Standardization in patient safety: the WHO High 5s project

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Accepted for publication 19 January 2014

Abstract

Quality problem. Despite its success in other industries, process standardization in health care has been slow to gain traction or to demonstrate a positive impact on the safety of care.

Intervention. The High 5s project is a global patient safety initiative of the World Health Organization (WHO) to facilitate the development, implementation and evaluation of Standard Operating Protocols (SOPs) within a global learning community to achieve measurable, significant and sustainable reductions in challenging patient safety problems.

Goals. The project seeks to answer two questions: (i) Is it feasible to implement standardized health care processes in individual hospitals, among multiple hospitals within individual countries and across country boundaries? (ii) If so, what is the impact of standardization on the safety problems that the project is targeting?

Method. The two key areas in which the High 5s project is innovative are its use of process standardization both in hospitals within a country and in multiple participating countries, and its carefully designed multi-pronged approach to evaluation.

Status. Three SOPs—correct surgery, medication reconciliation, concentrated injectable medicines—have been developed and are being implemented and evaluated in multiple hospitals in seven participating countries. Nearly 5 years into the implementation, it is clear that this is just the beginning of what can be seen as an exercise in behavior management, asking whether health care workers can adapt their behaviors and environments to standardize care processes in widely varying hospital settings.

Keywords: patient safety, standard operating protocol, standardization, evaluation, medication safety, surgical safety

Overview

Patient safety is a fundamental principle of excellent patient care and a critical component of health care quality management. Execution of this principle is often perceived as being an individual responsibility of health care practitioners and is often not translated into health care process and system design. However, health care is almost always provided in a context of organization-specific processes and culture that usually differ significantly among health care organizations. Therefore, safe and effective care is dependent not only on the knowledge, skills and behaviors of front-line health care practitioners but also on care delivery design in specific health care settings. Thus, patient safety must be considered within the context of health care delivery processes and health care organization culture, and mechanisms for protecting patients from harm need to be designed with a clear understanding of the science of safety.

One of the biggest challenges in improving patient safety is how best to implement evidence-based interventions and best practices in a uniform way within a hospital, across hospitals within a country or even, ideally, in multiple countries. Patient safety initiatives around the world have enjoyed varying degrees of success, but they have not been designed
consistently nor has there been a standardized approach to their implementation. The High 5s project seeks to ‘bring local variations in health care practice into a global ideal of patient safety’ [1] by developing standardized interventions and tools that can be applied in any hospital in any country around the globe. The specific goals of the project are to determine the feasibility of implementing Standard Operating Protocols (SOPs) in a standardized way within individual hospitals, across hospitals within a country and in multiple countries and to measure the impact of such standardization on patient safety. Standardization on a grand scale is challenging, but to be globally relevant, it needs to be applicable across different cultures. If this goal proves to be achievable, this would help leverage the scalability to spread both the concept of standardization within health care and the SOPs themselves.

Ideally, new learning that is generated by this standardization initiative would be shared among health care institutions in the developed and developing world. The High 5s project plans to do just that by implementing targeted patient safety strategies through SOPs, undertaking comprehensive evaluations of this experience and then refining the SOPs and their associated evaluation approaches for use in interested countries around the world.

**Background**

The High 5s project is a World Health Organization (WHO) global patient safety initiative. It was launched in 2007 to facilitate the development, implementation and evaluation of SOPs that were developed to address known patient safety problems. The project has brought together multiple countries and institutions to form a global learning community with the combined aim of producing measurable, significant and sustainable reductions in the incidence of challenging hospital-based patient safety problems [2]. The founding countries were Australia, Canada, Germany, the Netherlands, New Zealand, the United Kingdom of Great Britain and Northern Ireland and the USA. France, Singapore and Trinidad and Tobago joined the High 5s project in 2008, 2009 and 2011, respectively.

The project initially focused on five risk areas (Box 1) whose successful address might have high impact on patient care in five countries over five years (hence the ‘High 5s’ project name). Three SOPs have been developed and are being tested. These include Managing Concentrated Injectable Medicines, Assuring Medication Accuracy at Transitions of Care and Performance of the Correct Procedure at the Correct Body Site.

Each participating country selected a Lead Technical Agency (LTA) to oversee coordination of High 5s activities among the national institutions and hospitals participating in the High 5s project. In addition, selected LTAs were tasked to lead the development of certain SOPs. Canada, for example, has led development of the SOP for medication reconciliation, the United Kingdom has led development of the concentrated injectables protocol and the USA has led development of the correct site surgery protocol. These three SOPs have been completed, and implementation is in progress. Development of the SOPs for communication during patient handovers and for hand hygiene has been deferred.

The High 5s project has applied established practices and interventions to support the development of standardized processes and tools to ensure that multiple levels of the system—from management to individual health care workers—are included in the improvement processes. This has also permitted development of a consistent system of monitoring that makes possible the production of comparable results locally, nationally and internationally. One of the challenges in developing a SOP is to ensure that it is neither too generic, nor too complex, nor too simplistic to have meaningful applications to a wide range of settings across the globe. At the same time, the SOPs have been designed to acknowledge and accommodate the real-world complexities, interdependencies and variability of health care processes in a variety of hospital settings. This acknowledgement has required their pretesting in selected hospitals prior to broad implementation in the sponsoring countries to ensure the appropriateness and usability of the SOPs.

Each SOP contains a set of instructions for implementing a defined patient care process by multiple users in a consistent and measurable way. It is anticipated that the SOPs will be further improved with user experience and analysis of collected data over time. Each SOP summarizes the problem, proposes a solution, presents the evidence for the solution, identifies potential barriers to adoption and delineates potential unintended consequences of the solution. SOPs are designed to apply quality improvement methods to effect process and systems improvement, as well as health care professional behavioral change needed for successful implementation. Patient and family roles in the implementation process are also described.

A standardized approach to evaluation, the ‘Impact Evaluation Strategy’, has been designed to assess the feasibility and impact of implementing the SOPs. Both quantitative and qualitative approaches are being used in this process. The use of a triangulated High 5s evaluation strategy allows the project to address the impact evaluation in different ways, thus enhancing confidence in the resulting findings. If the results are positive, this should enhance confidence in the validity of the protocols themselves. The following are the pillars of the High 5s Impact Evaluation Strategy, as described in the Evaluation section of this article:

- SOP implementation experience evaluation,
- SOP-specific performance measures,
- event analysis and
- baseline and follow-up patient safety culture survey.

**Box 1.** Five High 5s priority risk areas:

1. Managing concentrated injectable medicines (concentrated injectables).
2. Assuring medication accuracy at transitions of care (medication reconciliation).
3. Performance of the correct procedure at the correct body sites (correct site surgery).
5. Improved hand hygiene to prevent health care-associated infections.
The pretesting of each SOP was undertaken over a 2-month period in each of the countries implementing the SOP to permit revisions to and adaptations of the SOPs and their related evaluation processes prior to full-scale implementation of the SOPs.

Each participating country has been asked to select one or more SOPs for implementation and identify a minimum of ten hospitals per SOP that will train staff in the SOP and measurement techniques. Each participating hospital may choose to participate in one or more SOPs (of those SOPs selected by the country’s LTA). Each hospital site is required to submit data throughout the implementation period. In addition, visits to selected participating hospitals are to be undertaken annually by the LTA to conduct interviews and observe the implementation of the SOP directly. De-identified data are submitted to the WHO Collaborating Centre for Patient Safety (Collaborating Centre) for comparative evaluation and sharing of lessons learned.

The High 5s project aims to answer two main questions: (i) is it feasible to implement standardization in health care within individual hospitals, among multiple hospitals within individual countries and across country boundaries? (ii) What is the impact of standardization on the safety problems that the project is targeting? The High 5s project combines process standardization and intensive evaluation of the feasibility and impact of implementing SOPs on a global scale.

**High 5s project innovations**

The two key areas in which the High 5s project is innovative are in its use of process standardization both in hospitals within a country and in multiple participating countries, and its carefully designed multi-pronged approach to evaluation.

**Standardization**

The first innovative concept of the High 5s project is standardization. Standardization is the process of developing, agreeing upon and implementing uniform technical specifications, criteria, methods, processes, designs or practices that can increase compatibility, interoperability, safety, repeatability and quality: Process standardization is the specification and communication of a process at a level of detail sufficient to permit consistent and verifiable implementation by different users at different times and in different settings. Standardization reduces variation: ‘The tendency for a process to fail is also diminished in relation to the consistency with which it is carried out; that is, the degree to which it is standardized’ [3]. ‘This enables shared learning, facilitates team work and improves efficiency in personnel interactions by establishing optimum conditions. It also allows for consistency during changes in scale and the transfer of processes between people or organizations, attributes which are essential for global interactions’ [4].

There are a number of different applications of standardization; all aim to reduce variability. In test theory, standardization refers to assessments conducted under exact, specified and repeatable conditions [5]. In supply chain management, standardization refers to approaches for increasing commonality of either part, process, product or procurement [6]. Standardization processes can emerge ‘de facto’ or be written by a standards organization (in a closed consensus process with restricted membership or in a full consensus process open to all interested parties), by a government or regulatory body, or by a corporation or trade association [7].

**Standardization in non-health care industries.** The most commonly referenced examples of standardization are among ‘high reliability’ organizations and in other safety critical industries. High reliability organizations have well-ingrained safety cultures and standardized management approaches toward risk. Standardization is also used in international trade and is elemental to the requirements to join the World Trade Organization (WTO) [4]. The International Customer Service Institute has developed The International Customer Service Standard, a global standard for customer service excellence, which provides guidelines on what customers expect in return for their loyalty [8].

**Standardization in health care.** Despite the use of standardization in other industries and its obvious potential to minimize accidents and catastrophic errors, standardized health care processes have been slow to gain traction in demonstrating their impact on the delivery of health care. Experience with standardization in non-health care industries is decades ahead of health care. There, standardized safety approaches acknowledge the prospect of failure from the beginning of a process to its end—proactively identifying, assessing and mitigating risk; establishing appropriate barriers to potential hazards and establishing monitoring systems with standardized measures and defined accountabilities. This contrasts with health care where successful outcomes are often assumed to be the baseline. Some authors suggest that standardization could enhance the functioning of the health care team and its ability to provide safe care. Yet, achieving process consistency while retaining the ability to recognize and accommodate variation in inputs (for example, the patient’s severity of illness, co-morbidities and personal preferences) is a major challenge to standardization in health care [3].

In health care, evidence shows that divergent patterns of care result in worse clinical outcomes and that removal of variance can reduce risk, inefficiencies and costs. Standardization can be seen as enhancing the portability of expertise, irrespective of the country, the facility or the health care worker implementing the protocol [9]. The standardization of hospital processes should enable trained health care workers to perform effectively in any facility in the world. An analogy can be made to the level of standardization in the airline industry. A pilot trained to fly an Airbus A320 can fly an Airbus A320 belonging to any airline company in any country. Failure to standardize care has also been linked to inadequate treatment [10]. One study states that standardization represents an effort to eliminate unnecessary complexity of care processes so that patients can receive ‘the correct treatment in a safer environment’ [10]. For example, the implementation of a standardized protocol for insulin therapy has been shown to improve both the efficiency and safety of glycemic control [11]. Such practices also allow for direct comparison and interpretation of results.
Box 2. Why hasn’t wide scale standardization ‘worked’ in health care the way it has in other high-risk fields?

- Despite a consensus among patient safety experts that it is failures of systems that cause most injuries, continuing belief by almost all health care consumers and providers that it is individual health care professionals who are the major cause of harm [12],
- Failure to link the lack of standardization with the occurrence of errors and patient harm,
- High reliance on human vigilance rather than investing in technological innovations that improve the safety of high-risk processes,
- Lack of appropriate training for those expected to follow standardized processes,
- Failure to establish the standardized process as the default position,
- Difficulties in and resistance to standardizing the patient experience,
- Complexity of health care processes,
- Independent mind-set of health care facilities and health care practitioners,
- The diversity and multi-contextual nature of health care [13],
- Human resistance to standardization within and across different cultures,
- The perception that standardization sets a minimum acceptable standard that may limit the pursuit of innovation,
- Global differences in operating procedures that make it difficult to standardize protocols, and the concern that if systems become too standardized, behavior becomes automatic and offers false reassurance that risks are being minimized [14].

Box 3. Examples of standardization and guidelines applications in public health

- Antibiotic susceptibility test developed by Clinical and Laboratory Standards Institutions to measure antibiotic sensitivity [15],
- HbA1c assay developed by the International Federation of Clinical Chemistry and Laboratory Medicine to measure blood glucose to guide diabetes care [16],
- International Organization for Standardization development of ISO standards for medical laboratories (ISO 15189) [17, 18],
- WHO TB diagnostic test sputum smear examination to detect pulmonary TB [19],
- WHO TB standardized process to addressing TB—Directly Observed Treatment Shortcourse [20],
- The WHO Antiretroviral Treatment Guidelines [21, 22], which recommend a range of standardized HIV diagnostics tests, as well as standardization of laboratory equipment and laboratory policies to simplify antiretroviral therapy,
- WHO Guidelines on Hand Hygiene in Health Care [23], which provide standardized evidence-based recommendations to reduce health care-associated infection,
- WHO standards for biological products, such as vaccines, therapeutic products, blood products and selected in vitro diagnostic devices [24],
- WHO standardized checklists for: vaccine administration [25–27],
- WHO standardized Checklists for Safe Surgery [28] and Trauma Care [29] and
- WHO International Classification for Patient Safety [30].

Box 2 presents the reasons why standardization has not ‘worked’ in health care the way it has in other high-risk fields.

Standardization in public health. For the past 30 years, the WHO and other public health institutions have been working on standardization and guidance regarding public health interventions. Some examples are presented in Box 3.

Standardization in patient safety. There are several examples of standardization in the area of patient safety informatics [31] and classification and definitions [12, 32, 33], as well as recent developments in standardizing interventions [34], protocols [10, 35], outcome measurement [36], data collection [13], patient handovers [37], medication use [38], patient monitoring [39] and medical facility design [40].

The key to optimizing patient safety is to design systems that prevent the inevitability of human error from reaching the patient [41]. Standardization takes the sharing of success stories and best practices to a new level—providing access to evidence-based standardized processes for all health care workers. Health care workers themselves have underscored the need for standardization in patient safety. For example, pharmacists in Queensland, Australia, noted the problems associated with frequent staff changes and lack of consistency between drug charting and prescribing systems. Standardization was linked to fewer prescribing omissions. In addition, standardized clinical measures supported improved training [42, 43].

The benefits of implementing standardized patient safety processes and evaluating that implementation and its impact are outlined in Box 4.

Evaluation

The second innovative concept in the design of the High 5s project is its Impact Evaluation Strategy, which provides for an integrated, multi-pronged approach to evaluation. The triangulated impact evaluation approach being used in this project is necessitated by the general difficulties in assessing the impact of preventive patient safety interventions, particularly where the targeted adverse events in some instances occur relatively infrequently under usual circumstances. This approach permits address of the impact measurement challenge from different perspectives, i.e. qualitative data collection regarding the SOP implementation.
Box 4. Benefits of standardization in health care

- Standardization provides policy and decision-makers and health care workers a means for comparing outcomes resulting from standardized process implementation within or among health care organizations;
- Standardization better enables investigators to compare data and to interpret the relevance and efficacy of an intervention;
- Through standardization health care workers are able to relate to one another in meaningful ways (including the standardization of terms used);
- As more hospitals begin to use the same standard protocols with the same data fields, the ability to analyze risk will be enhanced;
- Standardization of architectural design of hospital surgical suites, patient care units (specifically, patient rooms, treatment rooms, etc.) and other care settings reduces health care worker cognitive dissonance and thus the risk of human error [40].
- Standardization of technology and devices (e.g. IV pumps, hip prostheses) increases the likelihood of user familiarity with available technology and devices and thereby reduces the risk of human error.
- Building on the same solid foundation, rather than struggling to grasp the range of safety concepts that might otherwise arise in an unstructured environment;
- Standardization will allow health care workers to learn from each other's experiences (i.e. new ideas on how to address problems—what has worked, what has not worked and why).
- Standardization will be incorporated into the architectural design of hospital facilities, including its technology and equipment to provide the highest level of safety [40].
- Health care workers who become proficient in applying the elements of an SOP will be constantly building on the same solid foundation, rather than struggling to grasp the range of safety concepts that might otherwise exist in an unstructured environment.
- Standardization will allow health care workers to learn more easily from each other's experiences, i.e. new ideas on how to address problems—what has worked, what has not worked and why.

Experience, quantitative performance measurement results, event analysis and organization culture assessment.

A secure web-based Information Management system (IMS) has been developed to facilitate the storage, analysis, dissemination and exchange of High 5s project data. The system is designed around a secure web-based application called TWiki (version TWiki-4.2.4, Plugin API version 1.2). Several levels of security have been incorporated into the IMS to protect data submitted during the High 5s project. Three types of data are gathered through the IMS: (i) narrative descriptions of the implementation experience, (ii) aggregate counts of hospital-level data used to calculate performance measures and (iii) de-identified and aggregated data from event analyses conducted by participating hospitals. This design permits participants to come together on a global electronic learning platform.

The participating hospitals and LTAs are also using a standardized approach—the High 5s Data Quality Management Programme—to assess and ensure the quality of their data. To manage data quality, the participating hospitals, LTAs and the Collaborating Centre share the following responsibilities:

- The hospitals are responsible for re-collecting data through independent observation or 're-abstraction' to determine the 'data element agreement rate'.
- The LTAs are responsible for overseeing the hospitals' implementation of data quality activities, identifying and evaluating results from and among their participating hospitals, and reporting to the Collaborating Centre the extent and nature of unresolved discrepancies and any identified data collection problems.
- The Collaborating Centre is responsible for overseeing the LTAs' data quality activities, assessing the data quality information received from the LTAs, reporting to the High 5s Steering Group, the degree to which High 5s data are complete and reliable, and presenting for discussion its views on the implications of these findings with respect to achieving the data quality goals of the High 5s initiative.

Assessment of data quality focuses on the completeness and reliability of the data for each component of the Impact Evaluation Strategy, including the narrative data, performance measurement data and event analysis data. The standardization of data collection and reporting contributes to the following objectives:

- Ensure comparability of performance and quality measures across health care organizations,
- Improve health care quality [44],
- Share information/data across health care organizations and increase the usefulness, integration and exchange of data [45],
- Improve efficiency of performance measurement over time [46] and
- Facilitate coordination and cooperation among all parties in performance measurement and health care quality improvement [46].

Components of the High 5s Impact Evaluation Strategy. (i) SOP implementation experience evaluation aims to determine whether a SOP can be implemented as it was designed in diverse hospital settings, what barriers were encountered and how those barriers were overcome. In order to evaluate the fidelity and portability of SOP implementation in multi-country settings, self-reported narrative data are being collected at the beginning of the High 5s project, at quarterly intervals throughout the project and at the end of the fifth or final year of implementation. Related LTA interview data are to be collected at selected hospitals annually.
(ii) SOP-specific performance measures have been designed to assess how effectively participants are using the SOP and to detect any reductions in patient safety-related problems by means of quantitative assessment. The standardized performance measures include SOP process measures and outcome measures. Standardization of SOP performance measures ensures data reliability and comparability. Performance measurement results are being presented in various formats in the High 5s IMS to support LTA and hospital needs and enable individual hospitals and countries to benchmark their data.

(iii) Event analysis is undertaken following an identified patient safety incident to determine whether there is a relationship to the SOP and, if so, whether factors in the design and/or implementation of the SOP contributed to the occurrence of that incident. The event analysis process is designed to yield important information as to the functioning of the SOP as well as how to improve the SOP and its implementation. In order to effectively identify events for analysis beyond those that are independently reported, participating hospitals are expected to use the specially designed methods, including chart review for specific prompts (where applicable). Minimum data set forms and checklists have been created to ensure thorough and credible event analysis and methodical de-identified reporting of specific SOP-related events. Where appropriate, aggregate or cluster event analysis processes may be applied where certain events appear to have common characteristics, in order to identify patterns of performance and enhance the effectiveness of actions for improvement.

Culture survey

The ‘Hospital Survey on Patient Safety Culture’ was developed by Westat under contract with the Agency for Healthcare Research and Quality (AHRQ) [47]. The survey and accompanying toolkit materials are available from the AHRQ website www.ahrq.gov/qual/hospculture. The purpose of conducting these surveys in participating hospitals is to determine whether there are any correlations between organization safety culture characteristics and the organization’s success or failure in effectively implementing SOPs.

Conclusion

The High 5s project seeks to determine whether individual hospitals, hospitals within a country, sharing the same health care delivery system, and hospitals in different countries having different languages and cultures are able to implement agreed-upon safety protocols in standardized ways. This requires careful and clear delineation of the protocols and an expectation of hospital adherence to the specified steps in the SOP and uniform application of the evaluation tools.

The High 5s project seeks to optimize the likelihood of success through realization of the following project characteristics:

- Collaboration and good will: the concepts of standardization applied throughout the project have consistently been based on group consensus among the participating countries,
- Achievement of country ministerial commitments to the project,
- Shared global vision coupled with local ownership,
- Provision of an evidence base for all steps in the SOPs and the Impact Evaluation Strategy,
- Project design that includes continuous improvement platforms and learning communities, which permit necessary local adaptations that do not change any SOP but modify the way it is implemented in manners acceptable to the hospitals and LTAs in the individual countries, (NB: Hospital or LTA modification of an SOP would violate the principle of standardization and compromise the comparability of data among participating hospitals. However, adaptation to local situations is seen as a necessary part of standardization according to Juran’s Quality Control Handbook [48,]),
- Acknowledgement that it is appropriate to adapt care to the individual needs of the patient but not to the individual preferences of any provider,
- Emphasis on the role of the health care team rather than individuals,
- Embodiment of the principles of patient and family-centered care by actively involving the patient and family in the process,
- Harnessing shifts in priorities in some countries where better health care value for money expended is now demanded, and patients are becoming more active participants in their own care and
- Acknowledgement that health care quality and patient safety issues are increasingly high-profile on national and international agendas.

Whether implementation of SOPs across hospitals within a country or in hospitals in multiple countries is feasible is the first question to be answered by the High 5s project. If the answer to this question is yes, the second question is whether successful implementation of these SOPs results in measurable positive impacts on patient safety that are persuasive. Much new information is being gleaned about the sociopolitical challenges of attempting to standardize care across the boundaries of multiple countries, as well as among hospitals in the same health care system within a country. In essence, this is just the beginning of what can be seen as an exercise in behavior management in quality improvement which asks whether health care workers can adapt their behaviors and environments to standardize care processes in widely varying hospital settings.

Acknowledgements

This work was carried out as part of the High 5s project set up by the World Health Organization in 2007 and coordinated globally by the WHO Collaborating Centre for Patient Safety, The Joint Commission in the United States of America, with the participation of the following Lead Technical Agencies including: Australian Commission on Safety and Quality in Healthcare.
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Funding

This work is being supported by the US Agency for Healthcare Research and Quality (grant/contract number HHSA290-2012-00006C).


