA issue not being taken seriously
June 2, 2005 ECH writes SJGH requesting response to IPC, Pharmacy, & ER Triage concerns
June 20, 2005 Response from SJGH -need to decrease turnaround time on MRSA swabs -alcohol hand gel installed -denied problem with PPE -housekeeping recommendations acted on immediately with exception of increased frequency. Require more resources -Further discussion at Operations Committee requested F/U- Issue not addressed at Operations Committee
July 2005- March 2006 Inability of ECH and SJGH to progress in containment of MRSA transmission
March 15, 2007- 1600-1800 *Implementation Team Meeting of SJGH, ECH Boards, Senior Mgmt -Review of SJGH CSR audit (added to agenda) -Review how scopes were cleaned -Review of consultant report of infectious disease specialist --low risk of blood borne pathogens that could cause infection --chart audit to be done on subset of cystoscopy patients -Discussed MRSA cases- (added to agenda) -Understanding: CSR closed and equipment being prepared for transport *Team developed to implement recommendations from Blackwell Operational Review
March 16, 2007 1300 h IPCC and MOH asked to assess IPC recommendations: 1) Housekeeping solutions changed 2) Contact precautions used for all new MRSA and previously positive MRSA patients 3) CSR was closed since Feb 14 Confirmed 1) and 3) were not implemented and 2) was a continuing problem
March 16, 2007 1800 h MOH order declared for SJGH
April 17, 2007 SJGH re-opened for medical admissions for limited beds
Feb 2005 IPCC requested to ECH for 6 month 0.5 FTE IPC or secondment from staff at Vegreville CC to get Vegreville (AC,CC,HC) MRSA under control. Decision never elevated to Operations Committee and was rejected by ECH 2 months later
April 25 2005 Meeting with IPCC and SJGH Nursing and Housekeeping. Uncontrolled outbreak for 18 months. Cleaning and Housekeeping is inadequate. Plan developed to decrease MRSA transmission
April 26, 2005 IPCC requests to ECH for extra housekeeping resources for SJGH. Extra funding rejected later by ECH. IPCC communicates same to SJGH.
Jan 29, 2007 Plan for enhanced surveillance of MRSA developed by IPCC ,MOH and SJGH
Feb 15, 2007 IPC directions given to SJGH to conduct chart audits of MRSA patients
Dec 2004 Hand gel supplies ordered for bathrooms
Nov 18 2004 Recognition by IPCC that patient bathrooms did not have sinks. Recommended hand gel installed in bathrooms.
Nov 2004 Hand gel bottles begin to be mounted in SJGH
July 25, 2006 Ethics Committee response supports disclosure of MRSA to potential CC residents and asks IPCC to take forward
April 2006 IPCC presentation to ECH Ethics Committee to get support for addressing MRSA. Introduced exclusion criteria for patient admission to reduce risk of MRSA infections and disclosure to families, patients considering Vegreville CC placement of MRSA endemic levels
ABBREVIATION LEGEND
AC- Acute Care CC- Continuing Care CSR- Central Sterilization Room F/U- Follow up ECH- East Central Health HC- Home Care IC- Infection Control IPC- Infection Prevention Control IPCC- Infection Prevention Control Co-ordinator. MOH- Medical Officer Of Health MRSA- Methicillin Resistant Staphylococcus aureus PPE- Personal Protective Equipment SJGH- St. Joseph General Hospital Veg- Vegreville

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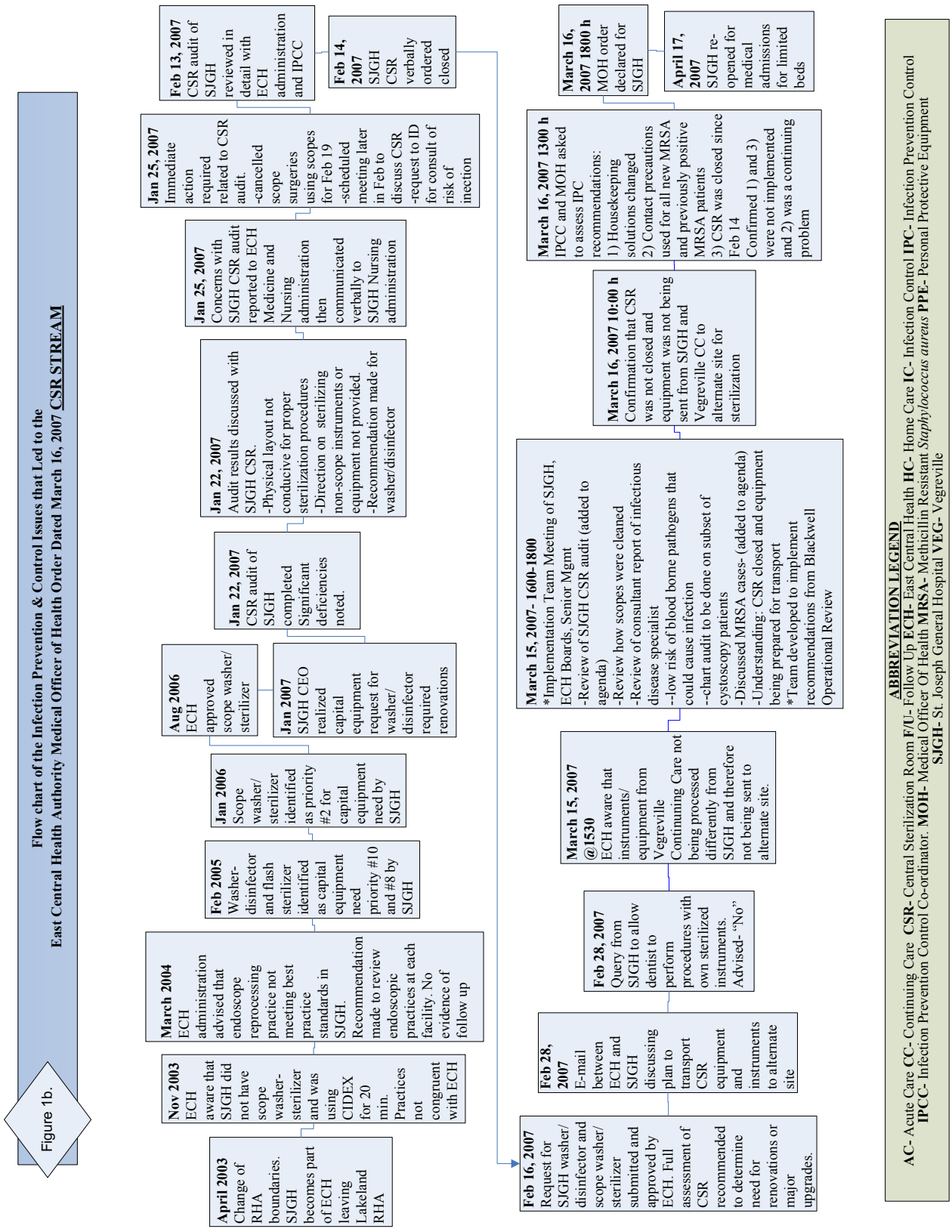
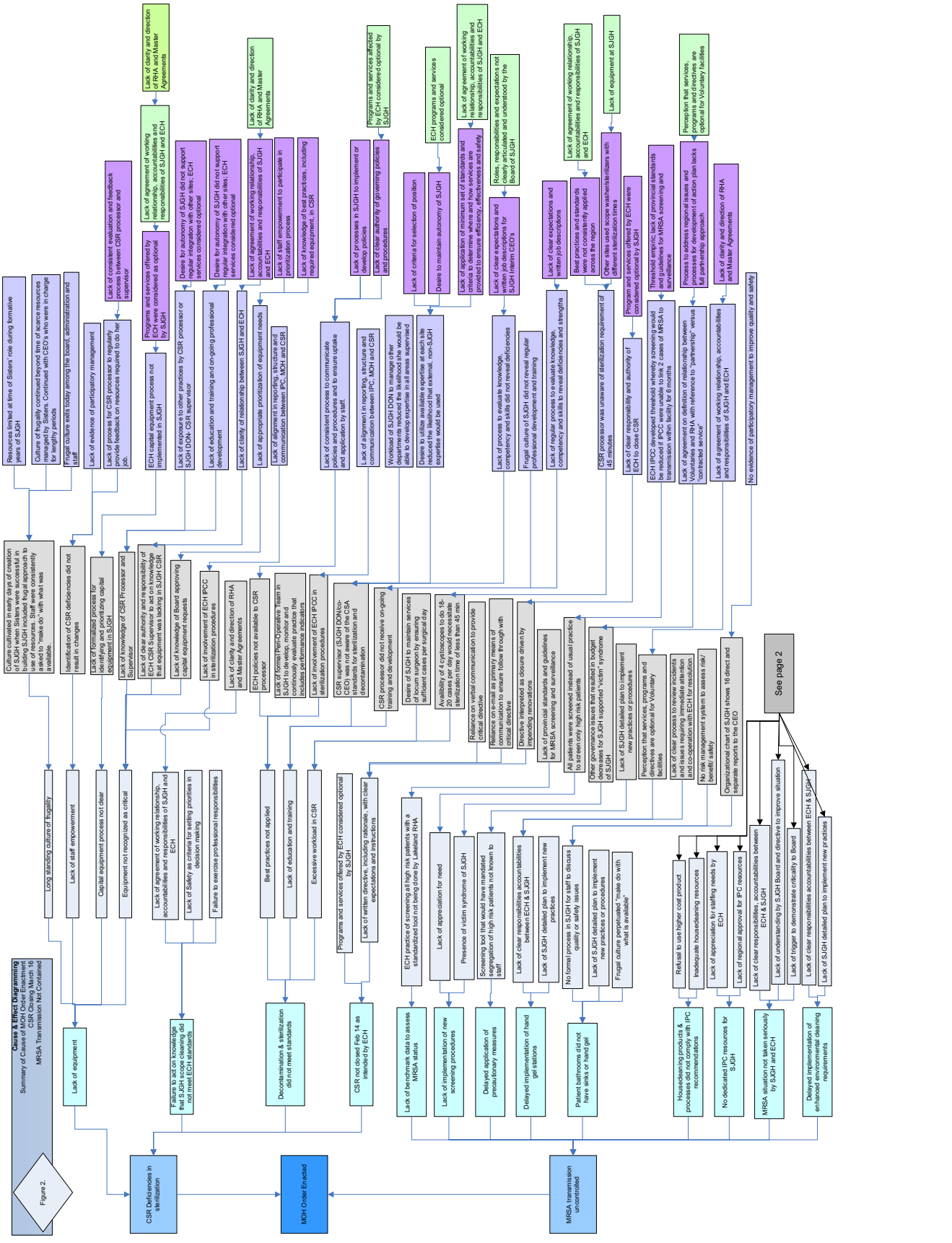
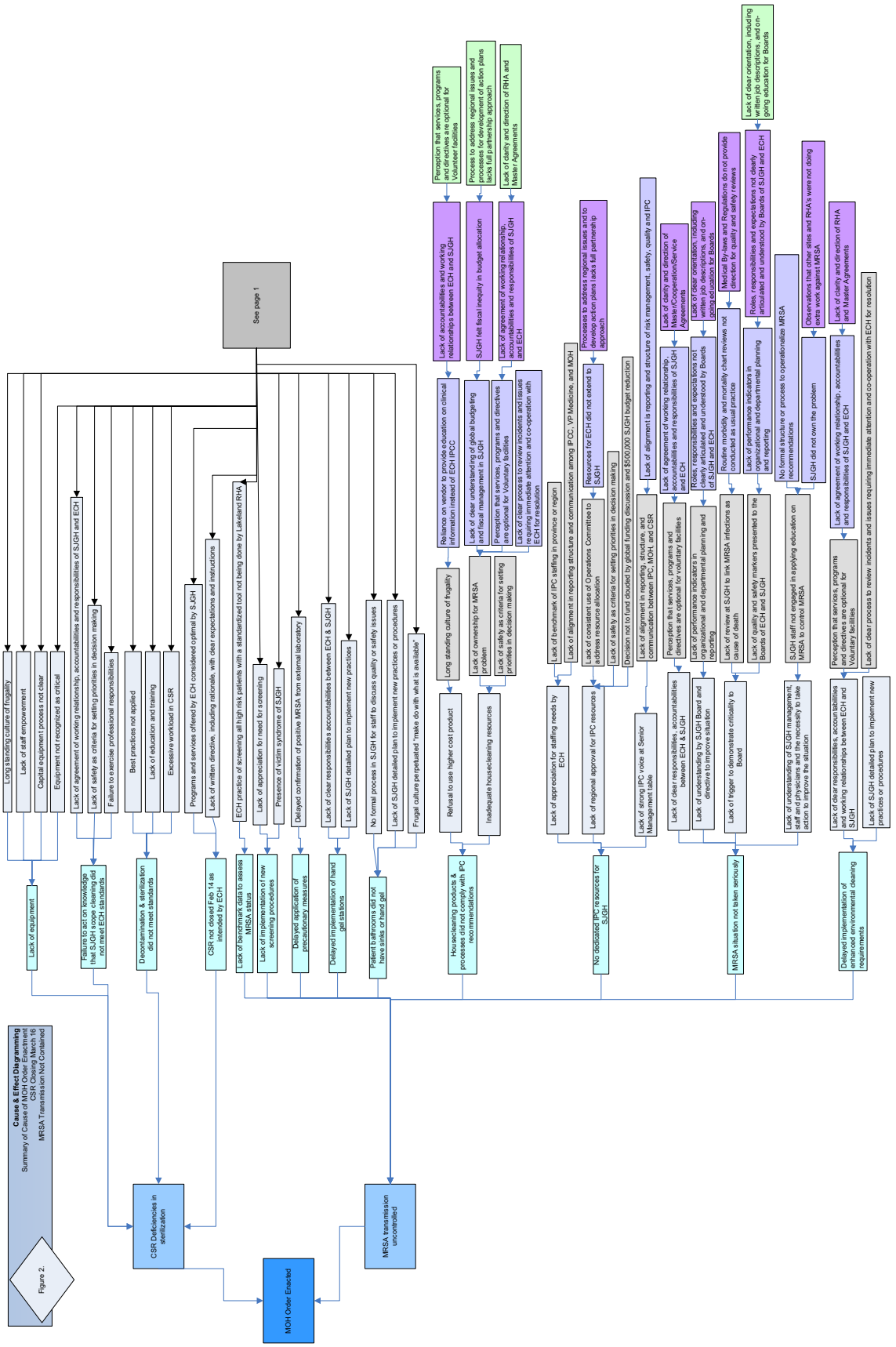


Figure 1b.
Flow chart of the Infection Prevention & Control Issues that Led to the East Central Health Authority Medical Officer of Health Order Dated March 16, 2007 CSR STREAM
April 2003 Change of RHA boundaries. SJGH becomes part of ECH leaving Lakeland RHA
Nov 2003 ECH aware that SJGH did not have scope washer-sterilizer and was using CIDEX for 20 min. Practices not congruent with ECH
March 2004 ECH administration advised that endoscope reprocessing practice not meeting best practice standards in SJGH. Recommendation made to review endoscopic practices at each facility. No evidence of follow up
Feb 2005 Washer-disinfector and flash sterilizer identified as capital equipment need priority #10 and #8 by SJGH
Jan 2006 Scope washer/ sterilizer identified as priority #2 for capital equipment need by SJGH
Aug 2006 ECH approved scope washer/ sterilizer
Jan 2007 SJGH CEO realized capital equipment request for washer/ disinfector required renovations
Jan 22, 2007 CSR audit of SJGH completed Significant deficiencies noted.
Jan 22, 2007 Audit results discussed with SJGH CSR. -Physical layout not conducive for proper sterilization procedures -Direction on sterilizing non-scope instruments or equipment not provided. -Recommendation made for washer/disinfector
Jan 25, 2007 Concerns with SJGH CSR audit reported to ECH Medicine and Nursing administration then communicated verbally to SJGH Nursing administration
Jan 25, 2007 Immediate action required related to CSR audit. -cancelled scope surgeries using scopes for Feb 19 -scheduled meeting later in Feb to discuss CSR -request to ID for consult of risk of inection
Feb 13, 2007 CSR audit of SJGH reviewed in detail with ECH administration and IPCC
Feb 14, 2007 SJGH CSR verbally ordered closed
Feb 16, 2007 Request for SJGH washer/ disinfector and scope washer/ sterilizer submitted and approved by ECH. Full assessment of CSR recommended to determine need for renovations or major upgrades.
Feb 28, 2007 E-mail between ECH and SJGH discussing plan to transport CSR equipment and instruments to alternate site
Feb 28, 2007 Query from SJGH to allow dentist to perform procedures with own sterilized instruments. Advised- "No"
March 15, 2007 @1530 ECH aware that instruments/ equipment from Vegreville Continuning Care not being processed differently from SJGH and therefore not being sent to alternate site.
March 15, 2007- 1600-1800 *Implementation Team Meeting of SJGH, ECH Boards, Senior Mgmt -Review of SJGH CSR audit (added to agenda) -Review how scopes were cleaned -Review of consultant report of infectious disease specialist --low risk of blood borne pathogens that could cause infection --chart audit to be done on subset of cystoscopy patients -Discussed MRSA cases- (added to agenda) -Understanding: CSR closed and equipment being prepared for transport *Team developed to implement recommendations from Blackwell Operational Review
March 16, 2007 10:00 h Confirmation that CSR was not closed and equipment was not being sent from SJGH and Vegreville CC to alternate site for sterilization
March 16, 2007 1300 h IPCC and MOH asked to assess IPC recommendations: 1) Housekeeping solutions changed 2) Contact precautions used for all new MRSA and previously positive MRSA patients 3) CSR was closed since Feb 14 Confirmed 1) and 3) were not implemented and 2) was a continuing problem
March 16, 2007 1800 h MOH order declared for SJGH
April 17, 2007 SJGH re-opened for medical admissions for limited beds
ABBREVIATION LEGEND
AC- Acute Care CC- Continuing Care CSR- Central Sterilization Room F/U- Follow Up ECH- East Central Health HC- Home Care IC- Infection Control IPC- Infection Prevention Control
IPCC- Infection Prevention Control Co-ordinator MOH- Medical Officer Of Health MRSA- Methicillin Resistant Staphylococcus aureus PPE- Personal Protective Equipment
SJGH- St. Joseph General Hospital VEG- Vegreville

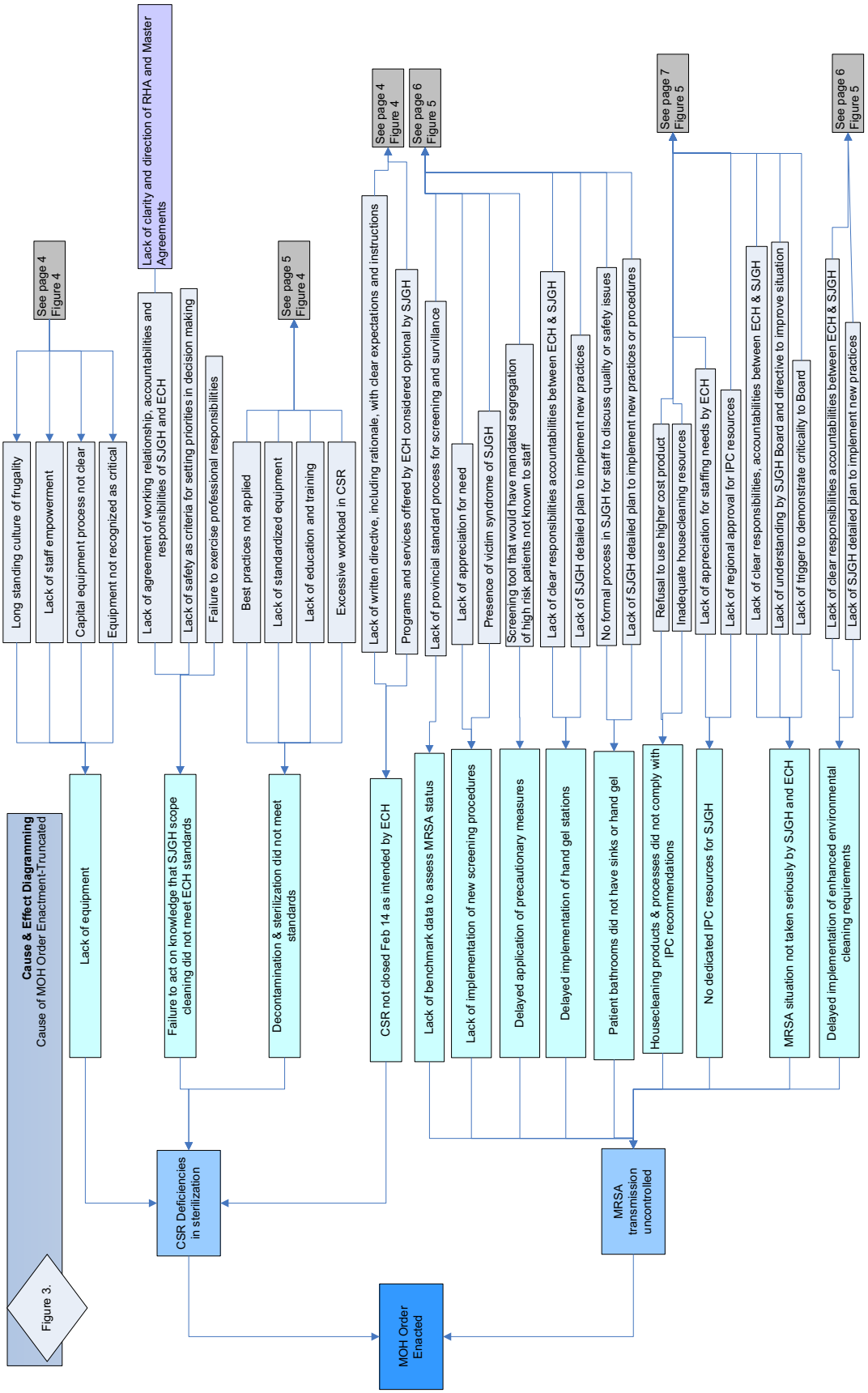
APPENDIX 2: 7. b. Cause and effects diagrams



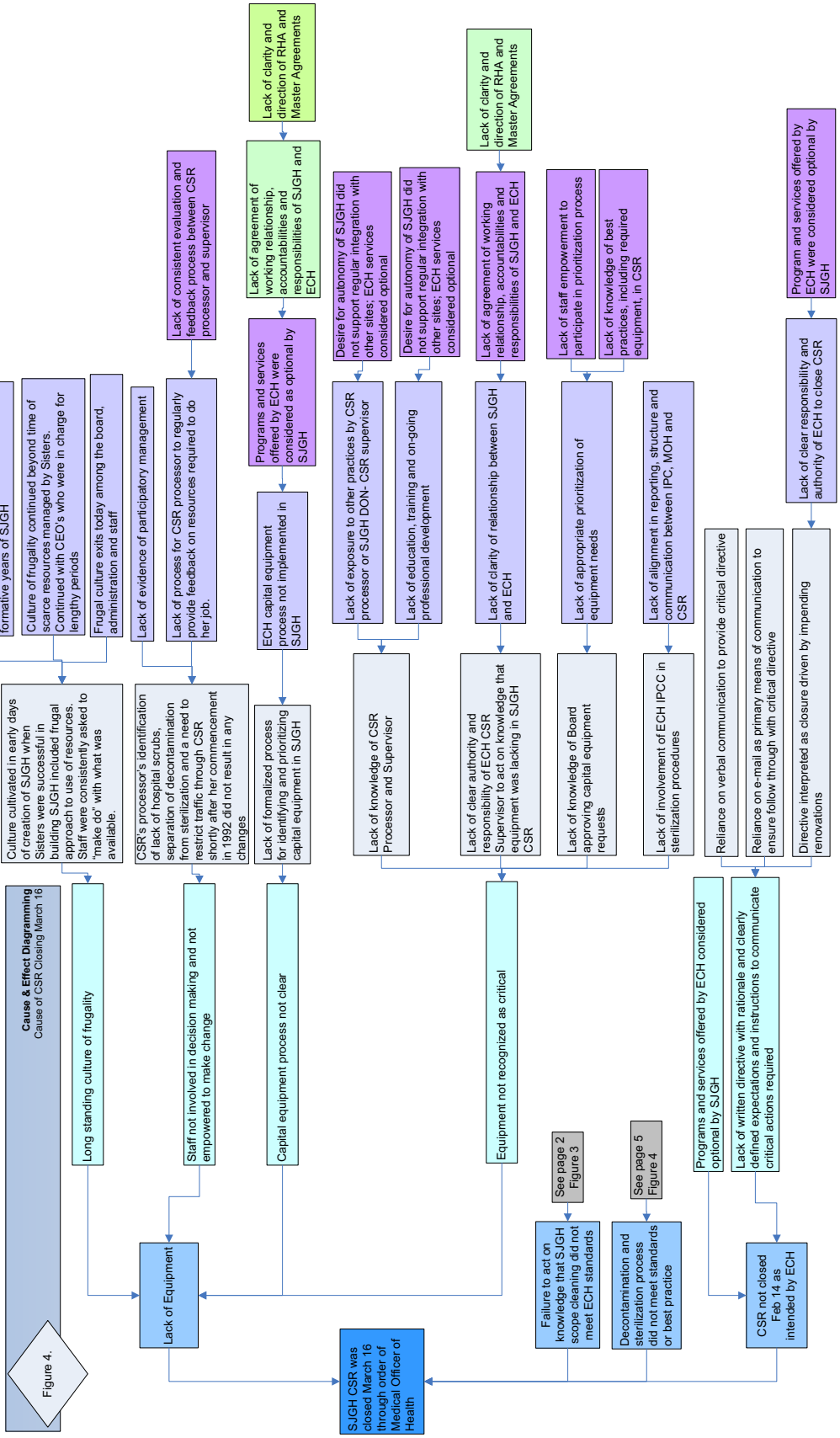
APPENDIX 2:


Cause & Effect Diagramming
Summary of Cause of MOH Order Enactment
CSR Closing March 16
MRSA Transmission Not Contained
Figure 2.
MOH Order Enacted
CSR Deficiencies in sterilization
MRSA transmission uncontrolled
Lack of equipment
Failure to act on knowledge that SJGH scope cleaning did not meet EOH standards
Decontamination & sterilization did not meet standards
CSR not closed Feb 14 as intended by ECH
Lack of benchmark data to assess MRSA status
Lack of implementation of new screening procedures
Delayed application of precautionary measures
Delayed implementation of hand gel stations
Patient bathrooms did not have sinks or hand gel
Housecleaning products & processes did not comply with IPC recommendations
No dedicated IPC resources for SJGH
MRSA situation not taken seriously
Delayed implementation of enhanced environmental cleaning requirements
Long standing culture of frugality
Lack of staff empowerment
Capital equipment process not clear
Equipment not recognized as critical
Lack of agreement of working relationship, accountabilities and responsibilities of SJGH and ECH
Lack of safety as criteria for setting priorities in decision making
Failure to exercise professional responsibilities
Best practices not applied
Lack of education and training
Excessive workload in CSR
Programs and services offered by ECH considered optimal by SJGH
Lack of written directive, including rationale, with clear expectations and instructions
ECH practice of screening all high risk patients with a standardized tool not being done by Lakeland RHA
Lack of appreciation for need for screening
Presence of victim syndrome of SJGH
Delayed confirmation of positive MRSA from external laboratory
Lack of clear responsibilities accountabilities between ECH & SJGH
Lack of SJGH detailed plan to implement new practices
No formal process in SJGH for staff to discuss quality or safety issues
Lack of SJGH detailed plan to implement new practices or procedures
Frugal culture perpetuated "make do with what is available"
See page 1
Reliance on vendor to provide education on clinical information instead of ECH IPCC
Lack of clear understanding of global budgeting and fiscal management in SJGH
Perception that services, programs and directives are optional for Voluntary facilities
Lack of clear process to review incidents and issues requiring immediate attention and co-operation with ECH for resolution
Long standing culture of frugality
Lack of ownership for MRSA problem
Lack of safety as criteria for setting priorities in decision making
Refusal to use higher cost product
Inadequate housecleaning resources
Lack of accountabilities and working relationships between ECH and SJGH
SJGH felt fiscal inequity in budget allocation
Lack of agreement of working relationship, accountabilities and responsibilities of SJGH and ECH
Perception that services, programs and directives are optional for Volunteer facilities
Process to address regional issues and processes for development of action plans lacks full partnership approach
Lack of clarity and direction of RHA and Master Agreements
Lack of appreciation for staffing needs by ECH
Lack of regional approval for IPC resources
Lack of strong IPC voice at Senior Management table
Lack of benchmark of IPC staffing in province or region
Lack of alignment in reporting structure and communication among IPCC, VP Medicine, and MOH
Lack of consistent use of Operations Committee to address resource allocation
Lack of safety as criteria for setting priorities in decision making
Decision not to fund clouded by global funding discussion and $500,000 SJGH budget reduction
Processes to address regional issues and to develop action plans lacks full partnership approach
Resources for ECH did not extend to SJGH
Lack of alignment in reporting, structure, and communication between IPC, MOH, and CSR
Lack of alignment is reporting and structure of risk management, safety, quality and IPC
Lack of agreement of working relationship, accountabilities and responsibilities of SJGH and ECH
Lack of clear responsibilities, accountabilities between ECH & SJGH
Lack of understanding by SJGH Board and directive to improve situation
Lack of trigger to demonstrate criticality to Board
Perception that services, programs and directives are optional for Voluntary facilities
Lack of performance indicators in organizational and departmental planning and reporting
Lack of review at SJGH to link MRSA infections as cause of death
Lack of quality and safety markers presented to the Boards of ECH and SJGH
Lack of clear orientation, including written job descriptions, and on-going education for Boards
Medical By-laws and Regulations do not provide direction for quality and safety reviews
Roles, responsibilities and expectations not clearly articulated and understood by Boards of SJGH and ECH
Lack of clear orientation, including written job descriptions, and on-going education for Boards
Lack of agreement of working relationship, accountabilities and responsibilities of SJGH and ECH
Roles, responsibilities and expectations not clearly articulated and understood by Boards of SJGH and ECH
Routine morbidity and mortality chart reviews not conducted as usual practice
Lack of performance indicators in organizational and departmental planning and reporting
No formal structure or process to operationalize MRSA recommendations
SJGH did not own the problem
Observations that other sites and RHA's were not doing extra work against MRSA
SJGH staff not engaged in applying education on MRSA to control MRSA
Lack of understanding of SJGH management, staff and physicians of the necessity to take action to improve the situation
Lack of agreement of working relationship, accountabilities and responsibilities of SJGH and ECH
Lack of clarity and direction of RHA and Master Agreements
Lack of clear responsibilities, accountabilities and working relationships between ECH and SJGH
Lack of clear process to review incidents and issues requiring immediate attention and co-operation with ECH for resolution
Lack of SJGH detailed plan to implement new practices or procedures

APPENDIX 2:


Cause & Effect Diagramming
Cause of MOH Order Enactment-Truncated
Figure 3.
Lack of equipment
Long standing culture of frugality
Lack of staff empowerment
Capital equipment process not clear
Equipment not recognized as critical
See page 4 Figure 4
Failure to act on knowledge that SJGH scope cleaning did not meet ECH standards
Lack of agreement of working relationship, accountabilities and responsibilities of SJGH and ECH
Lack of safety as criteria for setting priorities in decision making
Failure to exercise professional responsibilities
Lack of clarity and direction of RHA and Master Agreements
Decontamination & sterilization did not meet standards
Best practices not applied
Lack of standardized equipment
Lack of education and training
Excessive workload in CSR
See page 5 Figure 4
CSR not closed Feb 14 as intended by ECH
Lack of written directive, including rationale, with clear expectations and instructions
Programs and services offered by ECH considered optional by SJGH
See page 4 Figure 4
See page 6 Figure 5
Lack of benchmark data to assess MRSA status
Lack of provincial standard process for screening and surviliance
Lack of implementation of new screening procedures
Lack of appreciation for need
Presence of victim syndrome of SJGH
Delayed application of precautionary measures
Screening tool that would have mandated segregation of high risk patients not known to staff
Delayed implementation of hand gel stations
Lack of clear responsibilities accountabilities between ECH & SJGH
Lack of SJGH detailed plan to implement new practices
Patient bathrooms did not have sinks or hand gel
No formal process in SJGH for staff to discuss quality or safety issues
Lack of SJGH detailed plan to implement new practices or procedures
Housecleaning products & processes did not comply with IPC recommendations
Refusal to use higher cost product
Inadequate housecleaning resources
See page 7 Figure 5
No dedicated IPC resources for SJGH
Lack of appreciation for staffing needs by ECH
Lack of regional approval for IPC resources
MRSA situation not taken seriously by SJGH and ECH
Lack of clear responsibilities, accountabilities between ECH & SJGH
Lack of understanding by SJGH Board and directive to improve situation
Lack of trigger to demonstrate criticality to Board
Delayed implementation of enhanced environmental cleaning requirements
Lack of clear responsibilities accountabilities between ECH & SJGH
Lack of SJGH detailed plan to implement new practices
See page 6 Figure 5
CSR Deficiencies in sterilization
MRSA transmission uncontrolled
MOH Order Enacted

APPENDIX 2:


Cause & Effect Diagramming
Cause of CSR Closing March 16
Figure 4.
SJGH CSR was closed March 16 through order of Medical Officer of Health
Lack of Equipment
Long standing culture of frugality
Staff not involved in decision making and not empowered to make change
Capital equipment process not clear
Equipment not recognized as critical
See page 2 Figure 3
Failure to act on knowledge that SJGH scope cleaning did not meet ECH standards
See page 5 Figure 4
Decontamination and sterilization process did not meet standards or best practice
CSR not closed Feb 14 as intended by ECH
Programs and services offered by ECH considered optional by SJGH
Lack of written directive with rationale and clearly defined expectations and instructions to communicate critical actions required
Culture cultivated in early days of creation of SJGH when Sisters were successful in building SJGH included frugal approach to use of resources. Staff were consistently asked to "make do" with what was available.
CSR's processor's identification of lack of hospital scrubs, separation of decontamination from sterilization and a need to restrict traffic through CSR shortly after her commencement in 1992 did not result in any changes
Lack of formalized process for identifying and prioritizing capital equipment in SJGH
Resources limited at time of Sisters' role during formative years of SJGH
Culture of frugality continued beyond time of scarce resources managed by Sisters. Continued with CEO's who were in charge for lengthy periods
Frugal culture exits today among the board, administration and staff
Lack of evidence of participatory management
Lack of process for CSR processor to regularly provide feedback on resources required to do her job.
Lack of consistent evaluation and feedback process between CSR processor and supervisor
ECH capital equipment process not implemented in SJGH
Programs and services offered by ECH were considered as optional by SJGH
Lack of agreement of working relationship, accountabilities and responsibilities of SJGH and ECH
Lack of clarity and direction of RHA and Master Agreements
Lack of knowledge of CSR Processor and Supervisor
Lack of exposure to other practices by CSR processor or SJGH DON- CSR supervisor
Lack of education, training and on-going professional development
Desire for autonomy of SJGH did not support regular integration with other sites; ECH services considered optional
Desire for autonomy of SJGH did not support regular integration with other sites; ECH services considered optional
Lack of clear authority and responsibility of ECH CSR Supervisor to act on knowledge that equipment was lacking in SJGH CSR
Lack of clarity of relationship between SJGH and ECH
Lack of agreement of working relationship, accountabilities and responsibilities of SJGH and ECH
Lack of clarity and direction of RHA and Master Agreements
Lack of knowledge of Board approving capital equipment requests
Lack of appropriate prioritization of equipment needs
Lack of staff empowerment to participate in prioritization process
Lack of knowledge of best practices, including required equipment, in CSR
Lack of involvement of ECH IPCC in sterilization procedures
Lack of alignment in reporting, structure and communication between IPC, MOH and CSR
Reliance on verbal communication to provide critical directive
Reliance on e-mail as primary means of communication to ensure follow through with critical directive
Directive interpreted as closure driven by impending renovations
Lack of clear responsibility and authority of ECH to close CSR
Program and services offered by ECH were considered optional by SJGH

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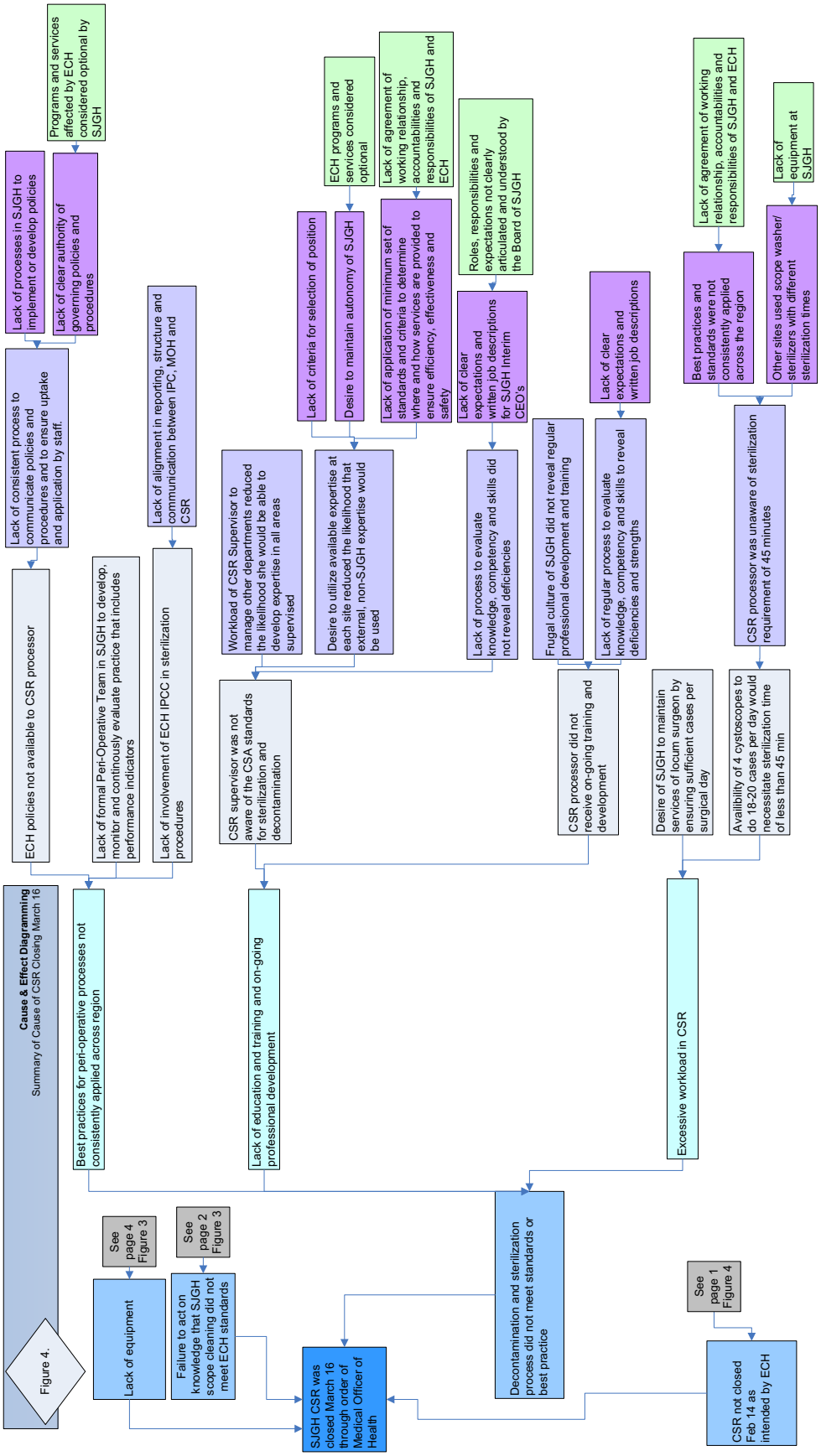
Cause & Effect Diagramming
Summary of Cause of CSR Closing March 16
Figure 4.
SJGH CSR was closed March 16 through order of Medical Officer of Health
Lack of equipment
Failure to act on knowledge that SJGH scope cleaning did not meet ECH standards
See page 4 Figure 3
See page 2 Figure 3
Best practices for peri-operative processes not consistently applied across region
Lack of education and training and on-going professional development
Excessive workload in CSR
Decontamination and sterilization process did not meet standards or best practice
See page 1 Figure 4
CSR not closed Feb 14 as intended by ECH
ECH policies not available to CSR processor
Lack of formal Peri-Operative Team in SJGH to develop, monitor and continously evaluate practice that includes performance indicators
Lack of involvement of ECH IPCC in sterilization procedures
Lack of consistent process to communicate policies and procedures and to ensure uptake and application by staff.
Lack of processes in SJGH to implement or develop policies
Lack of clear authority of governing policies and procedures
Programs and services affected by ECH considered optional by SJGH
Lack of alignment in reporting, structure and communication between IPC, MOH and CSR
CSR supervisor was not aware of the CSA standards for sterilization and decontamination
Workload of CSR Supervisor to manage other departments reduced the likelihood she would be able to develop expertise in all areas supervised
Desire to utilize available expertise at each site reduced the likelihood that external, non-SJGH expertise would be used
Lack of criteria for selection of position
Desire to maintain autonomy of SJGH
ECH programs and services considered optional
Lack of application of minimum set of standards and criteria to determine where and how services are provided to ensure efficiency, effectiveness and safety
Lack of agreement of working relationship, accountabilities and responsibilities of SJGH and ECH
Lack of process to evaluate knowledge, competency and skills did not reveal deficiencies
Lack of clear expectations and written job descriptions for SJGH Interim CEO's
Roles, responsibilities and expectations not clearly articulated and understood by the Board of SJGH
CSR processor did not receive on-going training and development
Frugal culture of SJGH did not reveal regular professional development and training
Lack of regular process to evaluate knowledge, competency and skills to reveal deficiencies and strengths
Lack of clear expectations and written job descriptions
Desire of SJGH to maintain services of locum surgeon by ensuring sufficient cases per surgical day
Availibility of 4 cystoscopes to do 18-20 cases per day would necessitate sterilization time of less than 45 min
CSR processor was unaware of sterilization requirement of 45 minutes
Best practices and standards were not consistently applied across the region
Other sites used scope washer/ sterilizers with different sterilization times
Lack of agreement of working relationship, accountabilities and responsibilities of SJGH and ECH
Lack of equipment at SJGH

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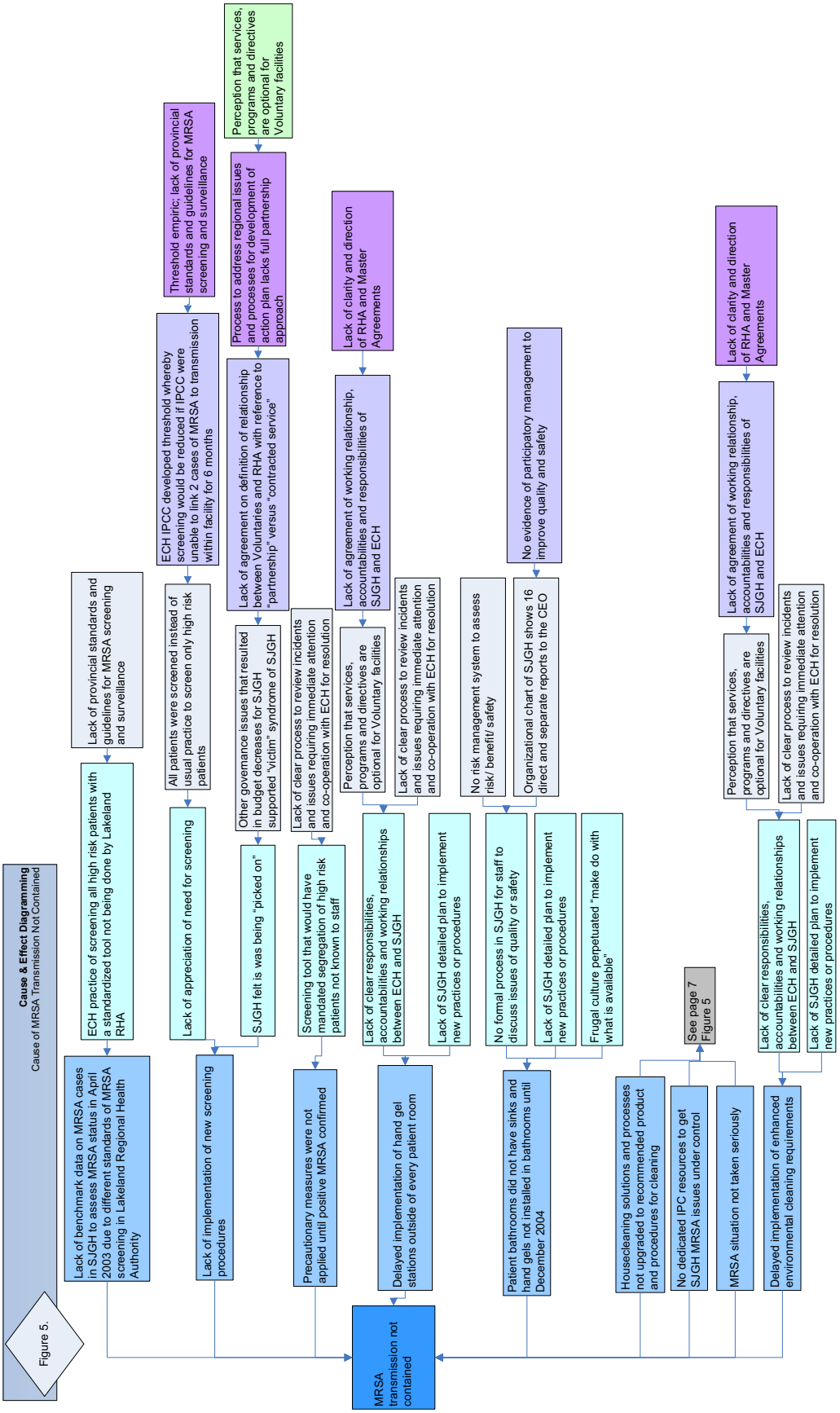
Cause & Effect Diagramming
Cause of MRSA Transmission Not Contained
Figure 5.
MRSA transmission not contained
Lack of benchmark data on MRSA cases in SJGH to assess MRSA status in April 2003 due to different standards of MRSA screening in Lakeland Regional Health Authority
ECH practice of screening all high risk patients with a standardized tool not being done by Lakeland RHA
Lack of provincial standards and guidelines for MRSA screening and surveillance
Lack of implementation of new screening procedures
Lack of appreciation of need for screening
All patients were screened instead of usual practice to screen only high risk patients
SJGH felt is was being "picked on"
ECH IPCC developed threshold whereby screening would be reduced if IPCC were unable to link 2 cases of MRSA to transmission within facility for 6 months
Threshold empiric; lack of provincial standards and guidelines for MRSA screening and surveillance
Other governance issues that resulted in budget decreases for SJGH supported "victim" syndrome of SJGH
Lack of agreement on definition of relationship between Voluntaries and RHA with reference to "partnership" versus "contracted service"
Process to address regional issues and processes for development of action plan lacks full partnership approach
Perception that services, programs and directives are optional for Voluntary facilities
Precautionary measures were not applied until positive MRSA confirmed
Screening tool that would have mandated segregation of high risk patients not known to staff
Lack of clear process to review incidents and issues requiring immediate attention and co-operation with ECH for resolution
Delayed implementation of hand gel stations outside of every patient room
Lack of clear responsibilities, accountabilities and working relationships between ECH and SJGH
Lack of SJGH detailed plan to implement new practices or procedures
Perception that services, programs and directives are optional for Voluntary facilities
Lack of clear process to review incidents and issues requiring immediate attention and co-operation with ECH for resolution
Lack of agreement of working relationship, accountabilities and responsibilities of SJGH and ECH
Lack of clarity and direction of RHA and Master Agreements
Patient bathrooms did not have sinks and hand gels not installed in bathrooms until December 2004
No formal process in SJGH for staff to discuss issues of quality or safety
Lack of SJGH detailed plan to implement new practices or procedures
Frugal culture perpetuated "make do with what is available"
No risk management system to assess risk/ benefit/ safety
Organizational chart of SJGH shows 16 direct and separate reports to the CEO
No evidence of participatory management to improve quality and safety
Housecleaning solutions and processes not upgraded to recommended product and procedures for cleaning
No dedicated IPC resources to get SJGH MRSA issues under control
MRSA situation not taken seriously
See page 7 Figure 5
Lack of clear responsibilities, accountabilities and working relationships between ECH and SJGH
Lack of SJGH detailed plan to implement new practices or procedures
Perception that services, programs and directives are optional for Voluntary facilities
Lack of clear process to review incidents and issues requiring immediate attention and co-operation with ECH for resolution
Lack of agreement of working relationship, accountabilities and responsibilities of SJGH and ECH
Lack of clarity and direction of RHA and Master Agreements
Delayed implementation of enhanced environmental cleaning requirements

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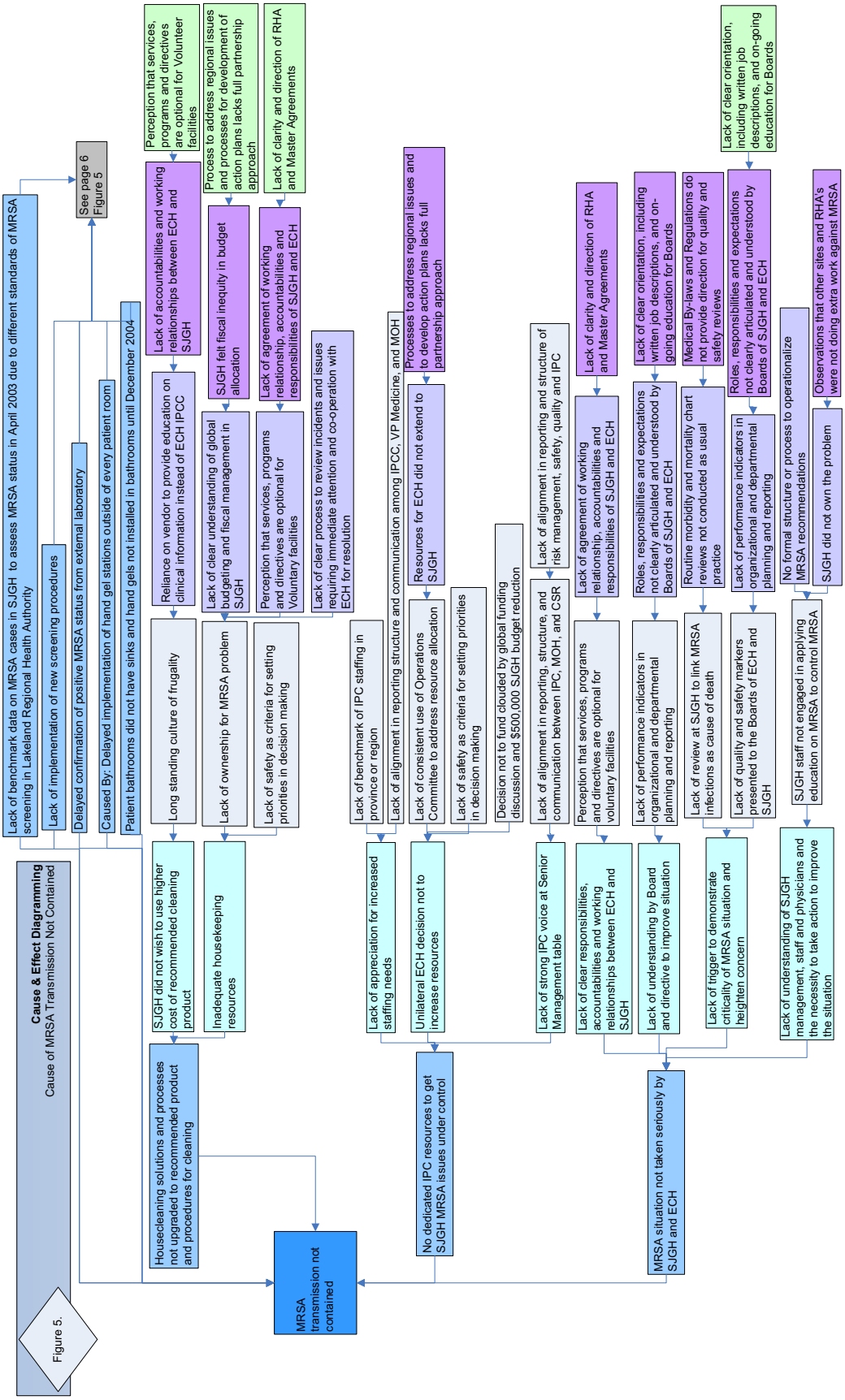
Cause & Effect Diagramming
Cause of MRSA Transmission Not Contained
Figure 5.
MRSA transmission not contained
Housecleaning solutions and processes not upgraded to recommended product and procedures for cleaning
SJGH did not wish to use higher cost of recommended cleaning product
Inadequate housekeeping resources
No dedicated IPC resources to get SJGH MRSA issues under control
Lack of appreciation for increased staffing needs
Unilateral ECH decision not to increase resources
Lack of strong IPC voice at Senior Management table
MRSA situation not taken seriously by SJGH and ECH
Lack of clear responsibilities, accountabilities and working relationships between ECH and SJGH
Lack of understanding by Board and directive to improve situation
Lack of trigger to demonstrate criticality of MRSA situation and heighten concern
Lack of understanding of SJGH management, staff and physicians and the necessity to take action to improve the situation
SJGH staff not engaged in applying education on MRSA to control MRSA
SJGH did not own the problem
Observations that other sites and RHA's were not doing extra work against MRSA
No formal structure or process to operationalize MRSA recommendations
Lack of benchmark data on MRSA cases in SJGH to assess MRSA status in April 2003 due to different standards of MRSA screening in Lakeland Regional Health Authority
Lack of implementation of new screening procedures
Delayed confirmation of positive MRSA status from external laboratory
Caused By: Delayed implementation of hand gel stations outside of every patient room
Patient bathrooms did not have sinks and hand gels not installed in bathrooms until December 2004
See page 6 Figure 5
Long standing culture of frugality
Lack of ownership for MRSA problem
Lack of safety as criteria for setting priorities in decision making
Reliance on vendor to provide education on clinical information instead of ECH IPCC
Lack of clear understanding of global budgeting and fiscal management in SJGH
Perception that services, programs and directives are optional for Voluntary facilities
Lack of clear process to review incidents and issues requiring immediate attention and co-operation with ECH for resolution
Lack of accountabilities and working relationships between ECH and SJGH
SJGH felt fiscal inequity in budget allocation
Lack of agreement of working relationship, accountabilities and responsibilities of SJGH and ECH
Perception that services, programs and directives are optional for Voluntary facilities
Process to address regional issues and processes for development of action plans lacks full partnership approach
Lack of clarity and direction of RHA and Master Agreements
Lack of benchmark of IPC staffing in province or region
Lack of alignment in reporting structure and communication among IPCC, VP Medicine, and MOH
Lack of consistent use of Operations Committee to address resource allocation
Lack of safety as criteria for setting priorities in decision making
Decision not to fund clouded by global funding discussion and $500,000 SJGH budget reduction
Resources for ECH did not extend to SJGH
Processes to address regional issues and to develop action plans lacks full partnership approach
Lack of alignment in reporting and structure of risk management, safety, quality and IPC
Lack of alignment in reporting, structure, and communication between IPC, MOH, and CSR
Lack of clarity and direction of RHA and Master Agreements
Lack of agreement of working relationship, accountabilities and responsibilities of SJGH and ECH
Perception that services, programs and directives are optional for voluntary facilities
Roles, responsibilities and expectations not clearly articulated and understood by Boards of SJGH and ECH
Lack of performance indicators in organizational and departmental planning and reporting
Lack of review at SJGH to link MRSA infections as cause of death
Lack of quality and safety markers presented to the Boards of ECH and SJGH
Lack of clear orientation, including written job descriptions, and on-going education for Boards
Medical By-laws and Regulations do not provide direction for quality and safety reviews
Routine morbidity and mortality chart reviews not conducted as usual practice
Roles, responsibilities and expectations not clearly articulated and understood by Boards of SJGH and ECH
Lack of clear orientation, including written job descriptions, and on-going education for Boards
Lack of performance indicators in organizational and departmental planning and reporting

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