High 5s: Addressing excellence in patient safety

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ABSTRACT: The High 5s project is a multi-country, multi-agency collaborative initiative to improve patient safety around the world. Launched by the World Health Organization (WHO) in 2006, the mission of the Project is to facilitate implementation and evaluation of standardized patient safety solutions within a global learning community to achieve measurable, significant, and sustainable reductions in challenging patient safety problems in hospitals from several countries over five years. The High 5s project is best characterized as supporting the development and application of innovative, specific standard operating protocols (SOPs) through the collection, reporting and analysis of data, and establishing an electronic collaborative learning community.

In 2002, the World Health Assembly recognized the need to promote patient safety as a fundamental principle of all health systems and called on the World Health Organization (WHO) to develop global norms and standards; promote the framing of evidence-based policies and mechanisms to recognize excellence in patient safety globally; encourage research on patient safety; and support country efforts to improve the safety of care.1 Subsequently, WHO initiated efforts to address patient safety and established the World Alliance for Patient Safety in 2004. WHO's Director-General stated that improving patient safety is in many cases the best way to protect the medical advances of the last 100 years.2 Changes at the level of practice of health-care workers, teams, organizations and whole health-care systems have been recognized by WHO as key to improving patient safety.3

The challenge of how best to ensure the timely and sustained implementation of evidence-based practices to help reduce the magnitude of adverse events and improve patient safety is a major area of focus of the High 5s project. Because such practices differ from one country and culture to another, there is a need for international standardization of safety practices, methods of implementation, evaluation and terminology, in order to develop effective approaches for improving patient safety.4 The High 5s project is structured as a collaboration between several countries, WHO's Patient Safety Programme and the WHO Collaborating Centre for Patient Safety designated as The Joint Commission and Joint Commission International (JCI). Its name derives from the project's initial intent to significantly reduce the frequency of five challenging patient safety problems in five countries over five years.

Some types of adverse events and their burden
A growing body of evidence points to the occurrence of adverse events in all health-care systems. The best available data have been from studies in developed countries, although enough evidence exists from developing nations and those with economies in transition to suggest that unsafe medical care is ubiquitous. A 2008 WHO report suggested that specific consequences, such as health care-associated infections, or adverse drug events, or unsafe surgical care can be categorized as outcomes of unsafe care. In addition, mechanisms such as latent failures in organizational structure reflecting poor structures, or underlying mechanisms in patient safety problems, such as poor communication between physicians, reflecting poor processes can lead to adverse events.4

Some types of adverse events can occur more frequently than others or have a higher impact on patient care and lives than others. The High 5s project initially focused on five risk areas that have a high impact on patient care. These are: medication errors, including the injection of concentrated medicines, unsafe surgical procedures, health care-associated infection and communication failures during patient handovers.

Medication errors are a major problem for patient safety, mainly occurring as medications are procured, prescribed, dispensed or administered, but occur most frequently during prescription and administration: an estimated 1.5 million people are harmed and several thousands killed each year in the United States of America, costing at least US$ 3.5 billion annually.5 In some countries up to 67% of patients' prescription medication histories have one or more errors6 and up to 46% of medication errors occur when new
orders are written at patient admission or discharge. Many developed nations report that medication adverse events are a leading cause of injury and death within their health-care systems. Adverse events are also the result of errors associated with concentrated injectable medicines (sodium heparin, potassium chloride, morphine) and most frequently result in serious harm and death. These incidents are caused by mis-selection of the wrong product due to look-alike labelling and packaging or mix-up related to dose and rate of administration. Between 2005 and 2006, the UK National Patient Safety Agency received around 800 reports a month relating to injectable medicines with 25 incidents of death and 28 incidents of serious harm being reported. In Canada, 23 incidents involving KCL mis-administration occurred between 1993 and 1996.

The problems of surgical safety in developed countries confirm the magnitude and pervasiveness of the problem, with nearly half of all adverse events in hospitalized patients being related to surgical care and services. Wrong site, wrong organ, wrong site, wrong implant, and wrong person are not such a rare event as evidenced by the steady increase in the number of reported cases. In 2001, the sentinel event database of The Joint Commission in the United States of America included 150 cases of wrong site, wrong person or wrong procedure surgery. In 2004, the United States Department of Veteran's Affairs National Patient Safety Center determined that wrong surgeries were being reported at a rate of approximately one per 30,000 or about one per month. In the United Kingdom, data from the National Patient Safety Agency's National Reporting and Learning System (2001-2002) identified 44 patient safety incidents associated with wrong procedure, site, operating list, consent, patient name and notes.

A large body of evidence has emerged since the 1990s on health care-associated infection (HCAI). In developed countries, HCAI affects 5–10% of hospitalized patients and can affect 9–37% of those admitted to Intensive Care Units. In Europe approximately 5 million HCAI are estimated to occur in acute care hospitals in Europe annually, with a corresponding economic burden of €13–24 billion. In the USA, the estimated HCAI incidence rate was 4.5% in 2002; approximately 99,000 deaths were attributed to HCAI. The annual economic impact of HCAI in the United States of America was approximately US$ 6.5 billion in 2004. Data from developing countries arise from studies conducted in single hospitals and therefore may not be representative of the problem.

Communication failures during patient handovers continue to result in discontinuity of care, adverse events and legal claims of malpractice. An Australian study of emergency department handover found that not all required information was transferred in 15.4% of cases, resulting in adverse events. A survey of junior doctors in the United Kingdom discovered that 83% believed that the handover process was poor. Written handover was rarely received, accounting for only 6% of all handovers. In the United States of America a survey among trainees suggested that 15% of adverse events, errors or near misses happened as a result of a poor handover. Handover is also among the most common cause of malpractice claims especially among trainees, accounting for 20% of cases.

Collaborating to make a difference
Fortunately, interventions and strategies to reduce these major but avoidable patient safety problems are available and are being implemented in health-care institutions around the world. The challenge is to test the feasibility of using standard operating protocols to address patient safety problems, across multiple countries and cultures. The High 5s project has embraced existing interventions and strategies, in order to support the development and application of standardized patient care processes to achieve measurable, significant, and sustained reductions in prevalent patient safety problems, and evaluating their impact. Through promoting the uptake and adaptation of these processes, the High 5s project aims to demonstrate their effectiveness and learn from their systematic implementation.

The mission of the High 5s project is, therefore, to facilitate the implementation and evaluation of standardized patient safety solutions within a global learning community to achieve measurable, significant, and sustained reductions in highly important patient safety problems. At the 2007 Commonwealth Fund's International Symposium on Health Care Policy, ministers of health and health leaders from Canada, Germany, the Netherlands, New Zealand, the United Kingdom and the United States of America signed a letter of intent to collaborate on the High 5s project, formally recognizing the critical and urgent need to act in cooperation and unison to solve and prevent major patient safety problems. More countries joined the High 5s project in 2008 and 2009 including Australia, France, Saudi Arabia and Singapore.

Each country identified a lead technical agency (LTA) (Table 1) to mobilize participating hospitals in each country and oversee the implementation and evaluation of protocols. By mid 2009, each agency selected one or more SOPs to implement and was in the process of enrolling at least 10 hospitals for each protocol. These hospitals will comprise a learning laboratory and will be given recognition for their acceptance of this challenge and for their leadership in working to standardize patient care processes.

The LTA in each country coordinates and supports the implementation of SOPs in the participating hospitals, and monitors the impact of the SOPs through applying the evaluation tools. Each agency will collect data from participating hospitals and submit to the WHO Collaborating Centre for Patient Safety for analysis and tracking, and eventually for dissemination and exchange of knowledge and learning to support effective patient safety processes worldwide.

Standard Operating Protocols
The overall aim of the High 5s project is to gain an understanding of the way in which protocols are implemented and their impact on improving patient safety processes and outcomes. An SOP contains a set of instructions for implementing a defined patient care process by multiple users in a consistent and measurable way. A major innovation is the concept of standardization across different countries and different hospitals so that each protocol is understood, delivered through training, implemented and measured the same way locally, nationally and globally. The High 5s project is designed to generate learning that will permit the continuous refinement and improvement of the SOPs, as well as assessment of the feasibility and success of implementing standardized approaches to specific patient safety problems across multiple countries and cultures. The outcomes of the implementation and evaluation of the protocols is expected to
TABLE 1: PARTICIPATING COUNTRY LEAD TECHNICAL AGENCIES IN 2009

Australia: Australian Commission on Safety and Quality Healthcare
Canada: Canadian Patient Safety Institute
France: French National Authority for Health
Germany: German Coalition for Patient Safety
The Netherlands: Dutch Institute for Healthcare Improvement
Saudi Arabia: Ministry of Health
Singapore: Ministry of Health
United Kingdom: National Patient Safety Agency
United States of America: Agency for Healthcare Research and Quality

TABLE 2: MAJOR COMPONENTS OF THE HIGH 5S PROJECT

- Development and implementation of Standard Operating Protocols
- Impact Evaluation Strategy
- Data collection, reporting, and analysis
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TABLE 3: FIVE STANDARD OPERATING PROTOCOLS DEVELOPED TO SUPPORT THE HIGH 5S PROJECT

- Assuring Medication Accuracy at Transitions in Care
- Managing Concentrated Injectable Medicines
- Performance of Correct Procedures at Correct Body Sites
- Hand Hygiene to Prevent Healthcare-Associated Infections
- Communication During Patient Care Handovers

provide valuable lessons and new knowledge to support the advancement of patient safety around the world (Table 2).

SOPs for five patient safety solutions have been proposed using a phased development process which engaged both technical experts as well as leaders of patient safety initiatives in participating countries. The protocols are presented in Table 3.

Each SOP provides evidence and summarizes the problem, the strength of evidence that supports the solution, potential barriers to adoption, potential unintended consequences created by the solution, patient and family roles in implementing the solution.

Since the initiation of the High 5s project in 2007, three SOPs have been completed, while the finalization and implementation of two SOPs, namely hand hygiene to prevent health care-associated infection and communication during patient handovers, have been deferred to a later time.

The Assuring of Medication Accuracy at Transitions in Care SOP addresses the prevention of medication errors resulting from incomplete or mis-communicated information at points of transition in the patient care process, such as admission to the hospital, transfers within the hospital and discharge from hospital. This SOP seeks to prevent these errors by obtaining, at the time of admission, a complete and accurate list of each patient’s current home medications—including name, dosage, frequency and route; using that list when writing admission, transfer and/or discharge medication orders; and comparing the list against the patient’s admission, transfer and discharge orders, identifying and bringing any discrepancies to the attention of the prescriber and, if appropriate, making changes to the orders.

The Managing of Concentrated Injectable Medicines SOP addresses the prevention of medication errors associated with the preparation, storage, or administration of concentrated injectable medicines. The implementation effort focuses on the three injectable medicines that are most frequently associated with errors resulting in death or serious patient harm: concentrated potassium chloride solution; sodium heparin (>1000 units/ml); and injectable morphine preparations. This SOP seeks to prevent these errors by minimizing the storage and use of concentrated injectable medicine products by replacing them with ready-to-administer or ready-to-use injectable products that do not need to be diluted before use.

The Performance of Correct Procedures at Correct Body Sites SOP addresses a specific type of surgical complication: wrong site, wrong procedure, wrong person surgery, which is generally considered to be preventable and appears now to be far more common than previously recognized. This SOP seeks to prevent incorrect surgery through consistent, effective implementation of three complementary steps in the preoperative preparation of each surgical patient, as follows: a comprehensive preoperative verification process; surgical site marking; and final verification “Time Out” immediately before starting the procedure. Success of these efforts depends upon active involvement and effective communication among all members of the perioperative team including, to the extent possible, involvement of the patient.

In the High 5s collaboration, the Canadian LTA has led development of the medication reconciliation SOP, the United Kingdom LTA has led development of the concentrated injectables SOP, and the United States of America LTA has led development of the correct site surgery SOP. All countries participating in the High 5s project have provided technical expertise in the development of the implementation, performance measurement, event analysis, and evaluation frameworks that are integral to the SOPs.

Evaluation Framework

Each SOP has an Impact Evaluation Strategy which includes on-site observation of SOP implementation, SOP-specific performance measures, an event analysis framework to identify occurrences that may represent SOP failures, and baseline and periodic hospital safety culture surveys. The evaluation strategy seeks to identify the factors underlying the adverse events of concern, match these factors against those that the SOPs are designed to prevent, and track changes in the safety cultures of the participating hospitals. The strategy involves the completion of questionnaires by participating hospitals at the onset, at quarterly intervals throughout the implementation period and at the end,
The evaluation strategy includes standardized performance measures relevant to the content and processes of each SOP, and the specific problem/outcomes that the SOP is designed to address.

about experiences related to the implementation of the protocols. In addition, each LTA will visit several participating hospitals each year to observe the SOPs in practice and interview hospital staff regarding issues of implementation, potential barriers, unintended consequences of implementation, impact and sustainability.

The evaluation strategy includes standardized performance measures relevant to the content and processes of each SOP, and the specific problem/outcomes that the SOP is designed to address. Aggregated data from each participating hospital will be entered into an information management system for further analysis. In addition, a comprehensive event analysis process will include the identification and investigation of SOP-related adverse events through the use of a minimum data set. This will enable an unprecedented level of data collection on the safety and effectiveness of each aspect of the SOPs.

A pre-test will be undertaken in a number of hospitals in each participating country to assess and refine the evaluation, performance measures and event analysis processes, tools and materials. To support activities related to the evaluation framework, a secure and sophisticated information management system has been developed to support data collection and analysis, including a data quality monitoring protocol to assure the validity of the project results.

The results of the evaluation will be used to improve the efficiency and effectiveness of a standardized approach to the management of each SOP and to assess the feasibility and efficacy of standardization.

Next steps and future direction
Following completion of LTA and hospital training on implementation and evaluation, each SOP will be pre-tested and piloted in individual representative hospitals in each participating country to ensure the appropriateness of strategies and tools prior to full-scale implementation that is due to commence in early 2010 for a maximum duration of 5 years. Participating hospitals will be given high visibility and recognition for their willingness to implement and evaluate the SOPs and for their leadership in working to standardize patient care processes.

Clearly, from a global perspective, ensuring the implementation of the SOPs in a small number of countries is not sufficient. Over time, this multi-country, multi-agency collaboration will work to facilitate and encourage partnerships with more countries, particularly developing countries, to support the adaptation and implementation of the SOPs. By doing this, the High 5s project will demonstrate an ability to advance globally the patient safety agenda and create a culture for shared learning and support that will benefit patients in both the developed and developing world.

References
25. Australia was one of the initial countries participating in the High 5s project and is leading the work on the ‘Communication During Patient Care Handovers’ standard operating protocol.