Root Cause Analysis of Medication Incidents

The Institute for Safe Medication Practices Canada (ISMP Canada), the Canadian Institute for Health Information, and Health Canada are the three collaborating parties in the development and implementation of the Canadian Medication Incident Reporting and Prevention System (CMIRPS). These organizations are working with the Canadian Patient Safety Institute and an advisory committee to strengthen Canada’s ability to effectively manage and coordinate information about medication incidents. One of ISMP Canada’s roles in the CMIRPS is to assist with root cause analysis (RCA) for selected medication incidents. For information on ISMP Canada’s other roles in the CMIRPS, see the ISMP Canada Website, http://www.ismp-canada.org/cmirps.htm.

To provide a standardized approach to the retrospective analysis of critical incidents and near-miss events in health care, ISMP Canada, Saskatchewan Health, and the Canadian Patient Safety Institute worked together to develop a Canadian Root Cause Analysis Framework. The RCA Framework is an analytic tool for performing a system-based review of incidents, including but not limited to medication incidents. It utilizes well established methods for analysis designed to help determine the root causes and contributing factors that led to an event and to identify strategies for implementing system improvements.

The goals of root cause analysis are to determine
- what happened
- why it happened
- what can be done to reduce the likelihood of a recurrence

The RCA Framework suggests the types of actions to be taken immediately after a critical incident, when and how to conduct an RCA, and how to select a multidisciplinary team to perform the RCA. Flow-charting methods are combined with questioning techniques based on human factors engineering principles to assist in determining the root causes/contributing factors. The root causes/contributing factors are then framed into “causal statements” which form the basis for developing the recommended actions. The RCA Framework also outlines strategies to measure the usefulness of such actions.

Effective RCA can prevent health care organizations from undertaking cursory reviews that focus too heavily on the performance of individuals at the “sharp end” of the health care system (the point where care is delivered). A systematic RCA will delve more deeply into the underlying causes of and factors contributing to an event and will include, for example, consideration of organizational, environmental, and regulatory factors. These “blunt end” factors influence how work is configured and accomplished, are often beyond the control of individual practitioners, and may not be immediately recognized as causal factors. True root causes represent the earliest points that may require adjustment to prevent harmful incidents. Figure 1 illustrates the potential for incomplete solutions if only apparent root causes are identified and fixed, or corrected.

RCA often reveals underlying system deficiencies that are not obvious, as well as issues that have become so familiar to those working in a particular environment that they are not identified as risks. RCA does not assign blame and is outcome directed, with emphasis on specific, high-leverage actions that take into account human factors engineering principles and the need to design systems with integrated safeguards.

Canadian health care providers are gaining knowledge and understanding about the impact of underlying system factors and the latent conditions that can increase the risk of incidents. Learning from incident analyses has been shared in previous issues of the ISMP Canada Safety Bulletin.

ISMP Canada provides educational workshops on RCA and can also be contracted to assist with analysis of sentinel events. For more information, send an email message to rca@ismp-canada.org, call 416-733-4158, or call toll free 1-866-544-7672.

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ISMP Canada’s Commitment to Patient Safety Research

Earlier this year, ISMP Canada held a strategic planning session involving its board of directors, selected staff members, and external advisors. One of the strategic directions adopted by participants was to increase the organization’s involvement in patient safety research.

On December 2, 2005, the Canadian Patient Safety Institute (CPSI) announced the winners of its first research funding competition. Twenty-eight winners, divided by theme into two groups (Applied Health Services Research Projects and Demonstration Projects), were selected. For full details on the selection process and the list of successful applicants, refer to the CPSI web page (http://www.patientsafetyinstitute.ca).

The Institute for Safe Medication Practices Canada (ISMP Canada) is a coapplicant and research team member in four of the winning proposals:

Theme 1: Applied Health Services Research Projects
   - Neil MacKinnon, Dalhousie University, Halifax, NS — Development of medication safety indicators
   - Karen Weisbaum, Queen’s University, Kingston, ON — Striking a balance: facilitating access to patient safety data while protecting privacy through creation of a national harmonized standard

Theme 2: Demonstration Projects
   - Tony Easty, University Health Network, Toronto, ON — Developing and implementing an effective method for independent double checking of high-risk clinical procedures
   - Kathryn Momtahan, University of Ottawa Heart Institute, Ottawa, ON — Using human factors and FMEA methods to evaluate labelling of injectables (ampoules) and the recently developed CSA standards for labelling

References: