The High 5s Project
Interim Report
December 2013
Acknowledgements

This Interim Report 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 Health Care, Australia; Canadian Patient Safety Institute, Canada and the Institute for Safe Medication Practices Canada, Canada; National Authority for Health-HAS, France, with CEPRAL (Coordination pour L’Evaluation des pratiques professionnelles en santé en Rhône-Alpes), France, OMEDIT Aquitaine (Observatoire du Medicament, Dispositifs medicaux et Innovation Therapeutique), France (from 2012-2015) and EVALOR (EVALuation LORraine), France (from 2009-2011); German Agency for Quality in Medicine, Germany and the German Coalition for Patient Safety, Germany; CBO Dutch Institute for Healthcare Improvement, the Netherlands; Singapore Ministry of Health, Singapore; Trinidad and Tobago Ministry of Health, Trinidad & Tobago; Former National Patient Safety Agency, United Kingdom of Great Britain and Northern Ireland; and the Agency for Healthcare Research and Quality, USA.

This work is a part of the High 5s Project which has been supported by the Agency for Healthcare Research and Quality, USA, WHO, and the Commonwealth Fund, USA.
This report is dedicated in memoriam to Jerod M. Loeb, PhD, friend, colleague, master of performance measurement and quality improvement. The unique feature of the work presented here is its multidimensional system of evaluation, for which Jerod was the guiding force. His intellect, integrity and joie de vivre brought out the best in each of us.
Contents

Executive Summary .............................................................................................................................................................................. 9

1. The purpose and objectives of the High 5s Project .......................................................................................................................... 14

2. The history, concepts, and overall strategy of the High 5s Project .............................................................................................. 16
   1. Historical background ........................................................................................................................................................................ 16
   2. Scope of the High 5s Project .............................................................................................................................................................. 17
   3. Unique features of the High 5s Project ............................................................................................................................................ 18
      3.1. Standardization ............................................................................................................................................................................. 18
      3.2. Evaluation .................................................................................................................................................................................... 19

3. The High 5s Project governance, structures, participating LTAs and hospitals, description of the work of the Steering Group and its several committees .................................................................................................................. 22
   1. Overall governance ............................................................................................................................................................................. 22
   2. Lead Technical Agency governance .............................................................................................................................................. 22
   3. Lead Technical Agency structure .................................................................................................................................................. 23
   4. Participating hospitals ................................................................................................................................................................. 25
   5. High 5s Steering Group ................................................................................................................................................................. 30
   6. High 5s Project Committees .......................................................................................................................................................... 30

4. The design of the Project and its protocols and evaluation framework, including an overview of methodologies, instruments and processes ............................................................................................................................................. 34
   1. Design of the Project ......................................................................................................................................................................... 34
   2. Standard Operating Protocols (SOPs) ............................................................................................................................................. 34
   3. High 5s evaluation framework ....................................................................................................................................................... 34
      3.1. SOP implementation experience ............................................................................................................................................ 35
      3.2. SOP-specific performance measures ....................................................................................................................................... 35
      3.3. Event analysis .............................................................................................................................................................................. 38
      3.4. Patient safety culture survey .................................................................................................................................................... 40
5. Qualitative and quantitative interim findings ................................................................. 44
   1. Summary of culture survey findings ........................................................................ 44
      1.1. Culture surveys in participating Member States ............................................ 45
   2. Context survey of Medication Reconciliation ......................................................... 48
      2.1. Medication Reconciliation context survey findings in Member States .......... 49
   3. Context survey of Correct Site Surgery ................................................................. 50
   4. Interim findings .......................................................................................................... 51
      4.1. Summary of qualitative findings .................................................................... 51
      4.2. Member State implementation experiences and qualitative findings .......... 56
      4.3 Summary of event analysis findings ................................................................ 65
      4.4. Summary of quantitative findings .................................................................. 67
      4.5. Member State quantitative and event analysis findings .................................. 80

6. Interim outcomes ........................................................................................................... 90
   1. Feasibility .................................................................................................................... 90
      1.1. Overall issues .................................................................................................... 90
      1.2. Summary of in-country experiences ............................................................. 92
   2. Impact ......................................................................................................................... 99
      2.1. Overall issues .................................................................................................... 99
      2.2. Summary of Member State experiences ....................................................... 101

7. Developing networks and awareness raising for the High 5s Project ............................... 110
   1. Developing global networks and awareness raising .............................................. 110
   2. National networks and awareness raising ............................................................ 112

8. High 5s Steering Group meetings and international hospital meeting .............................. 116
   1. Steering Group meetings ....................................................................................... 116
   2. International hospital meeting ............................................................................... 116

9. Next steps ..................................................................................................................... 118
   1. Overview ............................................................................................................... 118
   2. The cross High 5s Medication Reconciliation map .............................................. 118
   3. Next steps by LTAs ............................................................................................... 118

Annexes ........................................................................................................................ 125
**Acronyms**

<table>
<thead>
<tr>
<th>Acronym</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>ACS</td>
<td>American College of Surgeons</td>
</tr>
<tr>
<td>ADE</td>
<td>Adverse Drug Event</td>
</tr>
<tr>
<td>ACSQHC</td>
<td>Australian Commission on Safety and Quality in Health Care</td>
</tr>
<tr>
<td>AHRQ</td>
<td>Agency for Healthcare Research &amp; Quality</td>
</tr>
<tr>
<td>APS</td>
<td>German Coalition for Patient Safety</td>
</tr>
<tr>
<td>AZQ / AQuMed</td>
<td>German Agency for Quality in Medicine</td>
</tr>
<tr>
<td>CBO</td>
<td>Dutch Institute for healthcare Improvement (a TNO company)</td>
</tr>
<tr>
<td>CC</td>
<td>WHO Collaborating Centre for Patient Safety</td>
</tr>
<tr>
<td>CEPPRAL</td>
<td>Qualité et Sécurité en santé, France</td>
</tr>
<tr>
<td>CI</td>
<td>Concentrated Injectables</td>
</tr>
<tr>
<td>CPSI</td>
<td>Canadian Patient Safety Institute</td>
</tr>
<tr>
<td>CI</td>
<td>Concentrated Injectables</td>
</tr>
<tr>
<td>CSHP</td>
<td>Canadian Society of Hospital Pharmacists</td>
</tr>
<tr>
<td>CSS</td>
<td>Correct Site Surgery</td>
</tr>
<tr>
<td>BPMH</td>
<td>Best Possible Medication History</td>
</tr>
<tr>
<td>EA</td>
<td>Event Analysis</td>
</tr>
<tr>
<td>ED</td>
<td>Emergency Department</td>
</tr>
<tr>
<td>EHR</td>
<td>Electronic Health Record</td>
</tr>
<tr>
<td>EMGO</td>
<td>Institute for Health and Care Research, The Netherlands</td>
</tr>
<tr>
<td>EMR</td>
<td>Electronic Medical Record</td>
</tr>
<tr>
<td>EVALOR</td>
<td>French EVAuation en LORraine</td>
</tr>
<tr>
<td>FMEA</td>
<td>Failure Mode and Effects Analysis</td>
</tr>
<tr>
<td>HAS</td>
<td>French National Authority for Health</td>
</tr>
<tr>
<td>HCO</td>
<td>Healthcare Organization</td>
</tr>
<tr>
<td>HRO</td>
<td>High Reliability Organization</td>
</tr>
<tr>
<td>IIPs</td>
<td>Institute for Patient Safety</td>
</tr>
<tr>
<td>IMS</td>
<td>Information Management System</td>
</tr>
<tr>
<td>ISMP Canada</td>
<td>Institute for Safe Medication Practices Canada</td>
</tr>
<tr>
<td>JCI</td>
<td>Joint Commission International USA</td>
</tr>
<tr>
<td>LTA</td>
<td>Lead Technical Agency</td>
</tr>
<tr>
<td>MDS</td>
<td>Event Analysis – Minimum Data Set</td>
</tr>
<tr>
<td>Med Rec</td>
<td>Medication Reconciliation</td>
</tr>
<tr>
<td>MoH</td>
<td>Ministry of Health</td>
</tr>
<tr>
<td>MMP</td>
<td>Medication Management Plan</td>
</tr>
<tr>
<td>MMS</td>
<td>Medicare &amp; Medicaid Services</td>
</tr>
<tr>
<td>NIAZ</td>
<td>The Netherlands Institute for Accreditation in Healthcare</td>
</tr>
<tr>
<td>NIVEL</td>
<td>The Netherlands Institute for Health Services Research</td>
</tr>
<tr>
<td>OR/OT</td>
<td>Operating Room/ Operating Theatre</td>
</tr>
<tr>
<td>PCEHR</td>
<td>Personally Controlled Electronic Health Record</td>
</tr>
<tr>
<td>RHAs</td>
<td>Trinidad &amp; Tobago Regional Health Authorities</td>
</tr>
<tr>
<td>ROP</td>
<td>Required Organizational Practices</td>
</tr>
<tr>
<td>SOP</td>
<td>Standard Operating Protocol</td>
</tr>
<tr>
<td>WHO</td>
<td>World Health Organization</td>
</tr>
</tbody>
</table>
Experience with standardization in non-health care industries clearly shows that standardized processes lead to improved safety and service excellence. In health care, the standardization of hospital processes may enable trained health-care providers to perform more consistently and reduce latent tendencies for processes to fail, that is, to reduce errors.

The High 5s Project (the Project) was launched in 2007 to examine the concept of standardization in clinical processes by implementing targeted patient safety improvement strategies. The High 5s name derives from the Project’s original intent to significantly reduce the frequency of 5 challenging patient safety problems in 5 countries over 5 years.

A key objective was to develop and assess Standard Operating Protocols (SOPs) in a range of health-care systems and cultures, and to provide evidence of the benefits of standardization in health care as one of the means to effect safety and excellence in performance. To this end, the Project initiated the development of SOPs for certain priority patient safety problems, undertook a comprehensive evaluation, and then refined the SOPs and its measurement strategies for later use by interested countries around the world.

The specific goals of the Project were to determine the feasibility of implementing SOPs in hospitals in multiple countries, and to measure the impact on patient safety. Standardization on such a large scale is challenging, and to be globally relevant, it needs to be applicable in different cultures and health-care environments. If this goal proves to be feasible, it will create leverage to spread both the concept of standardization and the SOPs themselves across the broader health care community.

To achieve these goals, a group of WHO Member States – Australia, Canada, France, Germany, the Netherlands, Singapore, Trinidad & Tobago, and the USA—the World Health Organization (WHO) Patient Safety Programme and the WHO Patient Safety Collaborating Centre (The Joint Commission), have joined forces to develop and implement SOPs that address recognized patient safety challenges.

Two unique features of the High 5s Project were the use of standardization across multi-country settings, and a carefully-designed, multi-pronged approach to evaluation. The major components of the High 5s Project work included:

- developing and implementing Standard Operating Protocols;
- developing an Impact Evaluation Strategy;
- collecting, analyzing and reporting data;
- learning from data through a Collaborative Learning Community;
- disseminating knowledge globally.

Five SOPs were initially drafted but due to resource constraints, only two were fully developed and implemented. These were the ‘Medication Accuracy at Transitions in Care’ (Med Rec) and ‘Correct Procedure at the Correct Body Site’ (Correct Site Surgery) SOPs. Concurrent performance measurement of these SOPs started in 2010 and will continue until 2014.

Governance and Lead Technical Agencies

The Project’s activities were planned and implemented by a Steering Group and five technical subcommittees, composed of representatives from the participating institutions and countries. Each Member State nominated a Lead Technical Agency (LTA) to coordinate and support the implementation of the SOPs in hospitals, and to monitor their impact using evaluation tools developed by the technical
subcommittees. Each LTA was responsible for coordinating the Project in its country, including hospital training, support for evaluation and event analysis and hospital data submission into a secure web-based Information Management system (IMS) developed by the Collaborating Centre to be used for data collection, analysis and reporting.

Design of the High 5s Project

An early challenge for the Project was to apply established best practices and evidence based interventions in quality improvement and patient safety to the development of standardized processes and tools. Steering Group members and other experts provided input to the process designs, which included development of a comprehensive system of evaluation that made possible the production of comparative results locally, nationally and internationally.

Each SOP summarizes a safety problem, proposes a solution, presents the evidence for the solution, identifies potential barriers to adoption, and delineates potential unintended consequences of the solution. Through step-by-step instructions and tools for implementing a defined patient care process, each SOP can be used by multiple users in a consistent and measurable way. The SOPs are intended to achieve systems change and healthcare professionals’ behavioral change by applying standardized, evidence-based quality improvement methods.

With regard to evaluation, the High 5s Project set out to answer two key questions.

1. Is it feasible to implement standardized processes in health care within individual hospitals, among multiple hospitals within individual Member States, and across country boundaries?
2. What is the impact of standardization on the safety problems that the project targets?

The basis for answering these questions was the ‘Impact Evaluation Strategy’ designed to assess the feasibility and impact of implementing the SOPs using both quantitative and qualitative approaches. This strategy applied evaluation approaches that allowed impact of the interventions to be measured from different perspectives, including:

1. qualitative evaluation of the SOP implementation experiences;
2. SOP-specific performance measures;
3. event analysis to identify and investigate occurrences that may represent SOP failures; and
4. hospital culture surveys.

An SOP implementation evaluation process was used to determine if the SOPs could be implemented as designed in diverse hospital settings, to identify barriers to implementation, and to identify ways to overcome these barriers. Self-reported narrative and interview data were (and continue to be) collected from the hospitals for a deeper understanding of the feasibility and impact of SOP implementation in multi-country settings and environments.

The second component of the evaluation strategy was performance measurement. Data, normally collected on a monthly basis, were used to assess the degree to which the SOPs were followed by the participating hospitals.

The third component employed event analysis. Each participating hospital was directed to actively seek and investigate a pre-determined set of patient safety problems (events) that should have been prevented by the SOP. A systematic analysis of the facts and contributing factors of a patient safety incident, and whether it was linked to the design and/or implementation of the SOP took place.

The fourth and complementary area of action was the voluntary administration of a patient safety culture survey in hospitals. These surveys were done to provide insight into the patient safety culture of hospitals participating in the High 5s Project and to sensitize frontline staff and hospital management about staff members’ perception of the hospital’s patient safety culture.

Interim Findings

All country-specific sections in this report reflect the status of 2nd quarter 2013.

Patient safety culture surveys

Overall, culture survey results showed the highest scores on teamwork issues within units (70% positive), and the lowest scores on handoffs and transitions (34% positive). The percentage of respondents giving the hospital’s work area/unit a patient safety grade of an ‘A-Excellent’ or ‘B-Very Good’ ranged from 70% to 21%. Percent of hospitals, by country, reporting one or more
events ranged from 78% to 37%. Culture survey results were limited by inconsistent statistical selection of samples of hospitals, variation in number of respondents per country, variable administration of the surveys, and variable quality of submitted data.

**Context surveys**
It was considered that the ‘context surveys’ would be useful to understand what external factors were influencing the uptake of the SOPs in the different Member States.

**Qualitative findings**
Hospitals shared their implementation experiences through quarterly and then six-monthly reports. For purposes of analyzing and reporting evaluation data, the hospitals were asked to determine whether implementation of a SOP was ‘full’—when all required components of the SOP were in place across all eligible locations and patient populations within the hospital—or ‘partial’. For the Correct Site Surgery SOP implementation, challenges related to assembling a representative group to oversee implementation, lack of resources, resistance to change, poor communication or lack of leadership were identified. Identification of areas of potential breakdown through a risk-assessment allowed them to implement controls, warnings or protections to minimize identified problem areas. Much was learned about SOP implementation from the initial pilot testing which most hospitals did before starting full SOP implementation. During piloting, the hospitals were able to identify barriers and correct them prior to full implementation through increased communication, enlisting staff and leadership support, and providing additional training. Further, many hospitals reported that they were not using the prescribed High 5s data quality methodology. However, most hospitals were performing some form of data quality monitoring, conducting audits, soliciting information from staff, engaging in project oversight meetings and identifying opportunities for improvement.

Hospitals’ implementation experiences for the Medication Reconciliation SOP emphasized lack of resources and challenges in assembling an oversight group. Most hospitals did not complete a formal risk assessment because of lack of resources or because it was considered a low priority. Those that did conduct risk assessment reported that it was beneficial in helping to identify potential areas for process breakdown. Although some hospitals reported that the SOP implementation was an extension of their existing medication reconciliation process, many barriers to implementation were reported including limited resources, data collection burden, insufficient communication, and resistance to change. Most responding hospitals indicated technical challenges and technical issues with the SOP performance measures.

A detailed description of implementation experiences for both SOPs in Member States is presented in the main body of the Interim Report. Overall, they point to leadership and stakeholder commitment and support as well as an organizational culture of safety, adequate resources, team cohesion, and ongoing training to be among the key factors for successful SOP implementation. The principle barrier was the burden of data collection, although hospitals themselves appreciated the value of measurement as a means to successful improvement. Another major challenge to implementation was resistance to change by providers and leaders.

**Quantitative findings**
Hospital performance measurement data were collected to provide a profile of each SOP implementation in Member States. Details are presented in section 5.4 of this report.

**Interim Conclusions**

**Feasibility**
In this context, feasibility refers to the degree to which an SOP can be implemented as it was originally defined, in a standardized way across hospitals within a country and in multiple countries. Over the course of the High 5s Project it became clear that some aspects of the SOPs were easier to implement than others. When participants encountered issues with the implementation of an SOP, they were invited to submit requests to adapt or revise components of the SOP. Overall, relatively few adaptations and revisions were required, suggesting that a high degree of standardization of health care processes was seen as feasible.

**Impact**
The SOPs had a significant impact in hospitals in all participating Member States. As a result of implementation of the SOP, certain process steps were introduced or improved in the Member States which were not part of everyday care previously. For example, site-marking was introduced in French
hospitals. In Singapore, the improvement in clinical practice and staff cooperation was reflected in the performance measure data, which showed 98% compliance with complete preoperative verification and Time Outs, and improvement in surgical site-marking from 40% to 97%. Safety components are now built into surgical work flows and a culture of shared ideas and learning among hospitals has been promoted.

In the case of the Med Rec SOP, the results were encouraging in that some hospitals managed to reduce medication inaccuracies substantially. Implementation of the SOP had an impact in improving the quality of the medication histories obtained, resolving discrepancies, and other related patient care activities.

In the case of the Correct Site Surgery SOP, the qualitative evaluation showed positive effects in stimulating organizational safety cultures, improving communication and teamwork in the OR and beyond, optimizing surgical care, improving the quality of patient records and demonstrating that hospital processes can be re-designed to provide better patient care. Because of the infrequency of incorrect surgeries, it is not possible at this point to demonstrate a measurable decline in the number of these events. However, implementing this SOP has resulted in an increase in the number of identified and resolved discrepancies in the surgical preparation process, each of which carries a risk of incorrect surgery.

Developing networks

A major goal of the High 5s Project was to build national and global networks. The initiative’s early focus concentrated on building government and ministerial support for implementing standardised patient safety solutions by encouraging Member States’ expert institutions to participate in the Project. In later stages, the design of all steps in the SOP development and the implementation and evaluation plan included engagement of networks of hospitals. The networks and the learning communities they comprised have been successful in raising awareness of the SOPs and the benefits they bring to institutions and patients. A good networking achievement was the participation of 31 hospitals at the ‘International Hospital Meeting’ at WHO Headquarters in October 2012, to exchange knowledge and implementation experiences and further strengthen and motivate hospitals’ commitment.

Another example of an effective networking tool is the interactive online map developed by the Institute for Safe Medication Practices (ISMP) Canada, the Med Rec SOP lead, to profile High 5s Project achievements in the participating Member States which have implemented the Med Rec SOP. The map includes Med Rec implementation site information and highlights High 5s Med Rec implementation publications and national supports such as accreditation standards. The anticipated spread of the Med Rec SOP will be reflected in this map.

Next steps

There is growing consensus that implementation and evaluation of the SOPs is progressing successfully in participating hospitals. Next steps for the LTAs involve the active spread of the SOPs and implementation experiences to more hospitals within each Member State and beyond. Plans to disseminate the SOPs and share the evaluation methodologies with more WHO Member States are also being developed. It is expected that at the last Steering Group meetings in 2014, discussions will focus on how to expand the networks to the developing world.
1. The purpose and objectives of the High 5s Project
The High 5s Project is a collaboration among a group of WHO Member States, the World Health Organization (WHO) Patient Safety Programme and the WHO Patient Safety Collaborating Centre - The Joint Commission to achieve measurable and sustainable reductions in challenging patient safety problems through the implementation of standardized operating protocols.

The basic assumption being tested in the High 5s Project is that process standardization, with minimal variation, can improve patient safety across national boundaries. This is being evaluated by assessing the feasibility and impact of implementing standardized approaches to specific patient safety problems across multiple WHO Member States and cultures.

Achieving process consistency, while retaining the ability to recognize and accommodate variation in the input (for example, the patient’s severity of illness, co-morbidities), is one of the major challenges to standardization in health care. Process variation to meet individual patient needs is essential in care delivery. But variation to meet the preferences of health-care organizations or individual practitioners need not be. Standardization supersedes “best practice” when it comes to safety. To test this, the High 5s Project has taken this thesis to another level by standardizing certain processes within multiple organizations in different WHO Member States around the world.
The history, concepts and overall strategy of the High 5s Project
The Project is a global health sector collaboration reflecting the efforts of stakeholders in patient safety from the government agencies of Australia, Canada, France, Germany, the Netherlands, Singapore, Trinidad & Tobago and the USA, as well as research and patient safety organizations from these Member States, and other international organizations.

Working together, the High 5s partners achieve objectives that no single organization or patient safety agency could achieve individually. These include:

- accelerating the development and implementation of standardized patient safety solutions and addressing risk areas having a high burden of morbidity and mortality;
- testing them across different settings and country cultures;
- introducing robust tools for implementing and evaluating the solutions; and
- generating learning and sharing knowledge globally.

In action, the High 5s Project draws on the specific strengths of its current and former partners. Since the Project’s initiation the following types of organizations have contributed to its activities:

- Lead Technical Agencies and technical institutes from participating Member States;
- WHO Collaborating Centre for Patient Safety designated as The Joint Commission and the Joint Commission International;
- WHO.

The Member States involved in the initiation of the High 5s Project were Australia, Canada, Germany, the Netherlands, New Zealand, the United Kingdom of Great Britain and Northern Ireland, and the United States of America. France and Singapore joined the High 5s Project in 2008 and 2009 respectively. In 2010, Trinidad and Tobago joined as well. Several technical institutes/agencies from these countries have contributed to the work of the High 5s Project. These include:

- The Canadian Patient Safety Institute (CPSI);
- The Institute for Safe Medication Practices Canada, Canada (ISMP Canada);
- The former National Patient Safety Agency, UK.

The Project has been supported by the Agency for Healthcare Research and Quality, WHO, and the Commonwealth Fund. It is being coordinated by the WHO Collaborating Centre for Patient Safety- The Joint Commission and JCI (hereafter the Collaborating Centre).

1. Historical background

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 efforts by Member States to improve the safety of care. Subsequently, WHO initiated efforts to address patient safety and established the World Alliance for Patient Safety in 2004, renamed as the Patient Safety Programme in 2009.

At the 2005 annual Commonwealth Fund International Symposium on Health Care Policy, the need for developing and implementing standardized patient safety processes to reduce the magnitude of adverse events was discussed. The High 5s Project emerged as a result of:

- a shift in priorities to address the growing problems of unsafe care;
• an increasing recognition of the importance of patient safety process improvement as the means to safer care;
• a desire to see if standardized approaches might be the key to improving and maintaining safety across different settings and cultures;
• a growing interest among WHO, The Joint Commission, and the Ministers of Health of Australia, Canada, Germany, the Netherlands, the United Kingdom and the United States of America to develop, implement and evaluate standardized approaches for making care safer.

The High 5s name derives from the Project’s original intent to significantly reduce the frequency of 5 challenging patient safety problems in 5 Member States over 5 years.

At the 2006 annual Commonwealth Fund Symposium, Ministers of Health of Canada, Germany, the Netherlands, New Zealand, the United Kingdom and the United States of America signed formal letters of commitment to participate in and support the High 5s Project together with WHO, the Commonwealth Fund, and the Collaborating Centre. The Project began to take shape in late 2006 with the nomination of representatives from the Lead Technical Agencies (LTAs) of participating Member States who subsequently constituted the nucleus of the High 5s Steering Group.

Lead Technical Agencies

Each participating Member State nominated a LTA which subsequently coordinated and supported the implementation of Standard Operating Protocols (SOPs) at hospitals and monitored their impact through applying evaluation tools developed by the High 5s Project Steering Group members. LTAs underwent intense initial training and were 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 in their country’s health-care system.

Each LTA was responsible for identifying at least 10 hospitals per SOP it decided to implement; providing hospital training in the use of the SOPs and Project evaluation process and tools; and collecting data from participating hospitals and submitting it to the Collaborating Centre (CC) for analysis and tracking. Following completion of LTA and hospital training, the SOPs began to be implemented in some participating hospitals in the autumn of 2009. Data collection began in 2010 and will finish by September of 2014.

2. Scope of the High 5s Project

The mission of the High 5s 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.

The major components of the High 5s work included:

• developing and implementing SOPs;
• developing an Impact Evaluation Strategy;
• collecting, reporting, and analyzing data;
• developing a Collaborative Learning Community;
• disseminating knowledge learned globally.

The Project was designed to generate learning that would permit the continuous refinement and improvement of the SOPs within selected hospitals of participating Member States, as well as assessment of the feasibility and impact of implementing standardized approaches to specific patient safety problems across multiple Member States and cultures. The Project has built on existing structures in the participating Member States. SOP implementation was expected to provide valuable lessons and knowledge to support the advancement of patient safety around the world.

Five SOPs and associated evaluation instruments were developed between 2007 and 2009 to address the following challenges:

1. Medication Accuracy at Transitions in Care;
2. Correct Procedure at the Correct Body Site;
3. Use of Concentrated Injectable Medicines;
4. Communication During Patient Care Handovers;

The first two SOPs, ‘Medication Accuracy at Transitions in Care (Medication Reconciliation)’ and ‘Correct Procedure at the Correct Body Site (Correct Site Surgery)’ have been implemented by the participating Member States. Implementation of the third SOP ‘Use of Concentrated Injectable Medicines’ was initiated in the UK, but testing ceased in 2010 when this Member State disengaged from the High 5s Project. Planning towards
The implementation of this SOP has been re-initiated in 2013 by the Dutch Lead Technical Agency. Extensive investigation of the potential to implement a standardized approach to ‘Communication During Patient Care Handovers’ found that this SOP was heavily influenced by cultural and environmental issues that were not measurable and easy to standardize. Therefore, work on this SOP was abandoned in 2010. The ‘Health care-associated infections’ SOP was withdrawn from further development and testing because parallel work towards standardizing procedures to address health care-associated infections was taking place independently by WHO and other global organizations.

Table 1: SOP implementation by WHO Member States between 2009-2014

<table>
<thead>
<tr>
<th>Member State</th>
<th>CSS SOP</th>
<th>Med Rec SOP</th>
<th>Conc. Inject. SOP</th>
</tr>
</thead>
<tbody>
<tr>
<td>Australia</td>
<td></td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>Germany</td>
<td>✓</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>France</td>
<td>✓</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>The Netherlands</td>
<td>✓</td>
<td>✓</td>
<td>(initiated in 2013)</td>
</tr>
<tr>
<td>Singapore</td>
<td>✓</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Trinidad &amp; Tobago</td>
<td>✓</td>
<td></td>
<td></td>
</tr>
<tr>
<td>U.K.</td>
<td>✓ (stopped in 2010)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>U.S.A.</td>
<td>✓</td>
<td>✓ (initiated in 2013)</td>
<td></td>
</tr>
</tbody>
</table>

3. Unique features of the High 5s Project

Two unique features of the High 5s Project are the use of standardization across multi-country settings, and a carefully-designed, multi-pronged approach to evaluation.

3.1. Standardization

Standardization is the process of developing, agreeing upon, and implementing technical or uniform 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.’ This enables shared learning, facilitates multi-disciplinary teamwork and improves efficiency in 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.

Standardization in health care

The most commonly referenced examples of standardization are by high reliability organizations (HROs) in industries such as nuclear energy or aviation which have well ingrained organizational safety cultures and standardized management approaches toward risk. These HROs serve as an example for improving safety by focusing on standardizing the systems involved. Experience with standardization in these industries is decades ahead of health care. Their standardized safety approaches acknowledge the prospect of failure from the start of the process, and efforts are made to build in safety from the beginning to the end. This contrasts with health care, where successful outcomes are often assumed to be the baseline. Recent efforts to standardize health-care processes have been slow to demonstrate their impact on the delivery of care processes.

Standardization in patient safety

There are examples of standardization in the area of patient safety informatics, classification and definitions, and some recent development in standardizing interventions, protocols, outcome measurement, data collection.
patient handovers\textsuperscript{11}, medication use\textsuperscript{12}, and patient monitoring\textsuperscript{13}.

The key to optimizing patient safety is to design systems that prevent the inevitability of human error from actually reaching and harming the patient\textsuperscript{14}. Standardization takes the sharing of success stories and best practices to a new level – allowing sharing of new approaches among health-care workers. Health-care providers themselves have underscored the need for standardization in patient safety.

The benefits of implementing standardized patient safety processes and evaluating that implementation and its impact are outlined in Box 1.

\section*{Box 1: Benefits of implementing and evaluating standardized protocols}

- Standardization provides policy and decision-makers, and health-care workers a means to compare actions and outcomes implemented within or between groups.
- Standardization better enables investigators to compare data and to interpret the relevance and efficacy of an intervention.
- Through standardization, more health-care workers will be able to relate to one another in meaningful ways (including the standardization of terms used).
- As more and more hospitals begin to use the same protocols with the same data fields, the ability to analyze risk will be enhanced.
- Health-care workers who become proficient with SOPs will be constantly building on a 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 and why).

\section*{3.2. Evaluation}

The second unique feature of the High 5s Project relates to its integrated, multi-pronged approach to evaluation. The triangulated impact evaluation approach being used in this Project was necessary because of the difficulties in assessing the impact of preventive patient safety interventions, particularly where the targeted adverse event can occur relatively infrequently, such as in the case of wrong-site surgery. The High 5s Project evaluation approach addresses the impact measurement challenge from different perspectives, including qualitative data collection regarding the SOP implementation experiences, quantitative performance measurement results, event analysis, and organization culture assessment. These methods were used to assess the feasibility and impact of implementing standardized patient safety protocols.

A secure web-based Information Management System (IMS) was developed to facilitate the storage, analysis, dissemination and exchange of data. The system was designed around a secure web-based application called TWiki (version TWiki-4.2.4, Plugin API version 1.2). Several levels of security were incorporated into the IMS to protect data submitted. Three types of data were gathered through the IMS:

1) narrative descriptions of the implementation experience;
2) aggregate counts of hospital-level data used to calculate performance measure results; and
3) 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.

Participating hospitals and LTAs were also asked to use a standardized approach - the High 5s Data Quality Management Programme - to assess and ensure the quality of their data. To manage data quality, hospitals, LTAs and the CC assumed the following responsibilities:

- the hospitals were responsible for re-collecting data through independent observation or ‘re-abstraction’ to determine the “data element agreement rate” or to identify inconsistencies among the different components of the evaluation process.
the LTAs were responsible for overseeing the hospitals’ implementation of data quality activities, identifying and evaluating results from and among their participating hospitals, and reporting to the CC “the extent and nature of unresolved discrepancies and any identified data collection problems”;

the CC was responsible for overseeing the LTAs’ data quality activities. Assessing the data quality information received from the LTAs, reporting the reliability and completeness of submitted data to the Evaluation Committee and presenting its views on the implications of the findings on achieving 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 High 5s Impact Evaluation Strategy, including 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 systems;
- improve health-care quality;
- share information/data across health care systems and increase the usefulness, integration and exchange of data;
- improve efficiency of performance measurement over time; and
- facilitate coordination and cooperation among all parties in performance measurement and health care quality improvement.

---

6 The Health Roundtable Ltd. Australia. SAFE Patient Care Program 2009 – Standardising Actions for Excellent Patient Care.
15 Franklin, B.D., Standardization is key to improving patient safety. Pharmaceutical Journal, 2003; 271.
3 The High 5s Project governance, structures and participating organizations
The High 5s Project governance, structures, participating LTAs and hospitals, description of the work of the Steering Group and its several committees

1. Overall governance

The High 5s Project is a collaborative whose participants include representatives from the LTAs of the participating Member States, WHO, and the Collaborating Centre, and experts from associated national institutions or agencies which are not LTAs. In addition to the development of the SOPs and associated implementation and evaluation instruments, collaborative actions include participation in strategy setting, advocacy, fund-raising, Member State and hospital mobilization, Project implementation, data collection, evaluation and knowledge dissemination.

The Project’s plans and activities are governed by a Steering Group composed of representatives from the WHO Patient Safety Programme, the Collaborating Centre, the LTAs and associated experts. The Steering Group meets twice a year to review progress achieved; set future direction for the Project; approve technical plans, activities and products; review data; and review and act on committee recommendations.

The websites of the High 5s Project organizations, agencies, institutions and LTAs are presented in Annex 1.

2. Lead Technical Agency (LTA) governance

The Australian LTA: The Australian Commission on Safety and Quality in Health Care (the Commission) is a government agency which was established to lead and coordinate national improvements in safety and quality in health care across Australia. The Commission is responsible for the conduct and governance of the High 5s Project in Australia. The SOP selected for implementation in Australian hospitals was ‘Assuring medication accuracy at transitions of care’.

The French LTA: The French National Authority for Health (Haute Autorité de Santé, HAS), is an independent public authority, located near Paris. HAS contributes to the regulation of health system quality. Its mission is in the field of evaluation of health products, professional practices, organization of care and in public health. With the commitment of the French Ministry of Health, HAS joined the Project in 2008 as the French Lead Technical Agency. The SOPs selected for implementation were the ‘Assuring medication accuracy at transitions of care’ (Med Rec) and the Correct Site Surgery (CSS) SOPs. HAS is responsible for the overall management and has partnered with two regional organizations. These receive funding from HAS for supporting participant, hospitals and monitoring implementation and evaluation of the two SOPs:

- CEPRAL, a regional quality and security of care organization, has been responsible for follow-up and evaluation of the CSS SOP implementation;

- EVALOR (EVAlation en LOrraine) was responsible for the first two years of the Med Rec SOP implementation. In 2012, this task was turned over to OMEDIT (Observatory of Drugs, Medical Devices and Therapeutic Innovations of Aquitaine) whose mission addresses the quality and safety of medication throughout the care pathway.

The German LTAs: The German Federal Ministry of Health has been funding the High 5s Project in Germany since the end of 2007. Two organizations were appointed to share the tasks in implementing the High 5s Project on a national level:
• The German Agency for Quality in Medicine (AQuMed, ÄZQ): Located in Berlin, AQuMed is a non-profit organization owned by the German Medical Association and the National Association of Statutory Health Insurance Physicians. AQuMed coordinates health-care quality programmes with a special focus on evidence-based medicine, clinical practice guidelines, patient empowerment, patient safety programmes, and quality management;

• The German Coalition for Patient Safety (APS): The German Coalition for Patient Safety is a non-profit association of health-care professionals, institutions and patient organizations whose mission is to improve patient safety in Germany. The German Coalition for Patient Safety has appointed the Institute for Patient Safety (IfPS) of the University of Bonn to carry out its tasks in the High 5s Project.

The SOPs selected to be implemented by German LTAs were ‘Assuring medication accuracy at transitions of care’ and Correct Site Surgery (CSS).

The Dutch (Netherlands) LTA: With the support of the Dutch Ministry of Health, CBO Dutch Institute for Healthcare Improvement (a TNO company) located in Utrecht, assumed responsibility as the LTA in 2009. The purpose of Dutch participation in this international collaboration was primarily to introduce and put into practice international expertise in Dutch hospitals and provide technical support to national and international development of patient safety solutions. The SOP selected for implementation in Dutch hospitals was ‘Assuring medication accuracy at transitions of care’ (Med Rec). In 2013, the LTA started the ‘Concentrated Injectable Medicines’ SOP for implementation in Dutch hospitals.

The Singaporean LTA was formed to support the High 5s Project following the expression of interest to participate in the High 5s project by Singapore’s Minister of Health in May 2009. The LTA comprises representatives from the Standards and Quality Improvement Division in the Singapore Ministry of Health. The SOP selected to be implemented by Singapore’s LTA was Correct Site Surgery (CSS).

The Trinidad & Tobago LTA: In May 2011, Trinidad & Tobago participated at the High 5s Steering Group Meeting in Berlin to obtain first hand experiences from Member States on implementation of the SOPs. The Collaborative Action Statement was signed by the Minister of Health in August 2011, signaling the Ministry’s support to the Project, and confirming the Ministry of Health as the LTA for Trinidad and Tobago.

The SOP selected to be implemented by the Trinidad & Tobago LTA was Correct Site Surgery (CSS).

The United States of America (U.S.A.) LTA: The Agency for Healthcare Research and Quality (AHRQ) serves as the official U.S.A. LTA. Since it has no formal health care delivery responsibilities, AHRQ has delegated SOP implementation responsibilities to private sector groups. The first of these is the American College of Surgeons (ACS). The ACS is a scientific and educational association of surgeons that was founded in 1913 to improve the quality of care for the surgical patient by setting high standards for surgical education and practice. The ACS is headquartered in Chicago, Illinois. AHRQ is located in Rockville, Maryland, is committed to improving care safety and quality by developing successful partnerships and generating the knowledge and tools required for long-term improvement. AHRQ has been a financial supporter for the High 5s Project. Thus the ACS has assumed some of the LTA responsibilities.

The initial SOP selected to be implemented by the U.S.A. LTA was Correct Site Surgery (CSS). At the beginning of 2013, The Wheaton Franciscan system of hospitals volunteered to assume responsibility for implementing the Med Rec SOP.

3. Lead Technical Agency structure

The Australian LTA: The High 5s Project sits within the Commission’s Medication Safety Program and is overseen by an expert advisory group, The Medication Continuity Expert Advisory Group, which comprises representatives from medical, pharmacy, nursing and consumer organizations, state and territory departments of health, academia and individual experts from hospital, residential aged care and community health-care sectors. The group advises on the conduct of the Project and reports through the Commission’s Medication Reference Group to the Commission Board.

The High 5s Project is supported by a senior project officer and a project manager who are responsible for the day-to-day management of the project activities.
The French LTAs: The National Authority for Health (Haute Autorité de Santé, HAS) and the EVALOR/OMEDIT and CEPPRAL teams provide support and assistance to participating hospitals with respect to training, SOP implementation, and data collection, analysis and evaluation. A national pilot committee, led by HAS, was set up in 2010 and includes representatives from the Ministry of Health, sanitary agencies, the patient community, hospital federations, and scientific societies. This group met annually during the two first years of the Project. Two committees (one for each of the SOPs) – co-chaired by the LTA and including participating hospital representatives and scientific experts – have been set up and convene workshops every six months.

The German LTA: The two LTA partner organizations in Germany share the tasks and work closely together in implementing the High 5s Project on a national level:

- AQuMed is responsible for overall project management, recruiting hospitals, implementation of the SOPs, supporting the hospitals, and representing the German LTA on the international level of the High 5s Project;
- on behalf of the German Coalition for Patient Safety, the Institute for Patient Safety (IfPS) of the University of Bonn carries out its tasks in the High 5s Project. The IfPS is responsible for the evaluation tasks which encompass data management, analysis and feedback to hospitals.

The Ministry of Health convened an expert advisory committee consisting of leading national experts on the SOP topics. The expert advisory committee, representatives from the Federal Ministry of Health and the project teams from AQuMed and IfPS meet yearly to discuss strategic aspects of their involvement in the High 5s Project.

The Dutch (The Netherlands) LTA: The Dutch Institute for Healthcare Improvement (CBO) nominated a project leader and an advisor to oversee the tasks and work of the High 5s project in the Netherlands. National implementation networks for ‘Assuring medication accuracy at transitions of care’ and for Concentrated Injectable Medicines SOPs was then established. The implementation strategy for the SOPs was based on the ‘Breakthrough Series’ developed by the Institute for Healthcare Improvement in 1994. The objective of participating hospitals was to strengthen both the implementation of the national guidelines for Medication Accuracy at Transitions in Care (2008) and High Risk Medication (preparing for administration) (2009) the Medication Reconciliation and High Risk themes of the national patient safety programme (2008-2012).

The Singaporean LTA set up three key structures that aided the facilitation of the High 5s Project. First, it engaged two leading anaesthetists from two of the largest public hospitals in the country as part-time consultants to help in workflow redesign of operating theatres. Second, it set up a local High 5s Network comprising surgeons, anaesthetists, and OT nurse managers from all public hospitals. Each public hospital has two representatives participating in this Network. The Network was co-chaired by the LTA’s two part time consultants. Third, with regard to implementation of the Correct Site Surgery (CSS) SOP, the LTA funded each hospital with an operational executive to adapt the SOP checklists, collect data, conduct staff education and address identified gaps.

The Trinidad & Tobago LTA: Letters of invitation to participate in the High 5s Project were sent from the Ministry of Health to all five Regional Health Authorities (RHAs) to participate in the implementation of the Correct Site Surgery SOP in October 2011. All five RHAs indicated willingness to implement this SOP in the surgical units of their secondary care hospitals. The Health Care Protocol Officer of the Directorate of Quality Management of the Ministry of Health is the focal Project person and liaison with the project teams at the RHAs. Each project team is headed by a designated Project Team Leader whose responsibility is to ensure implementation of the SOP at the surgical units of the respective hospitals. The Quality Improvement Units at the RHAs and the Quality Directorate at the Ministry of Health provide technical and logistical support.

The U.S.A. LTA: AHRQ has supported the High 5s Project through an expert consultant, in-house technical contributions and funding of the global and technical activities of the Project over a period of four years. The American College of Surgeons provides support to the High 5s Project through two of its staff members who serve as consultants and provide technical expertise on the Correct Site Surgery SOP.
4. Participating hospitals

Table 2: Participating hospitals in each Member State

**Australia**
The Australian collaborative commenced in January 2010 with 18 health services comprising 28 hospitals recruited through an expression of interest process. Five health services have since withdrawn from the project. Reasons given for withdrawal included changes in priorities, loss of project champions, lack of resources, and the need to prioritize work to direct patient care. Participants comprise a mix of public and private hospitals of differing sizes and complexity from regional centres and capital cities in five states. See table 1 for list and description of the participating hospitals.

(Withdrawn from project in October 2012.)

<table>
<thead>
<tr>
<th>Hospital/health service</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>The Alfred Hospital</td>
<td>Acute care, 400 bed public tertiary referral hospital in Victoria</td>
</tr>
<tr>
<td>Armadale Health Service</td>
<td>Acute care, 250 bed public hospital in Western Australia</td>
</tr>
<tr>
<td>Epworth HealthCare</td>
<td>Acute care, 550 bed private hospital in Victoria</td>
</tr>
<tr>
<td>Greater Southern Area Health Service (9 hospitals)</td>
<td>9 rural public hospitals in southern New South Wales (total of 810 beds across 9 sites)</td>
</tr>
<tr>
<td>Logan Hospital*</td>
<td>Acute care 390 bed public hospital in Queensland</td>
</tr>
<tr>
<td>Mater Health Services (3 hospitals)</td>
<td>Tertiary hospital with public and private beds (in total approximately 1000 beds) consisting of Mater Adult Hospital (Public), Mater Children’s Hospital (Public and Private), Mater Mothers’ Hospital (Public and Private), Mater Private Hospital in Queensland</td>
</tr>
<tr>
<td>Noosa Hospital</td>
<td>Acute care, 92 bed private hospital in Queensland</td>
</tr>
<tr>
<td>North West Regional Hospital</td>
<td>Acute care, 120 bed public hospital in Tasmania</td>
</tr>
<tr>
<td>Prince of Wales Hospital</td>
<td>Acute care, 550 bed public tertiary referral hospital in New South Wales</td>
</tr>
<tr>
<td>Redland Hospital</td>
<td>Acute care, 150 bed public hospital in Queensland</td>
</tr>
<tr>
<td>Rockingham Peel Group</td>
<td>Acute care, 180 bed public hospital in Western Australia</td>
</tr>
<tr>
<td>Royal North Shore Hospital</td>
<td>Acute care, 560 bed public tertiary referral hospital in New South Wales</td>
</tr>
<tr>
<td>The Wesley Hospital</td>
<td>Acute care, 530 bed private hospital in Queensland</td>
</tr>
</tbody>
</table>
France
A total of 18 health-care organizations (HCO) were selected (November 2009) and entered the Project in 2010. The LTA defined selection criteria* and developed a questionnaire which was followed-up by an interview conducted with each potential hospital project coordinator. Altogether, nine hospitals were recruited for each SOP. In 2011, one hospital withdrew from the CSS project following the retirement of the initial surgical lead. Likewise, one hospital withdrew from Med Rec SOP implementation because of competing priorities, lack of leadership, and lack of resources. Currently, eight hospitals are participating in the implementation and evaluation of the two SOPs.

<table>
<thead>
<tr>
<th>CSS hospitals and health facilities</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>St Joseph St Luc Hospital in Lyon</td>
<td>Urban, private, non-profit hospital with 344 beds; multi specialties surgery, medicine and gynecology/obstetrics</td>
</tr>
<tr>
<td>Joseph Ducuing Hospital in Toulouse</td>
<td>Urban, private, non-profit hospital with 146 beds; multi specialties surgery, medicine and gynecology/obstetrics</td>
</tr>
<tr>
<td>Clinique du Cambresis in Cambrai</td>
<td>Private for profit surgical clinic with 50 beds; surgical specialties: orthopaedic, vascular, ophthalmology, visceral surgery</td>
</tr>
<tr>
<td>Centre Léon Bérard Cancer center in Lyon</td>
<td>Urban private non-profit center with 250 beds; multi-specialties surgery including reconstructive surgery</td>
</tr>
<tr>
<td>Centre hospitalier de Cornouaille in Quimper</td>
<td>Urban public hospital with 1 044 beds; multi specialties surgery, medicine and gynecology/obstetrics</td>
</tr>
<tr>
<td>Centre hospitalier de Chambéry in Chambéry</td>
<td>Urban public hospital with 1 643 beds; multi specialties surgery, medicine and gynecology/obstetrics</td>
</tr>
<tr>
<td>Centre hospitalier de Bourg en Bresse Fleyriat in Bourg en Bresse</td>
<td>Urban, public hospital with 584 beds; multi specialties surgery, medicine, gynecology/obstetrics</td>
</tr>
<tr>
<td>Pasteur hospital, a subdivision of the Nice University Hospital in Nice</td>
<td>Urban, public, academic, affiliated hospital with one surgical specialty (neurosurgery) and 49 beds</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Med Rec hospitals</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Association clinique la Croix Blanche Moutier Rozeille</td>
<td>Private health care facilities specialized in surgery; acute care: 48 beds</td>
</tr>
<tr>
<td>Centre Hospitalier Universitaire Nîmes</td>
<td>University hospital. acute care: 722 beds; Long Term Care, Complex Continuing Care: 295 beds; Psychiatry: 265 beds</td>
</tr>
<tr>
<td>Centre Hospitalier Saint Marcellin</td>
<td>General hospital; acute care: 30 beds; Long Term Care, Complex Continuing Care: 38; Home Care/Ambulatory: 30/132</td>
</tr>
<tr>
<td>Centre Hospitalier Universitaire Grenoble</td>
<td>University hospital; acute care: 1 388 beds; Long Term Care, Complex Continuing Care: 419; Psychiatry: 54</td>
</tr>
<tr>
<td>Centre Hospitalier Compiègne</td>
<td>General hospital acute care; acute care: 418 beds; Long Term Care, Complex Continuing Care: 142 beds; Home Care/Ambulatory: 37 beds</td>
</tr>
<tr>
<td>Hôpitaux Universitaires de Strasbourg</td>
<td>University hospital; acute care: 1 854 beds; Long Term Care, Complex Continuing Care: 287 beds; Psychiatry: 92 beds</td>
</tr>
<tr>
<td>Centre Hospitalier de Lunéville</td>
<td>General hospital; acute care: 162 beds; Long Term Care, Complex Continuing Care: 30 beds; Home Care/Ambulatory: 30 beds /132 beds</td>
</tr>
</tbody>
</table>
Germany

Germany currently has 16 hospitals implementing CSS and seven hospitals implementing the Med Rec SOP.

### CSS hospitals

<table>
<thead>
<tr>
<th>Hospital Name</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Allgemeines Krankenhaus Celle</td>
<td>An urban, non-profit, general hospital with 698 beds and nine Operating Rooms (ORs) in Celle, a town in the northern part of Germany</td>
</tr>
<tr>
<td>Altmann Klinikum Gardelegen</td>
<td>A small rural, non-profit, general hospital with 200 beds and three ORs in Gardelegen, a small town in the north eastern part of Germany</td>
</tr>
<tr>
<td>Altmann Klinikum Salzwedel</td>
<td>A small rural, non-profit, general hospital with 218 beds, and three ORs. It is closely linked with the other Altmann Klinikum mentioned above</td>
</tr>
<tr>
<td>Evangelische Elisabeth Klinik Berlin</td>
<td>A small urban, non-profit, general hospital with 160 beds in the center of Berlin</td>
</tr>
<tr>
<td>Evangelisches Krankenhaus Hubertus</td>
<td>A small urban, non-profit, general hospital with 210 beds and two ORs on the outskirts of Berlin</td>
</tr>
<tr>
<td>Evangelische Lungenklinik Berlin</td>
<td>A small urban, non-profit hospital with 164 beds, two ORs, with a specialized thoracic centre on the outskirts of Berlin</td>
</tr>
<tr>
<td>Evangelisches Krankenhaus Paul Gerhardt Stift Wittenberg</td>
<td>An urban, non-profit, general hospital with 412 beds and eight ORs in Wittenberg, a town in the eastern part of Saxony-Anhalt</td>
</tr>
<tr>
<td>Evangelisches Waldkrankenhaus Spandau</td>
<td>An urban, non-profit, general hospital with 474 beds and eight ORs on the outskirts of Berlin</td>
</tr>
<tr>
<td>Herzogin Elisabeth Hospital Braunschweig</td>
<td>An urban, non-profit hospital with 215 beds, six ORs and an orthopaedic focus in Braunschweig, a town in Lower Saxony</td>
</tr>
<tr>
<td>Klinikum Chemnitz</td>
<td>An urban, non-profit, general hospital with more 1720 beds and 23 ORs in Chemnitz, a town in Saxony</td>
</tr>
<tr>
<td>Klinikum Coburg</td>
<td>An urban, non-profit, general hospital with 522 beds and six ORs in Coburg, a town in Bavaria</td>
</tr>
<tr>
<td>GRN-Klinik Sinsheim</td>
<td>A rural, non-profit, general hospital with 225 beds and four ORs in Sinsheim, a small town in Baden-Württemberg</td>
</tr>
<tr>
<td>Martin-Luther-Krankenhaus Berlin</td>
<td>An urban, non-profit, general hospital with 285 beds and six ORs in Berlin</td>
</tr>
<tr>
<td>Städtisches Klinikum Solingen</td>
<td>An urban, non-profit, general hospital with 716 beds and eight ORs in Solingen, a town in North Rhine-Westphalia</td>
</tr>
<tr>
<td>University Hospital Aachen</td>
<td>A large university medical center with 1282 beds and 30 ORs in Aachen, a town at the border to the Netherlands and Belgium</td>
</tr>
<tr>
<td>University Hospital Freiburg</td>
<td>A large university medical center with 1484 beds and 27 ORs in Freiburg, a town at the border to Switzerland and France</td>
</tr>
</tbody>
</table>

### Med Rec hospitals

<table>
<thead>
<tr>
<th>Hospital Name</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diakoniekrankenhaus Hannover</td>
<td>An urban, non-profit, general hospital with 444 beds in Hannover, a town in Lower Saxony</td>
</tr>
<tr>
<td>Klinikum Lüneburg</td>
<td>An urban, non-profit, general hospital with 472 beds in Lüneburg, a town in Lower Saxony</td>
</tr>
<tr>
<td>Klinikum Coburg</td>
<td>An urban, non-profit, general hospital with 522 beds in Coburg, a town in Bavaria. (Note: This is also a CSS hospital)</td>
</tr>
<tr>
<td>Städtische Kliniken- Mönchengladbach Elisabeth Krankenhaus</td>
<td>An urban, non-profit, general hospital with 577 beds in Mönchengladbach, a town in North Rhine-Westphalia</td>
</tr>
<tr>
<td>University Hospital Aachen</td>
<td>A large university medical center with 1282 beds and 30 ORs in Aachen, a town at the border to the Netherlands and Belgium. (Note: This is also a CSS hospital)</td>
</tr>
<tr>
<td>University Medical Center Freiburg</td>
<td>A large university medical center with 1484 beds and 27 ORs in Freiburg, a town at the border to Switzerland and France. (Note: This is also a CSS hospital)</td>
</tr>
<tr>
<td>University Medical Center Hamburg-Eppendorf</td>
<td>A large university medical center with 1250 beds in Hamburg</td>
</tr>
</tbody>
</table>
The Netherlands is currently implementing the Med Rec SOP. A total of 15 hospitals, of which five are also Med Rec hospitals, are implementing the SOP for Safe Management of Concentrated Injectable Medicines.

### Med Rec hospitals - group 1/2011

<table>
<thead>
<tr>
<th>Hospital Name</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Antonius Hospital, Sneek</td>
<td>General hospital</td>
</tr>
<tr>
<td>Diakonessenhuis, Utrecht, Zeist, Doorn</td>
<td>General hospital</td>
</tr>
<tr>
<td>Fransiscus Hospital, Roosendaal</td>
<td>General hospital</td>
</tr>
<tr>
<td>HAGA Teaching Hospital, The Hague</td>
<td>Large teaching hospital</td>
</tr>
<tr>
<td>Medical Center Alkmaar, Alkmaar</td>
<td>Large teaching hospital</td>
</tr>
<tr>
<td>Rivas Beatrix Hospital, Gorinchem</td>
<td>General hospital</td>
</tr>
<tr>
<td>Sint Fransiscus Gasthuis, Rotterdam</td>
<td>Large teaching hospital</td>
</tr>
<tr>
<td>Tergooi, Hilversum, Blaricum</td>
<td>General hospital</td>
</tr>
<tr>
<td>Radboud University Nijmegen Medical Centre, Nijmegen</td>
<td>Academic hospital</td>
</tr>
<tr>
<td>VU University Medical Centre, Amsterdam</td>
<td>Academic hospital</td>
</tr>
</tbody>
</table>

### Med Rec hospitals - group 2/2011

<table>
<thead>
<tr>
<th>Hospital Name</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hospital Group Twente (ZGT), Almelo, Hengelo</td>
<td>General hospital</td>
</tr>
<tr>
<td>Elkerliek Hospital, Helmond</td>
<td>Non-teaching hospital</td>
</tr>
</tbody>
</table>

### Med Rec hospitals - group 3/2012

<table>
<thead>
<tr>
<th>Hospital Name</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gelderse Vallei, Ede</td>
<td>Teaching hospital</td>
</tr>
<tr>
<td>University Medical Centre, Groningen</td>
<td>Academic hospital</td>
</tr>
</tbody>
</table>

### Med Rec experts involved in group 1 support

<table>
<thead>
<tr>
<th>Hospital Name</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Erasmus Medical Centre, hospital pharmacist, Rotterdam</td>
<td>Academic hospital</td>
</tr>
<tr>
<td>Medical Centre Haaglanden, location Westeinde,</td>
<td>Large teaching hospital</td>
</tr>
<tr>
<td>ED Nurse Practitioner, The Hague</td>
<td></td>
</tr>
<tr>
<td>TweeSteden Hospital, hospital pharmacy technician, Tilburg</td>
<td>General hospital</td>
</tr>
<tr>
<td>Wilhelmina Hospital, ED doctor, Assen</td>
<td>General hospital</td>
</tr>
</tbody>
</table>

### CIM hospitals involved in group 1 support

<table>
<thead>
<tr>
<th>Hospital Name</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Albert Schweitzer Hospital Dordrecht</td>
<td>General hospital</td>
</tr>
<tr>
<td>Antonius Hospital, Sneek</td>
<td>General hospital</td>
</tr>
<tr>
<td>Elkerliek Hospital, Helmond</td>
<td>Non-teaching hospital</td>
</tr>
<tr>
<td>Erasmus Medical Centre, Rotterdam</td>
<td>Academic hospital</td>
</tr>
<tr>
<td>Flevo Hospital, Almere</td>
<td>General hospital</td>
</tr>
<tr>
<td>HAGA Teaching Hospital, The Hague</td>
<td>Large teaching hospital</td>
</tr>
<tr>
<td>Maasstad Hospital, Rotterdam</td>
<td>General hospital</td>
</tr>
<tr>
<td>Martini Hospital, Groningen</td>
<td>Large teaching hospital</td>
</tr>
<tr>
<td>Meander Medical Centre, Amsterdam</td>
<td>Large teaching hospital</td>
</tr>
<tr>
<td>Medical Center Alkmaar, Alkmaar</td>
<td>Large teaching hospital</td>
</tr>
<tr>
<td>Tergooi, Hilversum, Blaricum</td>
<td>General hospital</td>
</tr>
<tr>
<td>Rijnland Ziekenhuis Leiderdorp</td>
<td>General hospital</td>
</tr>
<tr>
<td>Reinier de Graaf Hospital, Delft</td>
<td>Large teaching hospital</td>
</tr>
<tr>
<td>St. Jansdal Hospital, Harderwijk</td>
<td>General hospital</td>
</tr>
<tr>
<td>Van Weel Bethesda Hospital, Dirkland</td>
<td>General hospital</td>
</tr>
<tr>
<td>Westfries Gasthuis, Hoorn</td>
<td>General hospital</td>
</tr>
</tbody>
</table>
Singapore
The following list provides a snapshot of the hospital sizes in Singapore. The smallest is Jurong Health Services with 400 beds; this hospital will be relocating in a few years’ time to a bigger establishment that will house 700 beds. The largest hospital is Singapore General Hospital at close to 1,500 beds.

<table>
<thead>
<tr>
<th>CSS hospitals</th>
<th>Description</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Changi General Hospital</td>
<td>753 beds</td>
<td><a href="http://www.cgh.com.sg">www.cgh.com.sg</a></td>
</tr>
<tr>
<td>KK Women’s and Children’s Hospital</td>
<td>739 beds</td>
<td><a href="http://www.kkh.com.sg">www.kkh.com.sg</a></td>
</tr>
<tr>
<td>National University Hospital</td>
<td>1,007 beds</td>
<td><a href="http://www.nuh.com.sg">www.nuh.com.sg</a></td>
</tr>
<tr>
<td>Singapore General Hospital</td>
<td>1,449 beds</td>
<td><a href="http://www.sgh.com.sg">www.sgh.com.sg</a></td>
</tr>
<tr>
<td>Tan Tock Seng Hospital</td>
<td>1,293 beds</td>
<td><a href="http://www.ttsh.com.sg">www.ttsh.com.sg</a></td>
</tr>
<tr>
<td>Khoo Teck Puat Hospital</td>
<td>550 beds</td>
<td><a href="http://www.ktp.com.sg">www.ktp.com.sg</a></td>
</tr>
<tr>
<td>Jurong Health Services - operating at former Alexandra Hospital site</td>
<td>400 beds</td>
<td></td>
</tr>
</tbody>
</table>

Trinidad & Tobago
The five public hospitals provide 24-hour general, specialized surgical and medical services to the population. The patient populations vary among the RHAs. Currently, only four of the five hospitals have piloted the CSS SOP in their respective surgical units.

<table>
<thead>
<tr>
<th>CSS hospitals /facilities</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>San Fernando General Hospital</td>
<td>An urban hospital of more than 300 beds, with 12 in-patient operating rooms, and 12,344 surgical cases performed in the latest calendar year</td>
</tr>
<tr>
<td>Port of Spain General Hospital</td>
<td>A regional governmental hospital of more than 300 beds, with six in-patients operating rooms, and 5,561 surgical cases performed in the latest calendar year</td>
</tr>
<tr>
<td>Sangre Grande Hospital</td>
<td>A suburban hospital of 100-299 beds, with three in-patient operating rooms, and 2,694 surgical cases performed in the latest calendar year</td>
</tr>
<tr>
<td>Scarborough General Hospital</td>
<td>A regional governmental hospital of 100-299 beds, with two in-patient operating rooms, and 2,342 surgical cases performed in the latest calendar year</td>
</tr>
<tr>
<td>Eric Williams Medical Sciences Complex</td>
<td>An urban academic hospital of more than 300 beds, with 8 in-patient operating rooms and 4,908 surgical cases performed in the latest calendar year</td>
</tr>
</tbody>
</table>

United States of America
The following list provides a snapshot of the hospitals participating in the High 5s Project in the U.S.A.

<table>
<thead>
<tr>
<th>CSS hospitals /facilities</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baylor University Medical Center</td>
<td>Large Teaching and Research Hospital</td>
</tr>
<tr>
<td>Washington University School of Medicine</td>
<td>Large Teaching and Research Hospital</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Med Rec hospitals /facilities</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Wheaton Franciscan Elmbrook</td>
<td>Small hospital; part of the Wheaton Franciscan System</td>
</tr>
<tr>
<td>Wheaton Franciscan Healthcare Franklin Hospital</td>
<td>Small hospital; part of the Wheaton Franciscan System</td>
</tr>
<tr>
<td>Wheaton Franciscan St. Francis Hospital</td>
<td>Small hospital; part of the Wheaton Franciscan System</td>
</tr>
<tr>
<td>Wheaton Franciscan St. Joseph Hospital</td>
<td>Small hospital; part of the Wheaton Franciscan System</td>
</tr>
<tr>
<td>Wheaton Franciscan Wisconsin Heart Hospital</td>
<td>Small hospital; part of the Wheaton Franciscan System</td>
</tr>
</tbody>
</table>
5. High 5s Steering Group

The Steering Group is responsible for overseeing the High 5s Project planning, management, coordination and technical direction as outlined below:

1) Strategic planning

- Political and technical direction.
- Strategic planning.
- Global and country-level Project advocacy and capacity building at ministerial levels.
- Coordination with associated national institutions or agencies (not LTAs).

2) Management & coordination

- Global coordination of planning and activities; provision of logistics support and services to LTAs; and High 5s Project biannual meetings.
- Country-level coordination of planning and activities.
- Global communications.

3) Technical functions

- Development of Standard Operating Protocols (SOPs) and the Impact Evaluation Strategy and related tools.
- Support and coordination of High 5s Project national planning, implementation, data collection, analysis, and training activities.
- Development of a global learning community and associated tools and services as deemed necessary for implementation, data collection and analysis, evaluation and dissemination.
- Compilation and active dissemination of findings, outcomes, improved practices and lessons learned from the High 5s Project for worldwide publication.

6. High 5s Project Committees

There are five committees composed of representatives from the WHO, the CC, and LTAs. The committees advise, plan, develop and execute activities and are overseen by the Steering Group. The committees are:

1. Collaborative Learning;
2. Communications;
3. Evaluation;
4. Event Analysis; and
5. Publications.

Participation within each committee varies according to the task and activity to be achieved.

The Collaborative Learning Committee was established to develop an implementation plan for a High 5s Project core learning strategy including consideration of target audiences and levels and mechanisms of learning. Strategies were collaboratively designed and scheduled to prepare LTAs and hospitals for the implementation and evaluation of the three SOPs. They included in-person train-the-trainer workshops, provision of online resources, and online posting of Questions and Answers.

The Communications Committee was established to develop and implement a High 5s communications strategy that included consideration of target audiences and creation of common messages/themes for global use and for High 5s LTA members to use within their own countries.

The committee’s objectives are to communicate the concepts, strategies and actions of the High 5s Project in an effective manner with particular attention to:

- presenting the political profile of the High 5s Project to external audiences;
- supporting LTA activities with in-country communications and advocacy;
- meeting communication needs of the High 5s Steering Committee members; and
- engaging new partners to participate as part of the High 5s Project expansion strategy.

The Evaluation Committee has overseen the development of a consistent, integrated approach to the High 5s Project evaluation across the SOPs. Specific activities have included:

- development of materials and tools necessary to carry out the evaluation strategy;
- development of performance measures as well as a method for evaluating the SOP implementation experience;
- development of a process for maintaining the confidentiality of data and comply with LTA privacy requirements; and
- development and monitoring of the overall evaluation plan.

The Event Analysis Committee is a Subcommittee of the Evaluation committee which was established to develop the process by which each participating hospital would actively identify and investigate
a pre-determined set of patient safety problems (events) that are or could be related to the SOP.

These findings help to determine the effectiveness of the SOP and are intended to guide future revisions of the SOPs, as appropriate. Key activities include:

- delineation of SOP-specific prompts for the identification of SOP-related events for analysis;
- establishment of criteria for assessing the thoroughness and credibility of event analysis;
- determination of a minimum data set for the results of event analyses;
- develop a process for submission and review of the event analyses by the LTA;
- creation of a process for submitting an event analysis report to the Collaborating Center.

The Publications Committee was established to:

- identify a potential list of peer-reviewed High 5s publications;
- establish procedures for publishing data under the High 5s Project; and
- develop guidelines that govern publications, copyright issues, and data ownership and sharing.
The design of the Project, its protocols and evaluation framework
The design of the Project, its protocols and evaluation framework, including an overview of methodologies, instruments and processes

1. Design of the Project

The High 5s Project has applied established best practices and interventions to support the development of standardized processes and tools. These processes have included input from all levels of team members from management to individual health-care workers. This has also permitted development of a consistent system of monitoring that makes the production of comparable results possible locally, nationally and internationally.

2. Standard Operating Protocols (SOPs)

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. It contains a set of instructions for implementing a defined patient care process by multiple users in a consistent and measurable way. The SOPs were designed to be systematically implemented using quality improvement methods that include the following components:

1. oversight of the implementation;
2. project workplan;
3. risk assessment of the proposed process;
4. pilot testing;
5. spread methodology;
6. communication plan;
7. evaluation Strategy;
8. maintenance and Improvement strategy.

Institutions which led the development of the SOP

In this multi-country collaboration, the Canadian Patient Safety Institute and the Institute for Safe Medication Practices in Canada led the development of the Concentrated Injectable Medicines SOP. The Joint Commission and the Agency for Healthcare Research and Quality in the USA led the development of the Correct Site Surgery SOP. Participants from all of the LTAs, the Collaborating Centre, and consultants associated with Joint Commission International and the Institute for Safe Medication Practices in Canada provided technical expertise to support development of the implementation and evaluation frameworks that are integral to the SOPs.

3. High 5s evaluation framework

The High 5s Project aims to answer two main questions:

1. Is it feasible to implement standardized processes in health care within individual hospitals, among multiple hospitals within individual Member States, and across country boundaries?
2. What is the impact of standardization on the safety problems that the project targets?

The High 5s Project combines process standardization and intensive evaluation of the feasibility and impact of implementing SOPs on a global scale.

A standardized approach to evaluation, the ‘Impact Evaluation Strategy’ was designed to assess the feasibility and impact of implementing the SOPs. Both quantitative and qualitative approaches were used in this process. The Impact Evaluation Strategy included structured qualitative and quantitative evaluation of the SOP implementation experience, on-site application of SOP-specific performance measures, use of an event analysis framework to identify occurrences that may represent SOP failures, and a baseline hospital patient safety culture survey. The evaluation strategy identifies the factors underlying patient safety problems, matches these problems against those that the
SOPs are trying to prevent, and tracks improvements in patient safety in the participating hospitals.

Following LTA and hospital training on SOP implementation and use of the evaluation instruments, the materials and tools necessary to implement each SOP were pre-tested in individual representative hospitals in participating Member States for a two-month period. This was done to permit revisions and adaptations of the SOPs and their related evaluation processes prior to full-scale implementation of the SOPs in 2010.

3.1. SOP implementation experience

The goals of the SOP implementation evaluation process were to determine if one or more SOPs could be implemented as designed in diverse hospital settings, to identify barriers to implementation, and to identify ways to overcome said barriers. In order to evaluate the fidelity and portability of SOP implementation in multi-country settings and environments, self-reported narrative data was collected at the beginning of the Project, at six-monthly intervals throughout the project. Related interview data is also being collected at selected hospitals annually.

Methodologies, instruments and processes employed

A narrative of real-world experiences from individuals engaged in SOP-implementation provides a deeper understanding of the feasibility and impact of SOP implementation. On a biannual (every six months) basis, participating hospitals from each Member State were asked to complete a 67-item questionnaire that was divided into ten sections. These included implementation status, oversight, work plan, risk assessment, pilot test, spread methodology, communication plan, evaluation strategy, events analysis and maintenance. A summary of this data was compiled, classified by specific SOP (either Correct Site Surgery or Medication Reconciliation), and reported. Hospitals that had already completed the initial questionnaire were given the option from the 4th quarter 2012 to complete a brief implementation update form. This form included five open-ended questions which were designed to capture any new information regarding parts of the implementation experience that had most likely changed, such as implementation status, communication strategies, new strategies or barriers regarding maintenance, efforts to measure the effectiveness of the SOP, and any experiences of the hospital that might benefit other organizations. This brief update form was designed to reduce the reporting burden on hospitals and allowed for participants to describe, in only a few sentences, any significant changes over a period of six months. Use of this brief update form was optional; hospitals were given the option of completing the questionnaire in full.

3.2. SOP-specific performance measures

Implementation of each SOP is evaluated using performance measures that determine the extent to which the protocol was followed during implementation by the participating hospitals in multiple Member States and enable national and international comparability of data. The standard performance measures include SOP process measures and outcome measures. Standardization of SOP performance measures increases data reliability and comparability. Performance measurement results are presented in various formats within the High 5s Information Management System to support LTA and hospital needs and enable sites to benchmark and trend their data over time.
Methodologies, instruments and processes employed

The performance measure data is normally collected at monthly intervals in the secure High 5s IMS and international evaluation reports are generated at quarterly intervals. A list of the performance measures for each SOP is provided below.

Performance measures for ‘Medication Reconciliation’

H5sMR-1 Percent of patients with medications reconciled within 24 hours of the decision to admit the patient
H5sMR-2 The mean number of outstanding undocumented intentional medication discrepancies per patient
H5sMR-3 The mean number of outstanding unintentional medication discrepancies per patient
H5sMR-4 Percent of patients with at least one outstanding unintentional discrepancy

Performance measures for ‘Correct Site Surgery’

H5sCS-0 Proportion of verification checklists for all eligible surgical cases
H5sCS-1 Proportion of eligible surgical cases with a complete preoperative verification process (exclusive of site marking and Time Out)
H5sCS-2 Proportion of cases with properly marked surgical site
H5sCS-3 Proportion of cases with complete final Time Out
H5sCS-4 Proportion of cases with discrepancy noted at final Time Out
H5sCS-5 Proportion of cases undergoing surgery with unresolved Time Out
H5sCS-6 The proportion of surgical cases that are cancelled or postponed due to discrepancies identified at any point in the conduct of the SOP
H5sCS-7 Proportion of cases with incorrect surgery (wrong site, procedure or person cases).

Performance measures for ‘Concentrated Injectables’

H5sCI-01 Time between concentrated injectable adverse events
H5sCI-02 Time between adverse drug events delay or omission of administration of injectable medicines
H5sCI-03 The number of adverse events for specified concentrated injectables per 1 000 patient days
H5sCI-P1 Concentrated injectable medicines stored in unauthorized clinical areas
H5sCI-P2 Concentrated injectable medicines supplied to unauthorized clinical areas
H5sCI-P3 Ready-to-administer and ready-to-use injectable medicines supplied to unauthorized clinical area
H5sCI-P4 The number of clinical areas storing concentrated injectable medicines according to selected SOP specifications

Although performance measures for the implementation of the ‘Concentrated Injectables’ SOP were developed, implementation data were not collected.

Data quality

Data and information provided and collected have to be accurate to ensure a credible evaluation. The aim is to reach a level of data quality consistent with the limits of precision that are achievable with respect to the analytic tools and sample sizes defined for use in the High 5s Project. Only data that has been confirmed to meet the data quality criteria by both the hospital and the LTA is included in performance measure calculations.
National and international comparison data calculations

a) Country-level data (national comparison)
Country-level data points are calculated using a similar approach to the one employed for calculating an individual hospital’s performance on a specific measure. The major difference is that for rate and ratio measures, all the hospital numerator cases (from within a specific Member State) are summed, and all of the hospital denominator cases (from within a specific Member State) are summed before calculating the measure rate or ratio. The measure is calculated in the aggregate for all hospitals in a Member State during the specific time period. This calculation creates a weighted mean (weighted by the number of cases contributed by each hospital) rather than a grand mean (simply taking the average of the calculated hospital rates). The approach is slightly different for continuous variable measures (used for the Concentrated Injectables SOP). For these measures, the comparison group value is:

\[ \sum \frac{(each \ hospital \ value \ * \ the \ number \ of \ cases \ upon \ which \ that \ value \ was \ based)}{\sum \ of \ hospital \ cases} \]

b) International-level data (international comparison groups)
International-level data points are calculated using a similar approach to the one employed for calculating an individual hospital’s performance on a specific measure. The major difference is that for rate and ratio measures, all the hospital numerator cases (from all Member States) are summed and all of the hospital denominator cases (from all Member States) are summed before calculating the measure rate or ratio. The measure is then calculated in the aggregate for all hospitals contributing data during the specific time period. This calculation creates a weighted mean (weighted by the number of cases contributed by each hospital) rather than a grand mean (simply taking the average of the calculated hospital rates or the average of the national rates). The approach is slightly different for continuous variable measures (used for the Concentrated Injectables SOP). For these measures, the comparison group value is:

\[ \sum \frac{(each \ hospital \ value \ * \ the \ number \ of \ cases \ upon \ which \ that \ value \ was \ based)}{\sum \ of \ hospital \ cases} \]

c) Requests for measure revisions
Over the course of the Project, a number of requests to revise the measures were submitted. The Evaluation Committee considered each request and made recommendations to accept or reject the modification based upon the nature of the request and the degree to which it would impact longitudinal analyses. To date, there have been nine requests for measure revision: four were for measures related to Medication Reconciliation, three were for Correct Site Surgery, and two were for Concentrated Injectables.

In order to reduce data collection burden, Australia requested to reduce the frequency of data collection for measures MR 2, 3 and 4 for hospitals that had met an established performance threshold. The request was approved and hospitals that had consistently met a defined threshold were permitted to submit data quarterly. If a hospital later failed to meet the threshold, it would then return to monthly submissions until it could meet the expected benchmark for three consecutive months.

Canada requested a 24-hour time boundary for measures MR 2, 3 and 4. This request was approved because it allows for standardization and ease of data collection across all participating Member States.

Australia also requested changes to measures MR 2, 3 and 4. Specifically, they requested a tighter definition of what are to be included as documented intentional discrepancies and unintentional discrepancies. They further asked for specific examples of inclusions/exclusions. Finally, they requested additional language that would state that “medications prescribed for the first time on admission are intentional discrepancies and shouldn’t be included.” These requested changes were approved.

A request was made by the United Kingdom, and approved, to revise the measure statements for measures CI-02 and CI-03 to include the intended patient populations. In order to increase understanding of the SOP and to be consistent with measure CI-P1, that measure statement was changed to indicate that measure events are restricted to only those that caused harm to patients.

The United Kingdom also made a request to change the value statement for measure P1.
to read “It is important to monitor whether concentrated products are held in stock in unauthorized clinical areas.” Because measure P1 is not intended to measure the number of concentrated products held in stock, but instead measures the number of unauthorized clinical areas storing concentrated products, this change was approved and the language was amended in the performance measure value statement.

The U.S.A. requested that a new measure, CS-0, be created. This measure would capture the percent of eligible cases having a pre-operative verification checklist (total number of checklists/total number of eligible cases). This measure was created based on the assumption that it will help ensure that the correct data are used in the performance measure calculations.

Because of ambiguity in the labeling of the numerator data element for CS-1, Germany requested that the name of the numerator data element be changed from “Completed Pre-Operative Verification Checklist” to “Number of Eligible Surgical Cases with a Completed Pre-Operative Verification Process”. Because this change clarified the intent of the measure to ensure standardized data collection, this change to the data element was approved.

3.3. Event analysis

An ‘event’ is defined as an occurrence that happens to or involves a patient and which could have resulted, or did result, in unnecessary harm to the patient.

The evaluation framework includes an Event Analysis (EA) component that directs each participating hospital to actively seek and investigate a pre-determined set of patient safety problems (events) that should have been prevented in the clinical setting by the SOP. Hospitals are then asked to report specific de-identified information regarding the case to their LTA for review and submission to the High 5s Collaborating Centre.

Event analysis is undertaken after a patient safety incident takes place and aims to determine whether there is a link to the SOP implementation 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 yields 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 have been expected to use the specifically designed methods, including chart audits and checklist reviews (where applicable). Minimum Data Set (MDS) forms and checklists were also developed 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 were applied where certain events appeared to have common characteristics, in order to identify patterns of performance.

There are four types of events:

1. **Hazard**: a circumstance, agent or action with the potential to cause harm;
2. **Near miss/Close Call/Good Catch**: an event which did not reach the patient;
3. **No-harm**: an event which reached a patient but no discernible harm resulted;
4. **Adverse**: an event which resulted in harm to a patient.

Event analysis is defined as a systematic process whereby the facts, contributing factors and resultant recommendations are identified and reported as a means of investigating an event.

This aspect of the evaluation framework was intended to go beyond fact-finding, and to help understand the applicable contributing factors. The EA process provided an unprecedented opportunity to obtain and analyze findings regarding the safety and effectiveness of the SOPs.

The complexity of developing and implementing the SOPs delayed the High 5s Steering Group in finalizing and implementing the EA evaluation process. The Event Analysis Subcommittee played a key role in formalizing the proposed EA instructions for the participating hospitals. After the approval by the Steering Group, the instructions were posted on the High 5s Information Management System (see Annex 4A and 4B for the EA Overview for the Medication Reconciliation and Correct Site Surgery SOPs).

Each LTA provided specific instructions to participating hospitals regarding the methodology to be used by their participating hospitals to perform the event analysis. Where an LTA did not
have a preferred methodology, they could adopt one of the established event methodologies identified by the Event Analysis Subcommittee and approved by the Evaluation Committee. The sources of these methodologies were:

1. National Patient Safety Agency
   http://www.nrls.npsa.nhs.uk/resources?entryid45=59901
2. United States Department of Veterans Affairs National Center for Patient Safety
   http://www.patientsafety.gov/CogAids/RCA/
3. Canadian Patient Safety Institute
   http://www.patientsafetyinstitute.ca/English/toolsResources/IncidentAnalysis/Pages/default.aspx
4. The Joint Commission
   http://www.jointcommission.org/Framework_for_Conducting_a_Root_Cause_Analysis_and_Action_Plan

The Collaborating Centre offered specific training in any of the above methodologies requested by an LTA. Most, but not all, participating LTAs had in-country EA expertise and a standardized tool for analyzing events after they were identified. Some LTAs needed to first invest time and resources in building this capability before attempting to implement the High 5s EA evaluation process.

The EA principles were specified to facilitate a consistent, timely, thorough and credible approach. The goals of EA were to determine:

1. what happened?
2. why did it happen?
3. how can the likelihood of recurrence of this event be reduced?

Four types of ‘Event analysis’ were defined:

1. Concise
   Event analysis of these occurrences is usually conducted by someone who is aware of the details of the event and is knowledgeable about the involved process and effective solutions. The EA process is often completed within hours or days because of the less intensive approach. Events without patient harm may receive Concise Event Analysis or Cluster Analysis.

2. Comprehensive
   Event analysis is undertaken by an inter-disciplinary group of staff and physicians that is facilitated by a person(s) who is knowledgeable about the involved process(es), human factors and effective solutions development. The process may take up to 90 days because of the depth and breadth of the analysis. Events resulting in patient harm should receive ‘Comprehensive Event Analysis’.

3. Aggregate
   This is the optional but recommended process of analyzing data combined from the findings of several completed event analyses (concise or comprehensive) of similar event characteristics, in order to identify patterns of causation and enhance the effectiveness of actions for improvement.

4. Cluster analysis
   This is a process for analyzing three or more no-harm events having similar event characteristics as a group in order to identify patterns in causation and enhance the effectiveness of actions for improvement. Cluster analysis may be used instead of concise analysis if there are three or more no-harm SOP-related events of the same type within a month.

Identification of events for analysis

Initial development of the EA evaluation involved creation of a trigger tool for chart reviews in order to identify wrong site surgeries or medication reconciliation failures. The Australian LTA provided key expertise and leadership in pilot testing this strategy. Eventually an agreed upon strategy was formalized and implemented for the identification of events.

A. Medication Reconciliation events

Med Rec events are process issues or outcomes that are possible SOP-related events. Examples include:

- ‘Best Possible Medication History’ (BPMH) not obtained and/or reconciled within 24 hours of decision to admit;
- inaccurate or incomplete BPMH;
- inaccurate or incomplete resolution of any discrepancies;
- all discrepancies not resolved within 48 hours of decision to admit.

Two primary sources of SOP events for analysis are:

1. independently reported adverse events during or after the SOP is implemented;
2. independent ‘Observer Chart Audits’.
Chart audits are a defined independent double-check strategy to assess the quality of the Medication Reconciliation “process” that is performed in hospitals as part of the evaluation strategy to collect performance measures. During audits by the independent observer to measure MR-2 – MR-4, medication reconciliation process events/issues identified are flagged for EA.

B. Correct Site Surgery events

CSS SOP events are process issues or outcomes that are possible SOP-related events. Examples include:
- wrong site surgery;
- wrong limb prepped for surgery but error discovered before incision occurred.

Two primary sources of SOP events for analysis are:
1. independently reported adverse events during or after the SOP is implemented;
2. retrospective SOP checklist review.

The SOP checklist is a defined requirement to document steps in preparing each patient for surgery and for recording the outcomes relevant to the SOP. There are four outcomes requiring analysis that may be identified by a member of the health-care team concurrently and/or, a reviewer of the checklists on a retrospective basis:
- incorrect surgery (wrong patient, procedure, site or implant)
  - Hospital completes a Comprehensive Event Analysis;
- case that proceeds to incision with unresolved discrepancy
  - Hospital completes a minimum of a Concise Event Analysis;
- case cancelled because of SOP-related discrepancy
  - Hospital completes a minimum of Concise Event Analysis;
- case with discrepancy resolved at final Time Out
  - Hospital completes a minimum of Concise Event Analysis.

Hospitals can decide to complete a Comprehensive Event Analysis of certain events at their discretion. For these cases, they are also asked to consider aggregate analysis of any group of related individual event analyses. For no-harm cases of the same type in these categories, which occur at a frequency of three or more per month, cluster analysis can be conducted.

Data collection and reporting

The ‘Event Analysis- Minimum Data Set’ (MDS) forms were developed to capture the key findings of the analysis. Hospitals were asked to complete all fields of the applicable forms, and attach any additional information at their discretion, before submission to their LTA.

The LTA would subsequently review the submission and follow-up with the applicable hospital to ensure that all information was properly de-identified, understandable and complete. Criteria for accuracy and completeness are defined in Annex 5A and 5B. The LTA would then submit this data to the Collaborating Centre, where the information would be combined for analysis and de-identified High 5s reporting. The information would also be combined with other evaluation findings to determine if any changes should be made to the SOP.

3.4. Patient safety culture surveys

The ‘Hospital Survey on Patient Safety Culture’ was developed by Westat under contract with the Agency for Healthcare Research and Quality (AHRQ). The survey and accompanying toolkit materials are available from the AHRQ website www.ahrq.gov/qual/hospculture. In the context of the High 5s Project the culture survey was conducted as an additional voluntary evaluation component to provide insight into the patient safety culture of hospitals participating in the High 5s Project and to sensitize frontline staff and hospital management about staff members’ perception of the hospital’s patient safety culture. At the time the survey was administered, participating Member States included Australia, France, Germany, the Netherlands, Singapore and the United Kingdom. The Project then included the Medication Reconciliation, Correct Site Surgery and Concentrated Injectables SOPs.

The survey, designed to assess hospital staff opinions about patient safety issues, medical error, and event reporting, included 42 items that measure 12 areas or composites of patient safety culture. Each of the 12 patient safety culture composites is listed and defined in Table 3.

The survey also included two questions that asked respondents to provide an overall grade for patient safety for their work area/unit and to indicate the number of events they had reported over the past 12 months. In addition, respondents...
Table 3: Patient safety culture composites and definitions

| Patient safety culture composite | Definition: The extent to which...
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Communication openness</td>
<td>Staff freely speak up if they see something that may negatively affect a patient, and feel free to question those with more authority</td>
</tr>
<tr>
<td>2. Feedback and communication about error</td>
<td>Staff are informed about errors that happen, given feedback about changes implemented, and discuss ways to prevent errors</td>
</tr>
<tr>
<td>3. Frequency of events reported</td>
<td>Mistakes of the following types are reported: (1) mistakes caught and corrected before affecting the patient, (2) mistakes with no potential to harm the patient, and (3) mistakes that could harm the patient, but do not</td>
</tr>
<tr>
<td>4. Hand-offs and transitions</td>
<td>Important patient care information is transferred across hospital units and during shift changes</td>
</tr>
<tr>
<td>5. Management support for patient safety</td>
<td>Hospital management provides a work climate that promotes patient safety and shows that patient safety is a top priority</td>
</tr>
<tr>
<td>6. Non-punitive response to error</td>
<td>Staff feel that their mistakes and event reports are not held against them, and that mistakes are not kept in their personnel file</td>
</tr>
<tr>
<td>7. Organizational learning—continuous improvement</td>
<td>Mistakes have led to positive changes and changes are evaluated for effectiveness</td>
</tr>
<tr>
<td>8. Overall perceptions of patient safety</td>
<td>Procedures and systems are good at preventing errors and there is a lack of patient safety problems</td>
</tr>
<tr>
<td>9. Staffing</td>
<td>There are enough staff to handle the workload and work hours are appropriate to provide the best care for patients</td>
</tr>
<tr>
<td>10. Supervisor/manager expectations and actions promoting safety</td>
<td>Supervisors/managers consider staff suggestions for improving patient safety, praise staff for following patient safety procedures, and do not overlook patient safety problems</td>
</tr>
<tr>
<td>11. Teamwork across units</td>
<td>Hospital units cooperate and coordinate with one another to provide the best care for patients</td>
</tr>
<tr>
<td>12. Teamwork within units</td>
<td>Staff support each other, treat each other with respect, and work together as a team</td>
</tr>
</tbody>
</table>

Participating hospitals expressed interest in comparing their results with those hospitals in other participating Member States, as it provided a new source of information to help them identify and understand potential differences in patient safety cultures across Member States. For this reason AHRQ produced the High 5s ‘International Comparative Report’ (see Annex 2).

The report presented survey administration and respondent statistics across the Member States, as well as percent-positive results on the patient safety culture composites and survey items. Comparative results from U.S.A. hospitals included in the AHRQ Hospital Survey on Patient Safety Culture 2011 Comparative Database Report were also provided.
5 Qualitative and quantitative interim findings
Qualitative and quantitative interim findings

1. Summary of culture survey findings

Data from 6 Member States with a total of 59 hospitals was collected and analyzed for reporting purposes (Table 4). The High 5s participating hospitals administered the hospital survey to their staff between November 2009 and November 2010 and voluntarily submitted their data for inclusion in the database. The U.S.A. database numbers are based on the AHRQ Hospital Survey on Patient Safety Culture 2011 Comparative Database Report.

Table 4: Survey administration statistics

<table>
<thead>
<tr>
<th>Member State</th>
<th>No. of hospitals</th>
<th>Total No. of completed surveys</th>
<th>Total No. of staff asked to complete survey</th>
<th>Overall response rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>United Kingdom</td>
<td>12</td>
<td>2,657</td>
<td>Not Available</td>
<td>Not Available</td>
</tr>
<tr>
<td>Singapore</td>
<td>7</td>
<td>18,204</td>
<td>23,792</td>
<td>77%</td>
</tr>
<tr>
<td>France</td>
<td>7</td>
<td>621</td>
<td>1,000</td>
<td>62%</td>
</tr>
<tr>
<td>Germany</td>
<td>5</td>
<td>1,083</td>
<td>3,881</td>
<td>28%</td>
</tr>
<tr>
<td>Australia</td>
<td>24</td>
<td>3,485</td>
<td>8,410</td>
<td>41%</td>
</tr>
<tr>
<td>The Netherlands</td>
<td>4</td>
<td>127</td>
<td>253</td>
<td>50%</td>
</tr>
<tr>
<td>High 5s Total</td>
<td>59</td>
<td>23,520*</td>
<td>37,336*</td>
<td>63%*</td>
</tr>
</tbody>
</table>

* High 5s ‘Totals’ in these columns do not include United Kingdom due to missing data.

On average, hospitals across Member States scored highest on teamwork within units (70% positive), and scored lowest on handoffs and transitions (34% positive). The hospitals in Singapore were the most positive on seven of the 12 composites, and were also the least positive on two of the composites. The hospitals in the Netherlands were the most positive on five of the 12 composites, and were also the least positive on two of the composites. The hospitals in Germany were the least positive on four of the 12 composites.

The hospitals in Singapore had the smallest variability on all 12 composites across participating hospitals. Singaporean hospitals also had the highest average composite score (58%) while German hospitals had the lowest (46%) average composite score. The U.S.A database hospitals were more positive on four of the 12 composites and more positive or equal on all 12 composites in comparison to the High 5s average scores.

The hospitals in the United Kingdom had the highest percentage of respondents giving the work area/unit a patient safety grade of an ‘A-Excellent’ or ‘B-Very Good’ (60%), while hospitals in the Netherlands had the lowest percentage (21%). Hospitals in the Netherlands had the highest average percentage of respondents reporting one or more events (78%), while hospitals in Singapore had the lowest (37%).
Culture survey results by staff position were as follows:

- the High 5s average composite score for all physicians/consultants/medical officers was 51%, with a low of 47% in Germany to a high of 54% in Singapore;
- the High 5s average composite score for nursing was 53%, ranging from 45% for the Netherlands to 60% for Singapore;
- the High 5s average composite score for allied health professionals was 55%, ranging from 49% for Germany to 58% for France;
- the High 5s average composite score for administration/management was 57%, ranging from 49% for France to 69% for Netherlands.

Survey and data limitations

The survey results represented a large compilation of international patient safety culture survey data and therefore provided a useful reference for international comparisons. However, the following limitations apply to these data and should be kept in mind when considering the data:

1. The High 5s hospitals included for the report were not a statistically selected sample of all hospitals within each participating Member State and therefore were not necessarily representative of the status of the patient safety culture within each Member State.
2. The number of hospitals and the number of respondents varied greatly by Member State. For instance, Singapore submitted data from seven hospitals and 18,204 respondents, while Australia submitted data from 24 hospitals and 3,485 respondents. Given this wide range of participation, the ability to generalize the comparability of the results is limited.
3. Hospitals administered the survey in different ways. Most hospitals used paper only, while others used web only, and still others used a combination of these two methods of data collection. It is possible that these different methods led to mode effects in the survey scores. In addition, some hospitals surveyed all hospital staff, while others administered the survey to a sample of staff in selected work units/areas. In cases in which a sample was used, no information was available to determine the method used to select the sample.
4. Differences in scores across Member States may relate to a number of factors other than true differences in patient safety culture, making direct comparisons among Member States complicated. For instance, there may be significant cultural differences across Member States in how respondents interpreted the survey items and the ways in which they used the response scales. In addition, there are differences in the way health care is structured and provided across Member States that could affect responses. Furthermore, survey translations were developed by individuals within the Member States, but were not tested or externally validated before administration.
5. The data was cleaned for out-of-range values (e.g., invalid response values because of data entry errors) and blank records (where responses to all survey items were missing). Otherwise, data was presented as submitted. No additional attempts were made to verify or audit the accuracy of the data submitted.

1.1. Culture surveys in participating Member States

Australia

All participating hospitals were requested to complete the AHRQ Patient Safety Culture Survey. Seven hospitals chose to administer the survey throughout the hospital, while the remainder administered it in their emergency departments, wards and services participating in the Project. All hospitals administered the survey as hard copies with one exception where a mix of paper and online surveys was used. Twenty four hospitals participated in the survey.

The survey was conducted between May 2010 and December 2010.

Australian hospitals reported high positive responses to three patient safety culture composites: teamwork within units (77%); management support for patient safety (71%); and organizational learning – continuous improvement (69%). Conversely, only 34% reported a positive response on handoffs and transitions; 39% of staff surveyed believed that staffing levels were sufficient for patient care; and only half (49%) reported a positive response to teamwork across units (Table 1 in Annex 6).
Analysis of the data for the hand-offs and transitions composite found a variation in patient safety culture across work areas and among the different categories of staff. Clinical handover, staffing, teamwork across units, and engaging with junior medical staff were identified as potential areas for improvement. Hospitals were encouraged to review their individual survey results and to:

- identify:
  - lowest scoring safety culture composites across items, unit areas, and staff areas and look for linkages;
  - areas for improvement;
  - places where additional qualitative data needed to be collected; and
  - stakeholders who should be engaged in improvement activities
- discuss possible improvement strategies; and
- develop and implement an action plan for improvement and evaluate the plan impact.

**France**

The French LTA decided that only the ‘Correct Site Surgery (CSS)’ participating hospitals would complete the AHRQ culture survey, as the workload of the ‘Medication Reconciliation’ participating hospitals for the implementation and evaluation of this SOP was considered too great to permit their participation in the culture survey.

All of the CSS participating hospitals (nine in 2011) were asked to complete the AHRQ culture survey, but two of them did not participate: one because of organizational issues (delay in the implementation of the project) and the other because management did not approve the administration of the survey.

In the seven participating hospitals, 1,000 surveys were sent out and 620 completed responses were received (42% to 95% in the various hospitals). Questionnaires translated in French were distributed either hospital-wide (three hospitals) or in the units directly involved in SOP implementation in the four other hospitals. The LTA trained all the project coordinators and supplied to each hospital a tool-kit with communication models.

The challenge encountered by the project hospital coordinators was the lack of time to explain the safety culture survey and to collect the surveys. The areas with the three top scores were teamwork within units (59%), organizational learning – continuous improvement (58%) and openness of communication (56%). Areas with the three lowest scores were:

- handoffs and transitions (39%);
- non-punitive response to error (32%); and
- management support for patient safety (28%).

The overall level of patient safety was reported to be between acceptable to excellent by 94% of respondents. Feedback of the results was provided to the front line staff and managers by the LTA via conference call and site visit. Participating in the High 5s Project was considered to reflect positively on the safety culture.

**Germany**

Participation in the AHRQ culture survey was voluntary, but was encouraged by the LTA. Only the hospitals implementing the Correct Site Surgery SOP were invited to take part in the survey, because at the time the culture survey was administered internationally, the ‘Medication Reconciliation’ hospitals had not yet been recruited in Germany.

Some of the participating hospitals were keen to administer the survey a second time in order to compare the results.

All hospitals had concerns regarding data protection and had to obtain consent from the works council and management approval. Therefore the last section of the questionnaire (Section H: Background Information) had to be modified in a way that made identification of an responder impossible.

Five of the 16 CSS hospitals participated in the first survey and a total of 1,083 questionnaires were completed (response rate of approximately 30%). In the second survey three of these five hospitals participated and 252 questionnaires were completed.

For the summary of culture survey findings from Germany, see Annex 14.

**The Netherlands**

Dutch hospital participation in the culture survey was not mandatory. Four hospitals completed the culture survey in 2010 and after SOP implementation in 2011. They adapted the culture survey as an implementation intervention to create awareness among healthcare professionals.
Table 5 shows the distributed and returned questionnaires and response rates.

<table>
<thead>
<tr>
<th>Before SOP implementation</th>
<th>After SOP implementation</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Distributed &amp; returned</td>
</tr>
<tr>
<td></td>
<td>questionnaires</td>
</tr>
<tr>
<td>Hospital A</td>
<td>12/37</td>
</tr>
<tr>
<td>Hospital B</td>
<td>12/40</td>
</tr>
<tr>
<td>Hospital C</td>
<td>23/26</td>
</tr>
<tr>
<td>Hospital D</td>
<td>80/150</td>
</tr>
<tr>
<td>Total</td>
<td>207/403</td>
</tr>
</tbody>
</table>

No particular challenges were encountered in evaluating the patient safety culture in participating hospitals. After SOP implementation, hospitals scored higher on most Patient Safety Culture Composites. On the three composites of communication openness, feedback and communication about error, and frequency of events reported, hospitals had low scores. Before and after SOP implementation, management support for patient safety was unchanged.

To define drivers for patient safety, positively worded items, which about 75% of respondents endorsed by answering “Agree/Strongly agree,” or “Most of the time/Always”, were identified as strengths. The Netherlands did not utilize other mechanisms to evaluate the patient safety culture in the 15 participating hospitals, but there are many patient safety activities and projects in Dutch hospitals.

**Singapore**

The Singaporean LTA facilitated the AHRQ culture survey by asking all participating hospitals to complete the questionnaire in March 2010. Overall, there were not many challenges encountered in requiring hospitals to complete the survey. Singapore obtained a total of 18,204 respondents, a 77% overall response rate.

The overall survey results for Singapore hospitals showed that they were the most positive on seven of the 12 composites, though they were the least positive on two of the composites, namely:

1. non-punitive response to error (27% as compared to the highest score of 62% in the Netherlands); and
2. communication openness (44% as compared to the highest score of 77% in the Netherlands).

In addition, Singapore tied with United Kingdom for the lowest score of 36% for staffing. Nonetheless, Singapore hospitals had the highest average composite score of 58% with the lowest score being 46% by German hospitals. In terms of the average percentage respondents reporting one or more events, Singapore had the lowest reporting culture at 37%, while the Netherlands had the highest at 78%.

It would seem that the drivers for Singapore’s patient safety culture lie in its strong organizational learning-continuous improvement culture with a score of 81%, management support for patient safety with a score of 75%, and teamwork across units with a score of 62%.

The Singaporean LTA is currently working to encourage a culture of reporting mishaps by issuing patient safety alerts with each report so that institutions see the value in reporting as the reports are used to help other institutions avoid the same errors. Every six months, a sharing session is organized so institutions can learn from each error report and treat reporting as a learning opportunity rather than a punitive event.

**Trinidad & Tobago**

The aim of the AHRQ culture survey was to gain an understanding of hospital priorities and strategies regarding surgical safety. All five hospitals were required to complete the survey, and all five submitted completed survey forms to the Directorate, Health Services Quality Management, of the Ministry of Health. Only one survey was conducted in May 2012 at each of the five participating hospitals.
2. Context survey of Medication Reconciliation

The context for implementation of the Med Rec SOP in the participating Member States is very different and its implementation varies greatly in terms of numbers of hospitals, teams and support.

Box 2: The context survey

At the September 2011 High 5s Steering Group meeting, it was agreed that it would be useful to examine the context of the implementation of the Med Rec SOP in those Member States implementing the SOP—Australia, France, Germany and the Netherlands.

The objective of the context survey was to identify:
- the current landscape of Med Rec in the individual Member States;
- barriers and drivers affecting implementation in the participating Member States;
- successful tools and resources which could be shared globally.

Information was collected using an online survey.

The context survey focused on identifying barriers encountered by the participating Member States, as well as the role of external drivers and supports such as accreditation requirements and national policies. Despite many differences in the context of implementation, most Member States, reported similar barriers and facilitators when implementing the SOP.

The most significant barriers to Med Rec implementation reported by all Member States were a lack of staff and financial resources. The most significant facilitators included the presence of an accreditation system, pharmaceutical reforms and state policies, standards of practice for Med Rec, and internal leadership/external ambassadors for Med Rec within a hospital. A variety of health-care professionals have been involved in creating the ‘Best Possible Medication History’ (BPMH) in the different Member States.

Although the High 5s SOPs were expected to be implemented in acute care settings, there were efforts to extend Med Rec SOP implementation across the system in several Member States. Canada’s experience in this area suggests that there is a real need for improved communication and medication reconciliation from each health-care setting through to home care. There are many differences of health-care systems across the participating Member States. For example, in Germany, there are few, if any, pharmacists in hospitals, which makes implementation of this SOP challenging, while in the Netherlands a link with community pharmacy dispensing databases supports effective communication about medications. In light of such differences it is particularly commendable that four Member States have chosen to implement this SOP.

Limitations

Participating Member States and hospitals across and within Member States are in different stages of implementation of the Med Rec SOP and operate within very different health-care systems. Within the context survey, it was difficult to differentiate Med Rec activities implemented in health-care settings outside the High 5s Project and those within the High 5s Project. The survey results reflect a point in time and not a continuous timeline.

Some general considerations

The primary objective of the context survey was to provide information on the context in which the High 5s Med Rec SOP was implemented to understand what external factors were influencing the uptake of Med Rec in the different Member States.

This information was collected in addition to the quantitative performance data and hospital implementation experience data collection. The survey did not attempt to correlate hospital results and accreditation performance, but rather to determine whether sharing standards, resources, and experiences learned from the context survey could assist LTA’s to implement the SOP more effectively.

Further, best practice tools and resources obtained from the implementing teams of some LTAs are available to be shared among the other participating LTAs and hospitals. For example, Canadian tools which are part of the High 5s toolkit are uploaded onto the High 5s Wiki portal as they are updated by ISMP Canada. Member States with relevant Med Rec policies or accreditation standards were able to share policy-related information for the benefit of other Member States.
2.1. Medication Reconciliation context survey findings in Member States

Australia

Major drivers for Australian hospitals to participate in the High 5s Project included national and state policy, public hospital pharmaceutical reforms, and National Safety and Quality Health Service Standards. The existing Australian Pharmaceutical Advisory Council Guiding principles to achieve continuity of medication management, 2005 (Guiding principles) aligned with the High 5s Med Rec SOP. Australian states and territories implementing hospital pharmaceutical reforms required participating hospitals to implement the Guiding principles and report performance measure data. In some states, there were incentives for hospitals to perform Med Rec.

National Safety and Quality Health Service Standards, 2011, contain two criteria relating to medication reconciliation. In January 2013, it became mandatory for all hospitals to be assessed against these standards as part of the new Australian Health Service Safety and Quality Accreditation scheme.

Clinical pharmacy practice is well established in Australia, and professional practice standards for medication reconciliation have been available since 2007. Medication reconciliation in hospitals is almost exclusively performed by pharmacists. The increasing number of pharmacists employed in emergency departments has contributed to the spread of medication reconciliation in Australian hospitals.

The Australian Commission:

- continues to develop resource materials to support the spread of medication reconciliation;
- works with stakeholder organisations to gain multi-disciplinary buy in; and
- advocates improved access to patient medication information through information systems such as the Personally Controlled Electronic Health Record (PCEHR).

France

Medication reconciliation is not one of the requirements of the certification/accreditation procedure of the National Authority for Health. However, it is mandatory for all health-care organizations to be fully involved in medication reconciliation. The certification/accreditation guidelines encourage hospitals to implement several practices that should eventually evolve towards a more generalized implementation of medication reconciliation. For example, the management system for pharmaceutical care should take into account the need to ensure continuity of medication reconciliation from admission to discharge, including internal transfers. Patients should be encouraged to pass on information regarding their medications to health-care professionals on admission and every time they receive care. The latter depends on how proactive a patient is.

The national guidelines for drug management are consistent with the certification/accreditation procedure of the National Authority for Health. The safety of drug therapy, in particular, regarding the prevention of medication errors has become a major focus of national policy. A February 2012 circular recommends understanding the therapeutic management of the patient as a process and calls on focusing on high risk patients and high risk medication, as well as addressing the prevention of ‘never-events’ related to drugs and organizations.

Germany

Medication reconciliation is a relatively new activity in Germany which, prior to involvement in the High 5s Project, has not been systematically implemented and evaluated in German health-care facilities. Medication safety is a key priority for the Federal Ministry of Health, as evidenced by its issuance of national “action plans for the improvement of medication safety in Germany” for the years 2008-2009 and 2010-2012. These action plans list specific medication safety measures, including Med Rec elements, to be developed and tested in these time frames. In addition, the German Society of Hospital Pharmacists has published a statement in which Med Rec is described as a practice of pharmacists to support physicians and nurses.

In Germany, hospitals have a legal obligation to introduce and use a quality management system. Additionally hospitals can voluntarily be accredited according to a large variety of programmes. The degree to which medication safety standards are included in the quality management systems or certification criteria varies by programme.
The Netherlands

The Dutch Government developed a National Patient Safety Programme (2008-2012) to support hospitals in obtaining a certified system by December 2012. Hospitals are required to implement ten improvement themes to reduce preventable harm and reach the theme goals. Prevention of medication errors through medication reconciliation for elective patients and at discharge was one of those themes. The Netherlands have a national guideline for medication accuracy at transitions in care which recommends a current medication history within 24 hours for every patient at every transition. The Med Rec SOP supports the implementation of the national guideline for medication accuracy at transitions in care (2008). The application of the guideline of the Dutch Inspectorate of Health has been mandatory since January 2011. In addition, health insurance companies are playing a greater role in negotiations with hospitals about safe care for clients.

There is an accreditation and/or certification initiative overseen by the national patient safety programme (2008-2012). Another accreditation body is the Netherlands Institute for Accreditation in Healthcare (NIAZ); however, hospitals are not required to be accredited. The first (non-High 5s) hospital was accredited by Joint Commission International (JCI) in 2012 and the second in 2013.

3. Context survey of Correct Site Surgery

The context survey on Correct Site Surgery was conducted to better understand the existing supporting structures for this SOP. Two Member States returned completed CSS context surveys. These were France and Germany.

Key questions on the CSS context survey addressed reasons for selecting the CSS SOP, formal expectations for CSS-related procedures which existed prior to the introduction of the High 5s Project, requirements for reporting events outside of the hospital, and surgical safety requirements of accreditation systems.

Germany and France selected CSS as one of the SOPs to implement because of an increased awareness of the topic of wrong site surgery resulting from the WHO Safe Surgery campaign and expert/media exposure. In Germany, more and more hospitals started to implement surgical safety checklists and the responsible quality officers in the hospitals were looking to exchange implementation experiences and advice. In line with this, hospitals interested in joining the High 5s Project were asked which SOPs they were interested in, and CSS was the top topic chosen. In France, health-care professions were putting an increased emphasis on serious adverse events.

While there were no formal expectations of having a surgical checklist in operating theatres in Germany, a national surgical safety checklist, inspired by the WHO Surgical Safety Checklist, was implemented in France and mandated in 2010. This checklist also became a requirement for accreditation in France. In Germany, implementation of surgical checklists was driven by published recommendations by the Coalition for Patient Safety and various scientific and medical societies.

In Germany, while it is not mandatory to report events outside of hospitals, hospitals can voluntarily report ‘no harm’ events and occasionally harm-events to inter-institutional Critical Incident Reporting Systems databases. It is mandatory in France to report any serious adverse events and voluntary to report near misses.

France has a universal accreditation system. Pre-operative verification and final time-out for any surgery are required as part of the mandated process. There were no financial incentives offered.
in either Member State for quality improvement. However, negative consequences such as conditional accreditation, was associated with poor performance in France. In Germany, various certification programmes exist for hospitals, and each one applies different criteria relating to surgical safety.

4. Interim findings

4.1 Summary of qualitative findings

Implementation Status

The full scope of implementation of an SOP is defined as follows:

1. all of the required steps in the process are standardized;
2. all of the locations where those steps are to be put into effect are involved;
3. the population of patients to which those steps will apply (the eligible population) is involved.

A hospital is considered to be at ‘Full implementation’ when it has put all required components of the SOP into effect across all eligible locations and patient populations within the hospital. Once the SOP has been fully implemented, the degree to which it has been successfully implemented is determined primarily through hospital’s self-reporting the experience (i.e., the ‘Implementation Experience’ questionnaire) and through the High 5s performance measure results.

For purposes of analyzing and reporting evaluation data, the count of hospitals reporting their level of implementation at ‘Full implementation’ is based upon their self-reported status at the time each quarterly report is generated (typically two weeks prior to the release of the report).

To date, six Member States have been implementing either the Correct Site Surgery SOP or the Medication Reconciliation SOP or both. One Member State initiated implementation of the Concentrated Injectables SOP in 2013. Implementation of this SOP was terminated because the United Kingdom withdrew from the High 5s Project. Table 6 shows the implementation status of the SOPs.

Table 6: Implementation status reported by LTAs

<table>
<thead>
<tr>
<th>Standard Operating Protocol</th>
<th>No. of Member States implementing SOP</th>
<th>No. of hospitals indicating ‘Full Implementation’</th>
<th>No. of hospitals indicating ‘Not Full Implementation’</th>
<th>No. of hospitals with no indication of Implementation status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Correct Site Surgery</td>
<td>4</td>
<td>34</td>
<td>24</td>
<td>9</td>
</tr>
<tr>
<td>Medication Reconciliation</td>
<td>5</td>
<td>47</td>
<td>11</td>
<td>34</td>
</tr>
<tr>
<td>Concentrated Injectables</td>
<td>1</td>
<td>16</td>
<td>16</td>
<td>0</td>
</tr>
</tbody>
</table>

The primary reasons reported for not having achieved full SOP implementation in all participating hospitals and for both SOPs have been:

- insufficient resources;
- lack of existing policies;
- competing priorities;
- inadequate support from leadership; and
- resistance to change.

Qualitative findings on Correct Site Surgery

Oversight of SOP implementation

The majority of hospitals assembled a multidisciplinary group as a means to implement the SOP. Membership of the oversight group typically included nurses (operating theater nurses, anesthesia nurses, nurses from various surgical subspecialties, nursing directors), surgeons, physicians (various specialties), patient safety officers, quality directors, quality assurance officers and other quality personnel, controllers, risk managers, department chairs/chefs of services/directors of care, hospital administrators,
consultants, secretaries, and other administrative personnel. Frequently, a principle leader in the oversight group was identified as the individual who guided the SOP implementation process. In addition, more than half of hospitals indicated that they had role models or “champions” who assisted in the implementation process.

The most common challenge or barrier to assembling the oversight group was the lack of resources (funding and/or time). Resistance to change and staff buy-in were also frequently cited as significant barriers. Other barriers noted by participating hospitals included poor communication; lack of organizational leadership buy-in/support, and lack of department leadership buy-in/support. One participating hospital noted that the data collection and validation processes are labor intensive and required at least one dedicated full-time employee. Another hospital described difficulty in scheduling meetings, especially when physicians and surgeons were involved.

To overcome these barriers, hospitals employed the following strategies:

- improving communication;
- obtaining leadership support;
- providing training/education on the SOP;
- developing strategies to manage change, involve staff, improve the safety culture, increase communication, and provide recognition; and
- requesting assistance from the LTA.

Risk assessment
Half of the participating hospitals reported that they conducted a risk assessment as part of the SOP implementation process. Of those that conducted a risk assessment, the majority indicated that they followed the process described in the SOP materials. Most hospitals reported that the risk assessment process helped them identify potential areas for breakdown and allowed them to implement controls, warnings or protections to minimize identified problem areas. Through the risk assessment process, one hospital identified emergency cases and patients in non-surgical departments as potential areas for breakdown/failure. Controls were then put in place to include a monthly check of operating room cases, use of pre-operative checklists, and instructions that only patients with a completed checklist can enter the operating room theatre. Other hospitals developed printed guides and posters to remind staff to adhere to the SOP, and implemented new processes for administrative staff (as well as surgeons) to verify the operating room log.

Lack of staff involvement, resistance to change, lack of experience in conducting risk assessments, and lack of resources were the primary barriers to conducting risk assessments in approximately half of the hospitals. Others claimed that the process was already implemented, hospitals were already aware of their risks, the event was considered too rare to make it necessary, or they did not think that it was a requirement to conduct a risk assessment.

Pilot testing
Almost all of the hospitals reported that pilot testing was conducted prior to full SOP implementation. Pilot testing was conducted to help hospitals determine the feasibility and impact of SOP implementation on a small scale before widespread implementation occurred. Pilot tests were carried out in several units/wards including the operating theatre/surgical ward and orthopedic surgery, thoracic surgery, and gynecology services as well as other general wards. The major challenges and barriers to conducting pilot tests were resistance to change, data collection burden, and lack of resources. To address these barriers, hospitals increased communication, enlisted staff and leadership support, and provided education/training. Despite challenges, the majority of hospitals that conducted pilot testing reported that it positively impacted related activities and patient care.

Hospitals noted that the pilot tests increased awareness of safety before the surgical operation, assisted in encouraging pre-surgical operative site-marking, and increased attention to verifying patient identity.

Spread methodology
Approximately half of the responding hospitals implemented the SOP sequentially in various hospital locations. The other half implemented the SOP concurrently in all sites. Three quarters of responding hospitals integrated the SOP process into or added it to existing systems processes. Lack of staff buy-in, resistance to change, lack of resources and data collection burden were frequently cited barriers to spreading SOP implementation. Increased communication, training and education on the SOP, and leadership support were the most commonly employed strategies to address these barriers. One hospital reported...
that the project was discussed in the medical commission, and this led to additional resource allocation for the project. Another hospital provided continued training on the checklist procedure, conducted audits, and utilized the checklist training kit. Still some indicated that, despite efforts, the barriers and challenges continued to be a struggle.

High 5s Project information has been most commonly shared during department and project-specific meetings. Staff feedback has often been solicited directly by High 5s project coordinators. Most hospitals reported some formal acknowledgement of staff members that actively participated in the implementation of the SOP. Recognition often occurred at project meetings, grand rounds and in printed materials such as newsletters.

Evaluation
Approximately three quarters of responding hospitals indicated that they experienced challenges and barriers in implementing the performance measures. The primary barriers were lack of resources (funding and time) to gather the data, difficulty understanding the performance measure definitions and/or methodology, and lack of staff buy-in. For this reason, many hospitals reported that they were not using the prescribed High 5s data quality methodology.

Strategies to address barriers included improved communication with staff that had access to needed data, engaging staff, and enlisting the help and guidance of those in leadership positions. Additional steps taken to evaluate SOP implementation included observation audits, development of training programmes, computerized checklists, and development of databases to assist in the extraction of performance measure data.
One hospital noted, “With the High 5s SOP, between 2010 and 2012, we were able to prevent 12 potential events in pre-operative patients. We analyzed these events and found that nine errors occurred during surgical consultation, two errors occurred during site marking in the surgical unit and one error from the primary care physician (wrong side written on the letter to the surgeon).”

Strategies for maintenance and improvement
Most of the hospitals reported that they had been engaging in regular and ongoing monitoring of key aspects and activities related to the SOP. Hospitals were performing data quality monitoring, conducting audits (chart and electronic), soliciting information from staff, and engaging in project oversight meetings. Many hospitals identified opportunities for improvement that included better involvement of staff, more training, better definition of the site-marking procedure, simplification of the checklist, IT system enhancements, improved communication with surgeons, and revision of the time-out process. In many cases, opportunities for improvement had been identified but not resolved. Many hospitals reported ‘drifting’ from the intended SOP as time went on. The drifting was identified through data quality monitoring. To address drifting, hospitals provided increased educational/training opportunities and encouraged participation in project-related meetings.

Qualitative findings on Medication Reconciliation
Oversight of SOP implementation
Hospitals which responded to this issue reported that they had assembled an oversight group to help implement the SOP. Oversight groups usually consisted of pharmacists, nurses, physicians, quality managers, and a variety of other staff working in the patient safety area. The majority of respondents said that the principal leader of their oversight group was a pharmacist or pharmacy manager. Lack of resources (funding/time) was the most common barrier to assembling the oversight group. More effective communication, training and education on the SOP, and securing leadership “buy-in” were common strategies to address the challenges associated with assembly of an oversight group. Several hospitals noted the importance of expanding participation of key stakeholders beyond the pharmacy.

Risk assessment
Less than half of responding hospitals completed a risk assessment. The primary reason for not conducting a risk assessment was lack of resources (time and funding). In addition, risk assessment was considered a low priority activity for some hospitals. These hospitals already had processes in place for medication reconciliation, so found it unnecessary. However, those who did conduct
A risk assessment reported that it was beneficial in helping to identify potential areas for breakdown. In response to the risk assessment, a number of hospitals implemented controls, warnings or protections to minimize the potential for breakdown or failure. Examples of controls and protections that were implemented as a result of a risk assessment include improved communication through the hospital quality committee and the medication management committee, multi-disciplinary events analysis, and monthly pharmacist meetings to implement actions and monitor and review progress.

Pilot testing
Almost all of the hospitals completing the questionnaire conducted a pilot test of the SOP. For those that did not, lack of resources, data collection burden, lack of organizational support and resistance to change were cited as the most common barriers. Pilot tests occurred in a variety of units, including geriatrics, internal medicine, rheumatology, emergency and cardiac care. Routine auditing, use of independent observers, development of specific forms and procedures, and training and education on the SOP were the most common methods hospitals used to assure the consistency, timeliness and accuracy of the implementation. Most hospitals reported that implementation of the SOP had a positive impact on related activities and on patient care. Increased communication and more collaboration among hospitals, physicians and community health-care providers was a result of the pilot test noted by many hospitals. Many pharmacists indicated that they enjoyed being more directly involved in patient care and that implementation of the SOP improved the visibility, importance and understanding of the role of the pharmacist in the patient care process. Although some indicated that implementation of the SOP increased staff workload, most reported that it was a positive experience that led to improved electronic prescribing systems, new patient safety projects related to medication reconciliation, and funding for additional studies.

Spread methodology
Approximately half of the respondents implemented the SOP sequentially in their hospitals. Many noted that the SOP was just an extension of their existing medication reconciliation process. Several challenges to implementation were noted. These included lack of resources, data collection burden, insufficient communication, and resistance to change. To overcome these barriers, hospitals most frequently provided training and education, increased communication, involved staff in the process, and provided greater leadership support. Despite these efforts, several hospitals noted that many barriers still existed to successful SOP implementation.

High 5s Project information has been most commonly shared during department and project-specific meetings. Staff feedback was often solicited directly by High 5s Project coordinators. Most hospitals reported some formal acknowledgement of staff members who actively participated in the implementation of the SOP. Recognition often occurred at project meetings and grand rounds and in printed materials such as newsletters.

Evaluation
More than three quarters of responding hospitals indicated that they experienced challenges or barriers when implementing the SOP performance measures. The primary barriers/challenges were lack of resources dedicated to evaluation, lack of staff to perform the required independent observer role, lack of understanding/clarity regarding the performance measure definitions and methodology, and difficulty accessing medical records for data collection purposes. Some hospitals also experienced technical issues with sampling and achievement of high inter-rater reliability. In addition, some hospitals noted that nurses, physicians and patients were dissatisfied with the process because patients were asked twice about current medications with no clear advantage. One hospital noted that quality improvement, alone, is insufficient to motivate behavioral change. To address these barriers, most hospitals attempted to better engage staff and provide training and educational support on the evaluation component of the project. Others provided additional resources and staff such as a dedicated pharmacist to work on the project and assist with timely data collection. One hospital utilized students for data collection and maintained a log of clinical scenarios that are encountered and are outside the realm of the SOP.

Many hospitals have taken additional steps to evaluate the implementation of the SOP. These include analysis of interventions by pharmacists in response to unintentional medication discrepancies, analysis of the number of errors detected through timely medication reconciliation,
and attempts to build a business case for an extended-hours model to present to hospital executives and clinical staff. One hospital noted that, in the future, they intend to measure patient and physician satisfaction with the medication reconciliation process.

**Strategies for maintenance and improvement**

Participating hospitals took many different approaches to monitor the implementation process, including data quality monitoring, project oversight meetings, audits (direct observation and chart review), soliciting information from staff, and participation in LTA interviews. Several hospitals indicated that they continue to struggle with concurrent data collection and are several months behind.

Hospitals provided examples of improvement strategies that included development of data collection forms, development of written instructions/processes, training for data collection, and increasing documentation required of pharmacy staff. Through the auditing process, many hospitals noted “drifting” from the intended SOP process. To address drifting, additional project meetings occurred and supplemental education/training was made available to staff.

**Summary of qualitative findings: successes and lessons learned**

At this stage of the High 5s Project, it is clear that it is possible to implement specific patient safety protocols with some degree of standardization across multiple hospitals and multiple Member States.

Participating hospitals were able to successfully implement the key components of both the CSS and Med Rec SOPs. However, the SOPs could not be implemented as “one-size-fits-all” solutions. Some local customization of each protocol was necessary. This local customization (at both the country-level and hospital-level) was essential to secure initial buy-in. Customization was equally important for sustaining post-implementation changes.

Analysis of project data and the qualitative experiences of project participants will be used to produce a final set of SOPs that highlight key components of the SOP, as well as offering recommendations for local customization. Interim lessons learned are summarized below.

**A. General lessons learned**

- Data collection is burdensome. Many organizations have struggled to identify adequate resources for data collection. Very few organizations added resources for the High 5s Project, thus providing little earmarked staff time for SOP implementation, much less the associated data collection activities.
- Data collection and measurement are absolutely necessary for successful implementation (i.e., they helped demonstrate the need for SOP implementation, they provided the implementation team with a tool for demonstrating the impact of implementation efforts, and the act of data collection and feedback of measure results helped hospitals maintain attention on the patient safety area).
- Resistance to change (staff and leadership) is a challenge to implementation.
- Ongoing communication, education, and training are important to achieve and sustain compliance with the SOPs.
- Senior-level hospital leadership and support is critical to the full and successful implementation of the SOPs.
- On-site champions are critical to successful implementation.
- The exchange of information among hospitals (within Member States) and among LTAs (across Member States) helped to build and maintain enthusiasm for SOP implementation.

**B. Med Rec SOP**

- Implementation of this SOP was most successful when a pharmacist (or pharmacy staff) was available to perform the medication reconciliation.
- Pharmacists and pharmacy technicians tended to produce timely and accurate BPMHs.
- Limited pharmacy resources were a major limiting factor for implementation.
- Additional performance measures (or different measures) were useful. In particular, measures that identified the number of medication discrepancies within 48 hours of admission, and those discrepancies unresolved at 48 hours from admission, were used to demonstrate the importance of the SOP to clinicians and decision makers.
C. CSS SOP

- Surgeon resistance was a common challenge to SOP implementation. Thus, placing a surgeon in the role of SOP champion tended to facilitate implementation.
- Concerns that patients may be resistant to site marking were unfounded.
- In the absence of specific direction from the Ministry of Health, the High 5s checklists were not adopted “as-is.” Successful and sustained implementation required customization of the checklist so that it could be incorporated into existing tools (i.e., once adopted, it is much more difficult to terminate implementation if the checklist is built into existing processes).

4.2. Member State implementation experiences and qualitative findings

Australia

LTA role in implementation

Hospitals were recruited through an expression of interest process, and 18 health services were selected to participate. The project commenced in January 2010 with the first teleconference which was attended by over 60 participants from the 18 sites. Teleconferences continued to be held monthly throughout the first two years. In year three, they were reduced to every second month.

A two-day train-the-trainer workshop was held in Sydney on 19-20 April 2010 and was attended by 64 participants from the 18 health services. A second two-day workshop was conducted in October 2010 and two further one-day workshops were conducted in 2011. Several webinars were also held to provide further detail on the project methodology. A table of the activities conducted for the Australian sites is available in Annex 7. Copies of all presentations and materials used were placed on the Australian page of the High 5s website. The sites were supported by a dedicated project officer.

Resources

The Australian Commission developed a number of resources to assist hospitals to implement the SOP. These included:

- A national Medication Management Plan (MMP) form to record the Best Possible Medication Histories (BPMH), and document the reconciliation process, discrepancies and their resolution;
- Educational materials for health-care professionals using the MATCH UP Medicines theme;
- Information for consumers.

Examples of the resources are available in Annex 9.

Evaluation

Implementation experience was evaluated through the use of the implementation experience questionnaire, hospital interviews, and direct feedback from sites (see Annex 8). All sites were requested to complete the implementation questionnaire as per the schedule set by the Steering Group. Response rates were high.

Five hospitals were identified to participate in LTA implementation interviews. A mix of hospitals was selected from four states: a major teaching hospital, a private hospital, two metropolitan hospitals and a rural and regional health service (nine hospitals). The first round of interviews was conducted in 2011.

Challenges encountered

Ten out of 11 health services responding to the implementation experience questionnaire in June 2012 had implemented all the steps in the medication reconciliation (Med Rec) process; five health services had yet to spread the process to all locations. Insufficient resources and competing priorities were the most frequently identified reasons for not implementing the SOP in all locations.

Eight sites identified lack of resources as a barrier to implementing the SOP. Hospitals said they underestimated the resources they would need, especially for education and the evaluation process (the independent observer role, collection of performance measure data, and the event analysis). The burden of the data collection for performance measures MR 2-4 was an ongoing issue for all sites. Lack of resources for data collection delayed the start of data collection at several sites.

The five sites interviewed indicated that additional resources were needed to implement and sustain the SOP. This was particularly the case for hospitals that introduced the process in pilot wards and then moved to spread the process throughout the facility. Hospitals opting to employ nursing and medical...
staff to take the BPMH found they had to allocate extensive time to initial and ongoing training.

Resistance of health-care professionals other than pharmacists to engage in the process was another challenge for Australian hospitals. Prior to commencement of the High 5s Project, several hospitals had an existing medication reconciliation process in place that had been provided by pharmacy staff. These hospitals had a culture of medication reconciliation being “pharmacy business”. The hospitals experienced challenges on weekends and after hours when pharmacists were unavailable and when pharmacists were on leave.

In those hospitals where attempts were made to involve nursing staff and training was provided, there was resistance among the nursing staff to take on increased activities as well as a lack of confidence in their ability to participate in the process – it was seen as ‘not their job’.

Two examples of barriers to Med Rec implementation are presented in Box 3.

Box 3: Barriers to Med Rec SOP implementation in Australian hospitals

**Hospital 1.** Eight emergency department registered nurse “Pioneers” were trained to take a BPMH and conduct medication reconciliation however one year later these ‘Pioneers’ were not performing these processes, anecdotally because of time constraints.

**Hospital 2.** Nursing staff were not confident in conducting medication reconciliation on their own despite the training provided. Barriers to successful implementation by nursing staff were cited as time constraints, inadequate staff to perform the process, and lack of in-depth pharmaceutical knowledge.

Initially, independent observers had difficulty with understanding the performance measures and measuring consistently. Tightening the definitions of the types of discrepancies, providing additional training, and creation of a list of examples helped overcome this problem.

Other challenges experienced in implementing the SOP were those commonly experienced when implementing quality improvement projects:

- competing priorities in the organization;
- lack of support from hospital leaders;
- loss or transfer of key personnel;
- initial lack of clinician buy-in; and
- the introduction of an electronic health record that did not support the SOP.

‘Drivers’ of patient safety

Sites utilised a number of strategies to overcome the barriers to implementing the SOP and effect change in their organizations.

a) Engaging staff and obtaining ‘buy-in’.

Hospitals actively engaged staff in the project. All sites assembled a project oversight group. All groups included pharmacists and most included nurses. Doctors, quality and safety personnel, educators, and hospital leaders also participated. Nine of the 11 health services designated at least one role model or champion from each discipline involved in SOP related activities. Most hospitals developed a communication plan and used a variety of methods to communicate with staff about the project. These included regular feedback on performance measures and periodic reports on specific aspects of the project.

b) Training and education

Educating staff about the medication reconciliation SOP and training staff on taking a BPMH and reconciling medicines were key to the successful implementation of the SOP. Hospitals devoted considerable resources to training and employed a number of different approaches to education. Two examples of training and education on taking a BPMH are presented in Box 4.
c) Leadership support
Securing leadership support was cited by several sites as one of the key strategies they employed for overcoming the challenges and barriers experienced in trying to spread the SOP throughout the organisation.

d) Actions taken based on data
Data was used in a number of ways by the different sites including:
- obtaining buy-in to the project and engaging staff outside the pharmacy, including senior clinicians and the hospital executive;
- building a business case to extend the hours that medication reconciliation is performed;
- showcasing the quality of the process performed by staff and addressing any training needs identified;
- identifying gaps in processes and addressing these gaps; and
- demonstrating the hospital’s compliance with the National Safety and Quality Health Service (NSQHS) Standards for accreditation purposes.

Two examples of positive outcomes based on data are presented in Box 5.

Box 4: Training and education on taking a BPMH in Australian hospitals

**Hospital 3** introduced medication history taking using BPMH principles as part of medical intern orientation each year, followed by more focused case-based workshops on medication matching for interns, residents and registrars.

**Hospital 4** developed a simulation exercise to train clinicians (doctors, nurses and pharmacists) and students to take a BPMH. The hospital had access to a simulation ward and experienced facilitators who worked with the High 5s team at the hospital to develop the simulation exercise. A number of different scenarios were developed, and the participants were able to access different sources of information during the exercise, such as calling the patient’s community pharmacist – played by one of the hospital pharmacists. The use of simulation has the advantage of providing a safe environment for clinicians to practice their skills with no risk to patient care. It also allows participants to receive immediate feedback and to learn from others, including the patients.

Box 5: Positive outcomes based on data in Australian hospitals

**Hospital 3**. The dissemination of Med Rec performance measure results from the top levels in the hospital down through the Patient Safety Sub-Committee, including to hospital executives, has resulted in executive engagement.

**Hospital 5** used the performance measure data to restructure their clinical pharmacy duties by changing to a team-based structure and increasing the number of BPMHs completed and medication reconciliations documented.

e) Effect on patient care
About half the hospitals indicated that implementation of the SOP had an impact on related or interacting activities and on patient care. Most were considered positive and included:
- having a standard and improved protocol for medication reconciliation;
- improving processes through raising awareness of the processes of obtaining a BPMH, reconciling medicines and following up on discrepancies; and
- using data collected to plan interventions to follow up on discrepancies.

Implementation Surprises
The first surprise was the realisation by the sites that the SOP could not be implemented with existing resources and additional resources would be required to perform the medication reconciliation process and spread the process to a greater number of patients. Several hospitals were able to secure funding to employ additional pharmacists to introduce clinical pharmacy services to Emergency Departments and extend clinical pharmacy hours. Box 6 presents two examples of pharmacist services that were extended over weekends.
Private hospitals experienced difficulty implementing the SOP, as their staffing and work practices differ from public hospitals. Pharmacy services are limited, and there are no junior medical staff. Another surprise was the time commitment required for education and training, particularly at those sites implementing a multidisciplinary approach to medication reconciliation. In addition, junior medical staff regularly rotate through a number of hospitals, requiring a new cohort to be trained every three months.

All sites were surprised that collection and management of the data for the performance measures and the event analysis was so burdensome. This resulted in delays in data collection and reporting, particularly when there were staff changes and departing staff were not replaced.

Several sites were surprised by the number of discrepancies identified by the independent observer that remained unresolved 48 hours after admission. Initially, up to as many as 53% of patients at these sites had unresolved discrepancies. Sometimes these discrepancies were still unresolved at the time of discharge, causing delays in discharge. Two additional performance measures were developed to enable hospitals to collect data on these discrepancies (see section 5.4.5).

The introduction of an electronic health record (EHR) in the ED in some hospitals that did not support the medication reconciliation SOP resulted in duplication of work and threatened the continuation of the project in one site. This was completely unexpected and highlighted the importance of project teams being aware of information technology initiatives and engaging with IT services when introducing system changes.

Lessons learned
Successful implementation of the medication reconciliation SOP hospital wide requires:

- recognition that medication reconciliation is a patient safety priority;
- senior leadership support;
- resources;
- ongoing training; and
- integration of the process with hospital information systems.

Further information technology systems on the Australian medication reconciliation resources is provided in Annex 9.

France

LTA role in implementation

Hospitals were recruited to implement the Correct Site Surgery (CSS) and Medication Reconciliation (Med Rec) SOPs through an expression of interest resulting in commitments by 18 health-care organizations – nine hospitals for each SOP – to participate in and initiate the Project in 2010. Subsequently, one hospital withdrew from the CSS project following the retirement of the initial surgical lead. Likewise, one hospital withdrew from Med Rec SOP implementation because of competing priorities, lack of leadership, and lack of resources. Monthly communication with the hospitals was done through teleconferences.

Currently, eight hospitals are participating in the implementation and evaluation of each SOP.

A. Correct Site Surgery SOP

Evaluation

Monthly performance data were edited in an Excel file created to generate numerators and denominators. A sample of 20 anonymous checklists per hospital was reviewed by the LTA every month. The LTA
provided monthly feedback to the project hospital coordinators through a conference call and a report. This feedback aimed to promote the correct use of the checklist and to help the hospital teams to define the actions required to maintain or improve reliable performance measurement.

Time Out observational audits were conducted in addition to the monthly questionnaire, interviews and event analyses required by the SOP.

Challenges encountered

During the first two years of the High 5s Project (2010-2011) the challenges included:

- Difficulties in integrating the High 5s Checklist into the WHO Surgical Safety Checklist. Promoted by HAS, the WHO Checklist became mandatory in the French accreditation/certification process in 2010. This checklist does not include an expectation of site-marking, while the High 5s Checklist does. With the support of CEPPRAL, each participating hospital team worked towards integrating the checklists, and developed an individualized checklist that included all mandatory SOP items, while still retaining other items and the format of their choice. Some health-care organizations (HCOs) had worked on the patient clinical pathway and had developed a booklet that included similar procedures already implemented before initiation of the High 5s Project.

- Surgical site marking as required by the CSS SOP was new to all hospital teams. Its implementation caused organizational challenges. The reluctance of some surgeons to comply with this requirement was one of the challenges.

- It took one year before CEPPRAL was able to transmit data from participating hospitals to the Collaborating Center. Only four HCOs had valid data in 2011, but all eight HCOs had valid data in 2012.

Disseminating information and lessons learned remains a challenge, as half of the participating hospitals are still at partial implementation. With regard to the four hospitals at full implementation, the lack of specific resources dedicated to the project has been a persisting challenge for evaluation — in terms of review of performance measure data and analysis of events — and communication. The duration of the project and the turnover of staff (e.g., key leaders, surgeons, risk managers) has also been a challenge.

For most hospitals, the main barriers encountered have been lack of time to form multidisciplinary teams; develop leadership; achieve cultural changes; and mobilize surgeons and anesthetists. In addition, challenges encountered by a few hospitals have included competing priorities and lack of logistic support.

‘Drivers’ of patient safety

Across all hospitals the following stood out as strong drivers for patient safety:

- performance measures (see example at Box 7);
- benchmarking; and
- generation of “success stories” (see example at Box 8).

Box 7: Communicating results of performance measures by two French hospitals

Because of the resistance of some surgeons to implementing site-marking and Time Outs as required in High 5s CSS SOP, and in an effort to motivate participation, two hospitals communicated on a monthly basis the results of performance measures for a given surgeon. This was done by e-mail (individual results) and also posted outside the operating theatre (anonymously).

Box 8: Success stories are about errors stopped during the pre-operative phase

Teams were requested to report errors not evaluated in the High 5s Project to the LTA which assessed their frequency and time of occurrence and identified the steps where the errors had been intercepted. Up to the present, about 20 success stories have been collected. Annex 13 presents the framework used to collect such success stories.
Implementation surprises and lessons learned

- Commitment of paramedical staff (technicians and administrative staff) to the High 5s Project.
- Rapid uptake of the High 5s checklist by substitute nurses working during summer period in ORs and on the wards (reported by one HCO).
- Streamlining the Time Out (e.g., through the use of key words) provided teams with better communication and valuable Time Out (1 HCO).
- About 70% of all errors were intercepted in the pre-operative verification phase.
- Site-marking was well-accepted by the patients, none refused the site-markings.
- A culture change was seen where members of the non-medical staff felt empowered to speak up when discrepancies arose.
- Great involvement of frontline staff; and
- Greater participation of patients in the verification procedures.

B. Medication Reconciliation

Challenges encountered

- The appropriation of the Med Rec protocol by various teams, as well as inadequate understanding of the performance measures.
- Resistance to the BPMH completion deadline of 24 hours after patient admission. Reconciliation at 48 hours was considered more realistic and reflected better the work and progress made by the hospitals.
- The burden of data collection. The workload associated with the implementation of this SOP was a challenge and resulted in the application of the process to a limited number of care units in six out of the eight participating hospitals.

Implementation surprises or successes

- The increased understanding of the importance of the problem achieved through demonstrating the magnitude of the discrepancies between the medications prescribed and those actually taken and of the potential harm to patients resulting from those discrepancies.
- The development of tools to measure the potential significance of discrepancies.
- The ability of some participating hospitals to streamline their medication management process in order to perform on a regular basis a proactive medication reconciliation in the emergency room.
- The development of information technology tools to follow medication administration and changes throughout the patient course within the hospital and at discharge.
- The development of a clinical pharmacology capacity integrated into the care units.

Germany

Summary how LTA evaluated implementation

The below description applies only to the Correct Site Surgery SOP because no evaluation of implementation experiences has yet been conducted for the Med Rec SOP.

The evaluation component of interviews and implementation questionnaires was conducted as a part of a diploma thesis.

In addition to the High 5 Project requirements, the German LTA analysed additional matters of interest. This was because the implementation questionnaire was felt to be rather general in scope. Thus, the German LTA included SOP-specific questions in the questionnaire which focused on challenges encountered when implementing the specific SOP process steps. The expanded questionnaire was administered from December 2011 to February 2012 by the project coordinators.
in all 16 project hospitals; responses were received from 11 hospitals.

Semi-structured interviews were conducted in March 2012 with the project coordinators in three hospitals to gain more detailed information about barriers, drivers and the resources required for implementation, as well as the potential for future sustainability. The interview findings were analysed using a systematic qualitative evaluation method (method of Meuser & Nagel).

Challenges encountered

The main challenges for the hospitals’ implementation processes were resistance to change, oncompliance of staff/management, and a lack of resources (funding/time). Hospitals described how individual “sceptics” could torpedo progress in implementation and that these sceptics needed to be addressed individually.

In relation to the SOP process steps, the German LTA identified the following main barriers: resistance to change; frontline staff not sufficiently acquainted with written standards on verification process; difficulties in adapting to new process; conflict about the preferred site mark; and team Time Out not taken seriously and not exemplified by role models.

Summary of findings

Key strategies for overcoming the challenges encountered in the implementation process were improved communication, involving staff/management, and training/education on the SOP. Essential strategies for overcoming barriers related to the SOP process steps were the provision of written instructions on the SOP, individual ‘pep talks’, retraining and further education, and adjustment of the checklist.

Important drivers in implementing the CSS SOP were the similar process design in different departments; employees having previous experience with standardization; interdisciplinary and cross-hierarchical composition of the implementation oversight group; regular meetings of the project work group; and the fact that clinical leaders used the checklist, thereby providing a role model function.

Important factors identified in the interviews included:

- intense support is necessary especially for the implementation start and training phases;
- pilot site testing paves the way and unlocks drivers for implementation; and
- substantial time and effort are needed for data management because there is variable checklist documentation quality.

There is no information available as to how the hospitals used the data from the implementation questionnaires.

On the LTA side, at the end of the project, recommendations will be derived from these results and published in order to produce guidance for other health care organisations planning on implementing similar processes.

Lessons learned

Some important lessons learned relating to the implementation process:

- feedback of some hospitals: “It’s not just a checklist, it has helped us to fundamentally change the way we look at our process”. Thus the systematic implementation of the SOP radiates to other not yet standardised processes;
- the local tailoring of the instruments (i.e., the checklists) was relevant to the acceptance by the participating hospitals;
- departments (and hospitals) ‘infect’ one another with enthusiasm in relation to the SOP; and
- acceptance for the new process and completing the checklists is generally higher in nursing staff than among physicians.

For more information see Annex 15.
The Netherlands

**Box 10: Two quotes about the High 5s Project**

- ‘Yes, it is proven that it works. It was a positive experience, because of the interaction with other participating hospitals and it really worked to go on with implementation activities and measurements.’
- ‘For our hospital it was clear that it would be easier to implement medication reconciliation when being part of an international project, because of the status.’

Fifteen Dutch Med Rec hospitals are participating. The first-group of 11 hospitals completed the qualitative structured and web-based implementation questionnaires starting six months after SOP implementation in the summer of 2010 to March 2011. In measuring the follow-up to these questionnaires, most hospitals showed no significant changes, except for a few hospitals which restarted performance measurement or other activities when expanding the SOP implementation hospital-wide. Hospitals where the implementation progress was strong, continued to spread their activities successfully and experienced a sustained implementation of the SOP to become part of daily practice.

**Challenges encountered**

All hospitals intend to expand the implementation of the SOP to internal transfers and discharges, and patients younger than 65. Full implementation of the SOP has varied according to hospital size.

‘The best implementation and sustainability strategy for our hospital is ‘to make it not a hospital pharmacy thing.’

Dutch hospital leader

All hospitals assembled oversight groups and created a work plan that was evaluated by the LTA. The main challenges and barriers to spreading results hospital-wide included limited resources (funding and time); insufficient communication; lack of access to medical records or incident management systems; lack of leadership/staff buy-in; and resistance to change. The principal leader of the implementation process in all participating hospitals was a hospital pharmacist. Most hospitals chose to start the implementation on a small scale first before spreading the SOP hospital wide.

**Implementation surprises and lessons learned**

The implementation questionnaires from 2010 to 2012 showed no differences in six hospitals after successful implementation. One hospital wrote that the SOP is continuously under review and minor changes have been made. With no changes in the SOP implementation status in 2012, the SOP was implemented in two additional departments. The increase in the number of patients being verified within 24 hours was because extra staff had been assigned to support medication reconciliation.

In one hospital, a hospital-wide medication multidisciplinary medication committee was established at the end of 2012, and all communication about Med Rec was processed through this committee. Another hospital noted that staff members did not always want to sign for the medication reconciliation done by the pharmacy. New doctors are now being trained on the SOP implementation process and in using the electronic prescribing system in this hospital. Another hospital plans to expand the SOP implementation to patients at discharge (i.e. beyond the targeted High 5 population) in 2013, provide feedback of data to the units, provide a further educational programme, and continue with the qualitative measurements according to the High 5s SOP.

Box 11 presents some important lessons learned.
The six Dutch hospitals interviewed highly recommend the Med Rec SOP developed by the High 5s Project. Some of their quotes include:

- implementation for other hospitals is not only recommended; it should be considered a necessity;
- we surely recommend implementation of this SOP to other hospitals. You can try to do this on your own, but you might encounter pitfalls;
- the exchange of knowledge and experience is very helpful; however, you still have to translate the SOP to your own local setting;
- most of the hospitals advice was to let the pharmacy technician interview patients: ‘…..it is proven that interviews done by pharmacy technicians are of better quality than when done by doctors’;
- the hospitals have no doubt about continuing to pursue the Med Rec SOP implementation hospital-wide. One of the hospital staff said: ‘Oh yes! We want the SOP for all patients and all departments for emergency patients, elective admissions and discharged patients’;
- the strategy of one hospital has been never to worry too much about resources and budgets. As shared by one of its staff, ‘You always need to be proactive. Just start and do instead of believing something is impossible’;
- the key lessons learned from one hospital is that it was important to keep most of the SOP implementation in-house so there is no need to depend on others or other systems nor to compete with projects of other departments;
- another hospital mentioned that quality improvement is not about implementing the SOP only. Showing the benefits to all stakeholders is needed to create support from others. Generating awareness and communication are the most important aspects of success, as many people are involved in the SOP implementation.

Trinidad and Tobago

LTA role in implementation

The Correct Site Surgery SOP was selected for implementation as a means of standardizing patient safety solutions within surgical units in selected hospitals. There were no formal expectations for correct site surgery procedures before introduction of the High 5s Project.

The LTA facilitated the piloting of this SOP at four of the participating hospitals during the latter half of 2012. The orthopaedic department was the chosen area for the pilot of the SOP.

There was a total of 27 849 surgical cases performed at all five participating hospitals in-patient surgical facilities in the year 2011. Of this number, there was an estimated one to two wrong site surgeries. Reporting of wrong site surgery is specified in the guidelines set out in the Ministry of Health’s Adverse Events Policy. This Policy was developed in collaboration with the Pan American Health Organization (PAHO) and issued by the Ministry of Health to both public and private health-care facilities in December 2011. Additionally, the WHO Surgical Safety Checklist was adopted and implemented at all public hospitals in 2010.

At each participating hospital, the project team leader completed the ‘Hospital Implementation Experience Questionnaire’ in collaboration with team members. The completed questionnaires were then forwarded to the Directorate Health Services Quality Management, Ministry of Health. Additionally, the team leader or representative reported on the status of implementation at the monthly High 5s team meeting. Meeting venues were rotated among the participating hospitals.
Challenges encountered

Major challenges common to all participating hospitals included the frequent turnover of team members, resistance to change by surgeons and nurses, lack of staff buy-in, and real or perceived implementation/data collection burden.

The support of the ‘Quality Improvement Unit’ staff at each hospital and regional health authority proved to be instrumental in partially addressing some of these challenges.

The United States of America

Challenges encountered

Even with automated data collection, a large commitment of time by participating hospital staff was needed to collect the data. The U.S.A. LTA found there was initial interest in the SOP; however, this was not enough once the burden on resource commitments became apparent.

Another complicating factor was confusion of purpose. Within the U.S.A., quality improvement efforts were already underway to work on this problem. The Joint Commission’s Center for Transforming Healthcare ran one in Rhode Island and produced materials and tool kits to combat the problem of wrong site surgery.

For the second round of recruitment of hospitals, the LTA tried to alleviate some of these issues. A modest hospital stipend is now being provided. In addition, the LTA is emphasizing the international aspects of the programme, as well as use the first hospital as a “mentor” hospital for the new hospitals interested in joining the Project.

4.3. Summary of event analysis findings

Overall interim findings

Five of the seven participating LTAs self-report that some in-country hospitals are completing event analyses. A number of participating hospitals and LTAs have used de-identified analysis reports and findings as the basis for case studies for teaching purposes.

A total of nine EA reports were submitted by LTAs to the Collaborating Centre in 2012 that related to 125 patients. Reports for three Concise and one Cluster analyses related to the Medication Reconciliation SOP (two of the patients reportedly experienced temporary harm and the other nine did not experience harm). Reports for one Concise and four Cluster analyses related to the Correct Site Surgery SOP (none of the 114 patients experienced harm).

Contributing factors identified by the hospitals included the following:

a. lack of effective oral/written communication, including inaccurate or incomplete documentation;

b. lack of effective teamwork;

c. individual provider/patient factors;

d. insufficient education and training;

e. lack of clarity related to policies and procedures.

It is anticipated that the number of event analysis reports submitted to the Collaborating Centre for analysis and reporting will increase during the last phase of the Project.

a) Medication Reconciliation

A high level summary of the four event analysis (EA) reports (total of 11 patients involved) received between January 1st to December 31st, 2012 is included in Graphic A. See Annex 5B for a complete summary of the EA submissions.
b) Correct Site Surgery

A high level summary of the five EA reports (total of 114 patients involved) received between January 1st and December 31st, 2012 is included in Graphic B. See Annex 5A for a complete summary of the EA submissions.

Graphic B: Summary of Correct Site Surgery EA Reports Submitted to the CC in 2012
a) Analysis

A small number of hospitals are reporting EA data for both Medication Reconciliation (n = 3) and Correct Site Surgery (n = 5) SOPs. Possible reasons include limited capability and/or capacity for identifying and analysing SOP-related events at participating hospitals. The data collection burden has been repeatedly identified as a challenge across all participating Member States, so it is likely that limited resources are being focused on implementation rather than evaluation.

Nonetheless, it is clear from this limited number of patients (n = 125) that process issues with SOP implementation have occurred in all reporting hospitals, with two patients experiencing temporary harm (Medication Reconciliation SOP). Only one hospital recommended making changes to the applicable SOP (Correct Site Surgery) to ensure the proper conduct of the Time Out, data collection and data documentation. All hospitals described local strategies to improve the implementation of the SOPs through targeted communication, policies and procedures, education, and teamwork, among other factors.

EA data remains a potentially rich source of information on the specific local challenges involved in implementing a clinical SOP.

4.4. Summary of quantitative findings

Correct Site Surgery

Table 7 and Figure 1 present quantitative interim data of CSS implementation. The line graphs include two displays of High 5s Project data, one by time period (i.e., monthly data points) and the other by cohort (i.e., data points aligned based upon the first instance of data submission for each organization).

The line graphs with monthly data points in the y-axis summarize hospital data submitted for each individual month, independent of when the hospital started the project. The country-level and international comparison lines are calculated as follows:

a) Country-level data (national comparison groups)

Country-level data points for an individual measure are calculated by aggregating all the hospital numerator cases (from within a specific country) and dividing this value by the sum of all of the hospital denominator cases (from within the country). The measure is calculated in the aggregate for all hospitals in the country during the specific time period. This calculation creates a weighted mean (weighted by the number of cases contributed by each hospital) rather than a grand mean (simply taking the average of the calculated hospital rates).

b) International-level data (international comparison groups)

International-level data points are calculated using a similar approach to the one employed to calculate a country’s performance on a specific measure. The major difference is that for rate and ratio measures, all the hospital numerator cases (from all countries) are summed and all of the hospital denominator cases (from all countries) are summed before calculating the measure rate or ratio. The measure is then calculated in the aggregate for all hospitals in contributing data during the specific time period. This calculation creates a weighted mean (weighted by the number of cases contributed by each hospital) rather than a grand mean (simply taking the average of the calculated hospital rates or the average of the national rates).

c) Confidence Intervals

The shaded areas around each line on the graph represent a 95% confidence interval. The 95% confidence interval indicates the estimated probability (95%) that the population parameter lies within the reported range of values (i.e., the degree of certainty that the true value lies within a range of values). The confidence intervals are calculated using a slightly different formula for rate-based proportion measures and ratio measures. The formula for each calculation is provided below (p = the rate, r = the ratio, n = the number of cases, SE = Standard Error).

\[
CI = p \pm (1.96 \times SE) \\
CI = r \pm (1.96 \times SE) \\
SE = \sqrt{\frac{p(1-p)}{n}} \\
SE = \sqrt{\frac{r}{n}}
\]

The cohort graphs use the same formula to calculate measure rates/ratios, but they aggregate data based upon each hospital’s first data point (rather than the month) as its first measureable experience with SOP implementation. Every subsequent monthly data point is aligned accordingly. For example, if Hospital A submitted its first data point in January of 2011, and Hospital
B submitted its first data point in July of 2012, both points would align as the initial data points for the hospitals.

Each subsequent monthly point was then aligned based upon the time from initial SOP implementation. This approach was used to track time since implementation and account for gaps in data collection. Continuing the example above, if Hospital A submitted data for February, March and June of 2011, the data points would be assigned as month 2, month 3, and month 6 (as opposed to point 2, point 3 and point 4). In this manner, the gap associated with the missing data points (i.e., April and May) is addressed. In order to aggregate hospital data within each country (and across the project), each data point was aggregated using the same approach, beginning with the initial data point for each hospital and calculating subsequent data points (while correcting for gaps in data collection).

Note: For both graphs, it is important to consider that the number of contributing hospitals could change from month to month, based upon the actual contributions of each hospital. The most current three months represented in each graph tend to contain fewer hospital contributions, as many hospitals have a considerable lag time in their data collection efforts. As a result, the confidence intervals for later months tend to be wider, and the rates more variable.

Table 7: General quantitative data on CSS

<table>
<thead>
<tr>
<th>Member State</th>
<th>Total No. hospitals implementing SOP(^{1,2})</th>
<th>Total No. of hospital submitted data to High 5s IMS</th>
<th>Average number of hospitals per month (07/2010-04/2013)</th>
</tr>
</thead>
<tbody>
<tr>
<td>MUN8NS1Z</td>
<td>8</td>
<td>4</td>
<td></td>
</tr>
<tr>
<td>KEC453YH1</td>
<td>7</td>
<td>6</td>
<td></td>
</tr>
<tr>
<td>FDQ17XVY</td>
<td>1</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>RJ94137U</td>
<td>16</td>
<td>12</td>
<td></td>
</tr>
<tr>
<td>International Comparison</td>
<td>32</td>
<td>23</td>
<td></td>
</tr>
</tbody>
</table>

1 Implementing = Eligible to enter data in the High 5s Information Management System
2 Only data that has been approved by both the hospital and the LTA meets the criteria to be included in performance measure calculations.

Figure 1: Interim quantitative data on CSS implementation

H5sCS-0 - Proportion of verification checklists for all eligible surgical cases
H5sCS-1 – Proportion of eligible surgical cases with a complete preoperative verification process (exclusive of site marking and Time Out)

Proportion of eligible surgical cases (All cases scheduled to be performed)

All Member States | RJ94137U | KEC43YH1 | MUN8NS1Z

Time period
Jul 10 | Oct 10 | Jan 11 | Apr 11 | Jul 11 | Oct 11 | Jan 12 | Apr 12 | Jul 12 | Oct 12 | Jan 13 | Apr 13

Proportion:
0% | 10% | 20% | 30% | 40% | 50% | 60% | 70% | 80% | 90% | 100%

H5sCS-1 – By cohort

Proportion of eligible surgical cases (All cases scheduled to be performed)

Time period
1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 | 15 | 16 | 17 | 18 | 19 | 20 | 21 | 22 | 23 | 24 | 25 | 26 | 27 | 28 | 29 | 30 | 31 | 32 | 33

Proportion:
0% | 10% | 20% | 30% | 40% | 50% | 60% | 70% | 80% | 90% | 100%
The High 5s Project Interim Report

H5sCS-2 – Proportion of cases with properly marked surgical site

Time period

<table>
<thead>
<tr>
<th>Time period</th>
<th>All Member States</th>
<th>RJ94137U</th>
<th>KEC43YH1</th>
<th>MUN8NS1Z</th>
</tr>
</thead>
<tbody>
<tr>
<td>Jul 10</td>
<td>100%</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Oct 10</td>
<td>90%</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Jan 11</td>
<td>80%</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Apr 11</td>
<td>70%</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Jul 11</td>
<td>60%</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Oct 11</td>
<td>50%</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Jan 12</td>
<td>40%</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Apr 12</td>
<td>30%</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Jul 12</td>
<td>20%</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Oct 12</td>
<td>10%</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Jan 13</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Apr 13</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

H5sCS-2 – By cohort
### H5sCS-3 – Proportion of cases with complete final ‘Time Out’

<table>
<thead>
<tr>
<th>Time period</th>
<th>All Member States</th>
<th>RJ94137U</th>
<th>KEC43YH1</th>
<th>MUN8NS1Z</th>
</tr>
</thead>
<tbody>
<tr>
<td>Jul 10 Oct 10</td>
<td>1.0</td>
<td>0.8</td>
<td>0.6</td>
<td>0.4</td>
</tr>
<tr>
<td>Jan 11 Apr 11</td>
<td>0.8</td>
<td>0.6</td>
<td>0.4</td>
<td>0.2</td>
</tr>
<tr>
<td>Jul 11 Oct 11</td>
<td>0.6</td>
<td>0.4</td>
<td>0.2</td>
<td>0.0</td>
</tr>
<tr>
<td>Jan 12 Apr 12</td>
<td>0.4</td>
<td>0.2</td>
<td>0.0</td>
<td>0.0</td>
</tr>
<tr>
<td>Jul 12 Oct 12</td>
<td>0.2</td>
<td>0.0</td>
<td>0.0</td>
<td>0.0</td>
</tr>
<tr>
<td>Jan 13 Apr 13</td>
<td>0.0</td>
<td>0.0</td>
<td>0.0</td>
<td>0.0</td>
</tr>
</tbody>
</table>

### H5sCS-3 – By Cohort

- **MUN8NS1Z**: Proportion of eligible surgical cases (eligible for a Time Out)
- **RJ94137U**: Proportion of eligible surgical cases (eligible for a Time Out)
- **KEC43YH1**: Proportion of eligible surgical cases (eligible for a Time Out)
- **All Countries**: Proportion of eligible surgical cases (eligible for a Time Out)
H5sCS-5 – Proportion of cases undergoing surgery with unresolved ‘Time Out’ discrepancies

Proportion of eligible surgical cases
(With Discrepancy at Final Time Out)

Time period

All Member States
RJ94137U
KEC43YH1
MUN8NS1Z

H5sCS-5 – By cohort

Proportion of eligible surgical cases
(With Discrepancy at Final Time Out)

Time period
H5sCS-6 – The proportion of surgical cases that are cancelled or postponed due to discrepancies identified at any point in the conduct of the SOP

Proportion of eligible surgical cases (eligible for a Time Out)

<table>
<thead>
<tr>
<th>Time period</th>
<th>1</th>
<th>0.8</th>
<th>0.6</th>
<th>0.4</th>
<th>0.2</th>
<th>0</th>
</tr>
</thead>
<tbody>
<tr>
<td>Jul 10</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>0</td>
</tr>
<tr>
<td>Oct 10</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>0</td>
</tr>
<tr>
<td>Jan 11</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>0</td>
</tr>
<tr>
<td>Apr 11</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>0</td>
</tr>
<tr>
<td>Jul 11</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>0</td>
</tr>
<tr>
<td>Oct 11</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>0</td>
</tr>
<tr>
<td>Jan 12</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>0</td>
</tr>
<tr>
<td>Apr 12</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>0</td>
</tr>
<tr>
<td>Jul 12</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>0</td>
</tr>
<tr>
<td>Oct 12</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>0</td>
</tr>
<tr>
<td>Jan 13</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>0</td>
</tr>
<tr>
<td>Apr 13</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>0</td>
</tr>
</tbody>
</table>

H5sCS-6 – By cohort

Proportion of eligible surgical cases (All cases scheduled to be performed)

<table>
<thead>
<tr>
<th>Time period</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
</tr>
</tbody>
</table>
H5sCS-7 – Proportion of cases with incorrect surgery (wrong site, procedure or person cases)

Proportion of eligible surgical cases
(All cases scheduled to be performed)

Time period

H5sCS-7 – By cohort

Proportion of eligible surgical cases
(All cases scheduled to be performed)

Time period
Medication Reconciliation

Figure 2 presents quantitative interim data of MR implementation. Please see the graph explanation in section 5.4.1 under CSS to understand the differences between the line graphs and cohort displays.

**Table 8: General quantitative data on Medication Reconciliation**

<table>
<thead>
<tr>
<th>Member State</th>
<th>Total No. hospitals implementing SOP¹</th>
<th>Total No. of hospital submitted data to High 5s IMS</th>
<th>Average number of hospitals per month (07/2010-04/2012)²</th>
</tr>
</thead>
<tbody>
<tr>
<td>DVLR6PNK</td>
<td>14</td>
<td>6</td>
<td></td>
</tr>
<tr>
<td>OFI427W6</td>
<td>15</td>
<td>5</td>
<td></td>
</tr>
<tr>
<td>2K01AJF0</td>
<td>9</td>
<td>6</td>
<td></td>
</tr>
<tr>
<td>VES234TZ</td>
<td>7</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>BH4537QS</td>
<td>2</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>International Comparison</td>
<td>47</td>
<td>17</td>
<td></td>
</tr>
</tbody>
</table>

¹ Implementing = Eligible to enter data in the High 5s Information Management System. One Member State has recently started to implement the Med Rec SOP but is not yet depicted in this count.

² Only data that has been approved by both the hospital and the LTA meets the criteria to be included in performance measure calculations.

**Figure 2: Interim quantitative data on Med Rec implementation**
Qualitative and quantitative interim findings

H5sMR-1 – The mean number of outstanding undocumented intentional medication discrepancies per patient

<table>
<thead>
<tr>
<th>Time period</th>
<th>Percent of Patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>Jul 10</td>
<td>3.5</td>
</tr>
<tr>
<td>Oct 10</td>
<td>3</td>
</tr>
<tr>
<td>Ian 11</td>
<td>2.5</td>
</tr>
<tr>
<td>Apr 11</td>
<td>2</td>
</tr>
<tr>
<td>Jul 11</td>
<td>1.5</td>
</tr>
<tr>
<td>Oct 11</td>
<td>1</td>
</tr>
<tr>
<td>Jan 12</td>
<td>0.5</td>
</tr>
<tr>
<td>Apr 12</td>
<td>0</td>
</tr>
</tbody>
</table>

H5sMR-2 – The mean number of outstanding undocumented intentional medication discrepancies per patient

- All Member States
- 2K01AJF0
- OFI427W6
- DVL6PNK
H5sMR-2 – By cohort

Time period

H5sMR-3 – The mean number of outstanding unintentional medication discrepancies per patient

Time period
Qualitative and quantitative interim findings

H5sMR-3 – By cohort

<table>
<thead>
<tr>
<th>Time period</th>
<th>Number of Discrepancies per Patient</th>
</tr>
</thead>
<tbody>
<tr>
<td>Jul 10</td>
<td>0.2</td>
</tr>
<tr>
<td>Oct 10</td>
<td>0.4</td>
</tr>
<tr>
<td>Jan 11</td>
<td>0.6</td>
</tr>
<tr>
<td>Apr 11</td>
<td>0.8</td>
</tr>
<tr>
<td>Jul 11</td>
<td>1.0</td>
</tr>
<tr>
<td>Oct 11</td>
<td>1.2</td>
</tr>
<tr>
<td>Jan 12</td>
<td>1.4</td>
</tr>
<tr>
<td>Apr 12</td>
<td>1.6</td>
</tr>
<tr>
<td>Jul 12</td>
<td>1.4</td>
</tr>
<tr>
<td>Oct 12</td>
<td>1.2</td>
</tr>
<tr>
<td>Jan 13</td>
<td>0.8</td>
</tr>
<tr>
<td>Apr 13</td>
<td>0.4</td>
</tr>
</tbody>
</table>

H5sMR-4 – Percent of patients with at least one outstanding unintentional discrepancy

<table>
<thead>
<tr>
<th>Time period</th>
<th>Percent of Patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>Jul 10</td>
<td>20%</td>
</tr>
<tr>
<td>Oct 10</td>
<td>40%</td>
</tr>
<tr>
<td>Jan 11</td>
<td>60%</td>
</tr>
<tr>
<td>Apr 11</td>
<td>80%</td>
</tr>
<tr>
<td>Jul 11</td>
<td>60%</td>
</tr>
<tr>
<td>Oct 11</td>
<td>40%</td>
</tr>
<tr>
<td>Jan 12</td>
<td>20%</td>
</tr>
<tr>
<td>Apr 12</td>
<td>0%</td>
</tr>
<tr>
<td>Jul 12</td>
<td>0%</td>
</tr>
<tr>
<td>Oct 12</td>
<td>20%</td>
</tr>
<tr>
<td>Jan 13</td>
<td>40%</td>
</tr>
<tr>
<td>Apr 13</td>
<td>60%</td>
</tr>
</tbody>
</table>
4.5. Member State quantitative and event analysis findings

Australia
Following the evaluation plan has been a challenge for all hospitals because of the burden of data collection for the performance measures, data quality requirements, and requirements for the event analysis. Ongoing collection of performance measure data (MR 2-4) is seen as not sustainable by some sites. The value of continuing to monitor measures MR 2-4 once the process was stable and the target had been reached was also questioned. One site withdrew from the project in late 2012, citing the need to prioritize their work because of resource constraints and preferring to provide direct patient care over data collection.

Performance measures
Performance measure data has been collected since mid-2010. As of November 2012, nine Australian hospitals were submitting data into the High 5s IMS. In addition, two hospitals in the group are conducting medication reconciliation but are not collecting data because of resource constraints. One health service with multiple hospitals has stopped collecting performance measure data for MR 2-4 because of lack of staff to conduct the independent observer role and meet data quality requirements.

Data submission into the High 5s IMS has been staggered, with hospitals starting data collection at different time points. A number of hospitals are now collecting MR 2-4 data on a quarterly basis, with three sites now moving to 6-monthly data collection. Rates can vary substantially when the comparative data is produced because of the number of hospitals contributing data in a particular month. Sample sizes across the period from August 2010 to November 2012 ranged from 2 to 10 hospitals. See figures in Annex 10.

Rates for measure MR-1 vary across hospitals depending on the stage of implementation, resources available, and the spread of the intervention in the organization. Between August 2010 and November 2012, rates for the percentage of eligible patients with medications reconciled within 24 hours of admission ranged from 16% to 96% across participating hospitals, with an average of around 51%. The trend line for MR-1 has been stable over this period. As medication reconciliation remains largely pharmacist-driven, there is a close association between MR-1 rates and available clinical pharmacist resources. Hospitals report that without additional clinical pharmacist resources, MR-1 rates are not likely to improve.

Rates for MR-2 are generally stable and low (less than 0.3) with a trend towards zero over time for the majority of hospitals. Australian hospitals
report they have used this measure to provide feedback to medication prescribers around the importance of clearly documenting intended medication changes. Similarly, rates for MR-3 are generally less than the SOP absolute target of 0.3 outstanding unintentional discrepancies per patient with a trend towards zero over time for several hospitals. The percentage of patients with at least one outstanding discrepancy (MR-4), also continues to decrease with time; however, there is variation in MR-4 rates across hospitals which is highlighted in the figures in Annex 10.

Event analysis

The collection of performance measure data has overshadowed the event analysis (EA) component of the evaluation with few sites reporting EAs. Twelve event analysis reports have been received from four hospitals, including 11 individual reports and one cluster analysis. All individual reports were concise analyses, with an assigned level of harm ranging from temporary harm to no harm. There have been no serious harm events reported.

In a sub-analysis of seven events, the most common contributing factors were identified as teamwork, education and training, and communication. There were no requests for changes to the SOP.

All events were the result of a failure to follow the SOP medication reconciliation process. Most events occurred during the BPMH stage (five) and when reconciling the medicines (four); only one report related to the resolution of a discrepancy.

Individual hospitals have used the event analysis reports as the basis for case studies for teaching purposes. Actions resulting from the reports have resulted in changes to the medication reconciliation form (one hospital), and regular orientation sessions for junior medical staff on the medication reconciliation form and process. Learning from the events has been shared among the hospitals participating in the High 5s Project.

Box 12: Learning from error

Hospital 5: An event analysis was conducted on a patient prescribed the incorrect medicines on admission to hospital. These medications were administered to the patient for a week until a pharmacist completed a BPMH for the patient and the errors were noted. All of the health-care professionals involved were informed of the errors, and this has been used as a teaching example to prevent this from happening again. This case was also presented at facility quality and safety meetings.

Other

Two additional performance measures were developed to allow hospitals to collect data on the discrepancies identified by the independent observer that remained unresolved 48 hours after admission. By late 2012, five hospitals were collecting data on the number of these outstanding unresolved discrepancies. In addition, three of these hospitals measured the potential for harm from the discrepancies using the National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP) severity scale to classify potential level of harm. The most common discrepancies were classified as NCC MERP Category D - an error occurred that reached the patient and required monitoring to confirm that it resulted in no harm to the patient and/or required intervention to preclude harm. This data, along with examples of actual discrepancies, has been used by sites to provide feedback to prescribers and encourage early resolution of discrepancies. (See Figure 3.)
France

Measures for Correct Site Surgery

Regarding the first months of evaluation, and based on the CSS performance measures, it appears that nearly all the hospitals made progress. The most striking improvement involves site-marking.

Number of CL initiated / eligible cases
During 2012, the measure CS-0 national average is 84% (Min = 55%, Max = 100%). Two hospitals with low CS-0 rates are facing persisting difficulties in making progress.

Pre-op verification CS-1
Significant variability has been observed among the different health-care organizations (HCOs) because of the reluctance of some professionals (i.e., surgeons, anesthetists) to conform to the process requirements. However, HCOs with an electronic checklist integrated in the data records have achieved good results, as traceability is less time-consuming and the acceptability of this preoperative component is better. In 2012, the French national average for measure CS-1 was 29% (Min = 2%, Max = 69%).

Site-marking
All of the hospitals except one improved their site-marking results. The mean value for measure CS-2 was 62% in 2012 (Min=26%, Max=87%). The hospital which did not show improvements demonstrated poor Project leadership for the, inappropriate site markings, such as marking the site with a cross on the palm of the hand, only partial implementation, and poor feedback to frontline staff.

Time Outs
The mean value for measure CS-3 was 66% (Min=32%, Max=89%). Discrepancies in the OR were mainly because of a lack of traceability. In addition evaluation of the Time Out by observational audits started in June 2012. Up to the present, the LTA has conducted four observational audits in the operating rooms of hospitals (audit grid designed by CEPPRAL).

Event analysis
Since the end of 2011, six hospitals have provided analysis forms to the LTA. Only two were correctly analyzed and therefore eligible for posting on the High 5s Project website. Event analysis was difficult because it was time consuming and there were insufficient resources to support this activity.
Interviews with participating hospitals
Since January 2012, nine annual visits which include interviews (individual and focus group) have been performed by HAS and CEPPIRAL. About 45 interviews have been conducted thus far and have involved 90 professionals (front-line staff and managers, physicians, surgeons, war nurses, secretaries, and anaesthetists). These interviews have been invaluable in communicating with the teams and HCOs as well as recognizing the efforts they have achieved.

Measures for Medication Reconciliation
During the first months of evaluation of medication reconciliation practice in France using the High 5s performance measures, it appears that all of the hospitals progressed as much in the number of reconciled patients as in the identification of discrepancies. In France, the principal data used by the LTA was measure MR-1 because it highlights the level of medication reconciliation implementation for each hospital. Indeed, from the beginning of the Project, the other measure results were very low, especially because the number of eligible patients reconciled was not a priority. It was felt to be more relevant to focus on measure MR-1 and on the number of unintentional intercepted discrepancies as it provides telling information for health-care professionals, the CEOs and the nation as a whole. For example, the medication reconciliation pilot hospital in France has, over a period of 18 months, succeeded in intercepting 1.664 unintentional discrepancies thanks to the medication reconciliation process. This result has a lot of teaching impact and allows the promotion of this practice with other professionals.

In France, the number of reconciled patients initially varied from one hospital to another, as shown by MR-1 rates which ranged between 2.5% and 63.4%. This heterogeneity is explained by the fact that two of the hospitals had a very low number of eligible patients because of the hospital size. However, over the first 13 months of implementation, the number of patients who had received formal medication reconciliation increased for all of the hospitals. From August 2011 to May 2012, the aggregated MR-1 results increased from 19.6% to 30.2%. In parallel, the number of discrepancies decreased from 321 to 159 over the same period, which evidences better understanding of the protocol by the teams as well as an improvement in their daily practices. Since the Med Rec teams do not encounter many unintentional discrepancies, it is difficult to involve them in event analysis. The Med Rec teams have been more interested in focusing on the analysis of the intercepted discrepancies and sharing the experience gathered by stopping them.

Germany
Measures for Correct Site Surgery
German hospitals collect data for the performance measures on carbon copies of the surgical checklist and send one copy to the LTA. To date, over 115,000 checklists from 16 hospitals have been scanned and imported into the national database. In addition to the High 5s measures data, key national data can also be analyzed (e.g. documentation quality, completeness of checklists, subgroup analysis of emergency cases) because of the availability of the complete checklist data. The German LTA has established a national feedback system consisting of individual hospital quarterly reports and bi-annual national benchmark reports which is much appreciated by the participants.

The German LTA conducted an analysis of the High 5s measures results for those checklists which were evaluated in the year 2012 (n=61,684). Four hospitals consistently performed at a high level for the measures CS-0 through CS-3. Two of these four hospitals were also part of the top 25% for measure CS-4. These hospitals, however, ranged completely differently for measures CS-5 and CS-6. The German LTA identified two hospitals which continuously ranked in the lower 25% for all of the first four performance measures. These hospitals also ranked in the lower 33% for measure CS-5. Both had presented a very low rate of case cancellations because of discrepancies (for CS-6, 0.00% and 0.01%). Two years after starting SOP CSS implementation, hospitals have reached consistent levels of performance on the measures. From review of checklists, it is evident that with regard to the first four measures, Project hospitals are divided into groups of high and low performers. For the measures dealing with discrepancies (CS-4 through CS-6), high and low performers cannot clearly be identified.

Measures for Medication Reconciliation
To date, the hospital which has officially started with the Med Rec SOP has calculated its performance measures for the months of March
through October 2012. In this hospital, since the beginning of implementation, Med Rec has been conducted on an average of 36 patients per month. The number of documentation errors has decreased slightly. The number of medication errors (unintentional discrepancies) has been reduced by 78%. The proportion of patients with at least one medication error has been reduced by 69%.

Event analysis

CSS: The German LTA has learned that Event Analyses have been conducted in some of the hospitals, but the results have not yet been shared with the LTA or the CC.

Other

By way of a baseline survey which the German LTA conducted, it was found that hospitals which had already established similar processes experienced a much smoother transition compared to those hospitals for which the SOP was a new process. This is also reflected in the process measure results.

The Netherlands

Process measures

All of the fifteen participating hospitals established baseline performance levels before implementing the SOP. Hospitals usually measured their performance for at least three months after implementation to show sustainability in the reduction of medication discrepancies. Hospitals would gather data for measures MR-1 through MR-4 until achieving at least a 75% reduction of discrepancies. Thereafter, most of the hospitals only measured MR-1 monthly and measures MR-2 through MR-4 occasionally (e.g., every six months). Two hospitals targeted almost 100% of their patients for measure MR-1. Hospitals generally felt no need to measure monthly only for the specific High 5s target population (patients 65 years and older admitted through ER) after the SOP performance had demonstrated sustainability. One hospital pharmacist said that, ‘As a hospital pharmacy, we do see every adolescent clinical patient within 24 hours. Probably now and then a patient will slip through the process, but we achieve 96%-100% monthly. There’s no need to keep on measuring MR-1 monthly, as the outcome will remain the same.’ Hospitals spread the SOP implementation to all age groups as this made implementation in daily practice easier. Some hospitals started implementation step-by-step, with a few categories of patients first. For each hospital, the impact of the SOP was all about the qualitative context of SOP implementation underlying the quantitative measures. An academic hospital highlighted that, ‘When we have no performance measurements in our hospital it does not mean that our reconciliation process is not of good quality. Measurements to monitor the process are also for the national patient safety programme. During the upcoming months, we will have internal sessions to provide feedback about how to create an effective dashboard to monitor reconciliation and to sustain the reconciliation process.’

Highlights of event analysis

The Dutch hospitals contributed to the development of the event analysis methodology and materials. Some hospitals piloted the draft event analysis process in the spring of 2011, which showed that the triggers identified in the medical records did not appear frequently enough to be used to support the event analysis process. In 2011, the event analysis methodology was modified and the new triggers and forms became available in 2012. One hospital in the Netherlands finished an event analysis and identified events potentially related to the SOP. All required forms were analyzed and reported to the LTA. This hospital experienced resource-based challenges/barriers, including the lack of staff to identify events for analysis, difficulty defining an independent observer role, and lack of staff and/or staff time to perform event analysis after event was identified. Action plans for improvement were formulated after completing the event analysis, and the hospital learned important information about the SOP implementation processes on local wards through carrying out the event analysis. A second hospital completed an event analysis at the end of 2012 and also identified events potentially related to the SOP.
Singapore

Measurement of improvement

The effects of the planned changes were measured by gathering compliance data collected according the following High 5s measures:

- CS-1. Completed Preoperative Verification Check List;
- CS-2. Properly Marked Surgical Site;
- CS-3. Complete Final ‘Time Out’;
- CS-4. Cases with Discrepancy Noted at Final ‘Time Out’;
- CS-5. Cases Undergoing Surgery with Unresolved ‘Time Out’ Discrepancies;
- CS-6. Case Cancellation Resulting From SOP Implementation;
- CS-7. Incorrect Surgery (wrong site, procedure or person cases).

The main points to highlight from the Singapore hospitals’ performance versus other Member States are that:

- Singapore’s national average consistently showed higher compliance rates than the international benchmark.
- Though hospitals have not all achieved 100% compliance for measures CS-1 through CS-3, their current rates have improved to a plateau at >90%.
- Measure CS-5 result suggested that Singapore hospitals tend to let discrepancies pass unresolved. However, on further investigation the discrepancies were found to be mostly related to documentation errors, such as ticking ‘No’ when it should be ‘NA’ and not because of non-compliance with the SOP. The High 5s Network is working within its own hospitals to close the gaps for these discrepancies. One of the ways they have chosen to do this is through events analyses which they are just starting to do now that the data collection and submission processes have been stabilized.
- Measure results for CS-6 and CS-7 have consistently been 0%.

Trinidad & Tobago

Implementation of the CSS SOP took place at four participating hospitals. Despite the challenges experienced, staff in the orthopaedic theatres were still willing to advance the SOP to other theatres. Figure 4 presents measure results in participating hospitals in Trinidad and Tobago.

Figure 4: Measures in participating hospitals

<table>
<thead>
<tr>
<th>CS-0 Eligible Surgical Cases</th>
<th>YES</th>
<th>NO</th>
<th>NA</th>
</tr>
</thead>
<tbody>
<tr>
<td>TRHA</td>
<td>105</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>SWRHA</td>
<td>100</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>NCRHA</td>
<td>100</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>ERHA</td>
<td>62</td>
<td>38</td>
<td>0</td>
</tr>
</tbody>
</table>
CS-1 Completed Preoperative Verification Checklist

<table>
<thead>
<tr>
<th></th>
<th>YES</th>
<th>NO</th>
<th>NA</th>
</tr>
</thead>
<tbody>
<tr>
<td>TRHA</td>
<td>85</td>
<td>14</td>
<td>1</td>
</tr>
<tr>
<td>SWRHA</td>
<td>82</td>
<td>18</td>
<td>0</td>
</tr>
<tr>
<td>NCRHA</td>
<td>80</td>
<td>20</td>
<td>0</td>
</tr>
<tr>
<td>ERHA</td>
<td>90</td>
<td>10</td>
<td>0</td>
</tr>
</tbody>
</table>

CS-2 Properly Marked Surgical Site

<table>
<thead>
<tr>
<th></th>
<th>YES</th>
<th>NO</th>
<th>NA</th>
</tr>
</thead>
<tbody>
<tr>
<td>TRHA</td>
<td>23</td>
<td>70</td>
<td>8</td>
</tr>
<tr>
<td>SWRHA</td>
<td>66</td>
<td>34</td>
<td>0</td>
</tr>
<tr>
<td>NCRHA</td>
<td>60</td>
<td>40</td>
<td>0</td>
</tr>
<tr>
<td>ERHA</td>
<td>100</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

CS-3 Complete Final Time Out

<table>
<thead>
<tr>
<th></th>
<th>YES</th>
<th>NO</th>
<th>NA</th>
</tr>
</thead>
<tbody>
<tr>
<td>TRHA</td>
<td>61</td>
<td>38</td>
<td>1</td>
</tr>
<tr>
<td>SWRHA</td>
<td>67</td>
<td>33</td>
<td>0</td>
</tr>
<tr>
<td>NCRHA</td>
<td>60</td>
<td>40</td>
<td>0</td>
</tr>
<tr>
<td>ERHA</td>
<td>95</td>
<td>5</td>
<td>0</td>
</tr>
</tbody>
</table>
### CS-4 Cases with Discrepancies noted at final time-out

<table>
<thead>
<tr>
<th></th>
<th>YES</th>
<th>NO</th>
<th>NA</th>
</tr>
</thead>
<tbody>
<tr>
<td>TRHA</td>
<td>0</td>
<td>100</td>
<td>0</td>
</tr>
<tr>
<td>SWRHA</td>
<td>21</td>
<td>79</td>
<td>0</td>
</tr>
<tr>
<td>NCRHA</td>
<td>2</td>
<td>98</td>
<td>0</td>
</tr>
<tr>
<td>ERHA</td>
<td>5</td>
<td>95</td>
<td>0</td>
</tr>
</tbody>
</table>

### CS-5 Surgery with Unresolved Discrepancies

<table>
<thead>
<tr>
<th></th>
<th>YES</th>
<th>NO</th>
<th>NA</th>
</tr>
</thead>
<tbody>
<tr>
<td>TRHA</td>
<td>0</td>
<td>100</td>
<td>0</td>
</tr>
<tr>
<td>SWRHA</td>
<td>5</td>
<td>95</td>
<td>0</td>
</tr>
<tr>
<td>NCRHA</td>
<td>0</td>
<td>100</td>
<td>0</td>
</tr>
<tr>
<td>ERHA</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

### CS-6 Case cancellation resulting from SOP Implementation

<table>
<thead>
<tr>
<th></th>
<th>YES</th>
<th>NO</th>
<th>NA</th>
</tr>
</thead>
<tbody>
<tr>
<td>TRHA</td>
<td>1</td>
<td>99</td>
<td>0</td>
</tr>
<tr>
<td>SWRHA</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>NCRHA</td>
<td>0</td>
<td>100</td>
<td>0</td>
</tr>
<tr>
<td>ERHA</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>
CS-7 Incorrect Surgery

<table>
<thead>
<tr>
<th></th>
<th>TRHA</th>
<th>SWRHA</th>
<th>NCRHA</th>
<th>ERHA</th>
</tr>
</thead>
<tbody>
<tr>
<td>YES</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>NO</td>
<td>100</td>
<td>0</td>
<td>100</td>
<td>0</td>
</tr>
<tr>
<td>NA</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

1. Feasibility

Feasibility refers to the degree to which an SOP could be implemented as it was originally defined, in a standardized way across hospitals within a country or in multiple countries.

1.1. Overall issues

One of the primary objectives of the High 5s Project has been to assess the feasibility of implementing standardized approaches to specific patient safety problems across multiple countries and cultures. The rigorous, multidimensional High 5s evaluation strategy is providing a qualified “yes” to the first of the key questions for the Project: is process standardization across different hospitals in different Member States feasible? Over the course of the High 5s Project it became clear that some aspects of the SOPs were more easily implemented in some participating Member States than in others. When participants encountered issues with the implementation of a SOP, they were invited to submit requests to adapt or modify components of the SOPs that were problematic or not working well. These requests were reviewed by the Collaborating Centre and the High 5s Steering Group and a decision was made to approve or reject the modification request. To date, 15 SOP modification requests have been submitted–two for Medication Reconciliation, 11 for Correct Site Surgery, and two for Concentrated Injectables. Each participating Member State submitted at least one request for modification. However, while there have been several country-specific adaptations to the SOP, the majority of participating hospitals have achieved full implementation of the protocol. That is, hospitals implemented all steps of the protocol in all locations and for the entire eligible population as specified in the SOP.

In some cases, modification requests led to revisions of the SOP. These revisions included changes to key definitions which helped to clarify the intent of a process or a concept across the varied languages and cultures of participating Member States. In other cases, revision requests identified opportunities for flexibility or local customization of the SOP. Such requests required the High 5s Steering Group to reconsider which elements of the protocol needed to be “standardized” and which aspects should be left to the discretion of the hospital. For example, the Correct Site Surgery protocol originally required that site marking be performed directly by the surgeon who was performing the procedure. The SOP was revised to allow the responsibility for site-marking to be delegated to another healthcare professional, as long as that individual was qualified, identified in the patient record, and directly involved in the procedure. In other words, the SOP continued to require a standardized site-marking process, but the individual hospitals could implement it in a way that fit best into its existing processes.

Modifications to the SOPs are presented in additional detail below:

Medication Reconciliation

Canada requested that the definition of ‘Best Possible Medication History’ be revised to include an expanded definition of ‘medication’ and to define what is meant by ‘currently taking’ a medication. The requested revisions were approved based on the assumption that they provided clarity and a more uniform understanding of the SOP across participating Member States.

The Netherlands requested to reduce the number of times the patient/family is consulted to obtain the patient’s current and past medication history. The request was that the patient/family be consulted only one time (instead of two) in order to more effectively and efficiently utilize staff time.
The request was approved, and the SOP was revised to allow for a more generalized model that allows more freedom and flexibility for hospitals to define their own process for obtaining the patient’s best possible medication history. This change helped to improve understanding of the SOP, reduce redundancy, and create a more efficient work flow.

**Concentrated Injectables (CIs)**

The United Kingdom requested a proactive reduction of authorized ward storage of concentrated injectables. The requested language change focused on the reduction of the number of clinical areas authorized to store CIs and, where authorized, put limitations on the types, amounts, concentrations and preparations of CI drugs stored in those areas (outside of the pharmacy). These language changes were approved, and the SOP was modified accordingly.

The United Kingdom also requested that information be added to the SOP that would help clarify the intended population for the SOP. This request was approved, and the wording was amended to read, “This SOP applies to inpatient clinical areas only.”

**Correct Site Surgery**

Singapore, Germany and France all asked that the procedure for site-marking be revised to allow for a delegated health-care professional (other than the operating surgeon) to mark the correct surgical site. The request was approved, and the language in the SOP was changed to reflect that:

1) another physician or registered nurse participating in the procedure or directly involved in patient surgical preparation can mark the site;
2) hospital policy must include the minimum qualifications and the role of the person delegated to perform site-marking;
3) the individual performing the site-marking is identified in the medical record or pre-operative verification checklist.

Singapore also requested a waiver of the verification of site and procedure during pre-operative testing since surgical site and procedure are not usually verified during this time. This request was approved, and the pre-operative verification checklist was revised accordingly.

In a few cases, requests for modifications to the SOP did not lead to revision of the SOP, but rather resulted in a country-wide adaptation of the SOP. These requests generally involved a conflict between an individual Member State’s existing standard, and a critical component of the SOP. In these cases, the Steering Group allowed an individual Member State to adapt the SOP to maintain consistency with the existing standard. There were two such instances, both involving the CSS SOP and standard practices in Germany.

In order to avoid the possibility of misinterpretation, the SOP prohibits the use of abbreviations in surgical documentation. However, because there are many established and commonly understood abbreviations currently used in Germany, as well as many long words in the German language that look similar, Germany requested permission to use abbreviations in the electronic operating room (OR) log. In participating German hospitals, these established abbreviations help distinguish words and also require less space in the OR log. A decision was made to make a country-specific adaptation rather than a revision to the SOP that would allow participating German hospitals to use abbreviations in electronic (only) OR logs.

The SOP also specifies a number of approaches to site-marking, including a prohibition on using “X” to mark a site. In many cases, “X” can be variously interpreted as a positive (i.e., “‘X’ marks the spot”) or negative indication (i.e., “Do NOT...”), which creates the potential for confusion and error. In Germany, however, the “X” has been recommended as a standard marking for the correct/intended site for surgery by the German Coalition for Patient Safety. This adaptation was approved for participating German hospitals to use “X” for the intended surgical site marking.

**Rejected requests**

A number of additional requests were also considered but rejected by the Steering Group. These requests all related to the CSS SOP; two related to site-marking and one related to patient positioning.

Germany asked to use only the intraoperative radiographic technique, not skin marking to mark the surgical site for spinal procedures. Because both skin marking and intraoperative marking are required as part of the SOP, this request was rejected.

Singapore asked to exempt obstetric and gynecological procedures from site marking.
because of the fact that the many ob/gyn procedures require exploratory surgery to determine the correct site for the surgery. This request was rejected based on the fact that the expected or anticipated surgical site should be marked in all surgical cases, regardless of specialty area.

Singapore also requested to waive the patient position verification during the Time Out because of the fact that the patient would be checked during prepping and draping and it is unlikely that the patient position would be inaccurate by the time the time-out occurs. This request was rejected because the verification of the patient position is part of a minimum set of items selected to be included in the final time-out. This list was determined by expert consensus to include the most measures for avoiding wrong-site surgery.

1.2. Summary of in-country experiences

Australia

By December 2012, all 12 hospitals in the collaborative had implemented the medication reconciliation process. Nine of these hospitals were submitting data into the High 5s IMS. Only one hospital was able to perform medication reconciliation on over 80% of its eligible patients within 24 hours of admission. This hospital had a seven-day-a-week pharmacy service with extended hours in the emergency department (ED). One hospital implemented a multidisciplinary process with doctors and nurses trained in taking a BPMH and reconciling medicines. In the other hospitals, pharmacy staff, mainly pharmacists, were responsible for taking the BPMH and reconciling medicines for admissions through the ED. Apart from the lack of engagement by medical and nursing staff in performing medication reconciliation the actual steps of the medication reconciliation process were implemented without change. Hospitals used a mix of paper and electronic tools to document the BPMH and record medicines reconciled.

However, not all hospitals followed all components of the implementation strategy.

Hospitals with a medication reconciliation process already in place did not run a pilot and those hospitals that had medication reconciliation already in place or that lacked expertise in the failure modes and effects analysis (FMEA) process did not complete the risk assessment.

Australia requested some modifications to the performance measures. They affected all hospitals. See table 9 for the modifications sought.

Table 9: Modifications to SOP sought by Australia

<table>
<thead>
<tr>
<th>Performance measure</th>
<th>Issues</th>
<th>Requested change</th>
<th>Outcome</th>
</tr>
</thead>
<tbody>
<tr>
<td>MR-1</td>
<td>Hospitals could not collect data on all admissions of eligible patients</td>
<td>Use sampling to collect MR-1</td>
<td>A sample of 50 was approved*</td>
</tr>
<tr>
<td>MR 2-4</td>
<td>Monthly data collection unsustainable</td>
<td>Collect 3 monthly or 6 monthly after consistently meeting target of &lt; 0.3 outstanding discrepancies/patient</td>
<td>3 monthly data collection approved after meeting target for 12 months, 2011* 6 monthly collection approved after 12 months of quarterly reports meeting target, 2012*</td>
</tr>
<tr>
<td>MR-1</td>
<td>Difficult to perform Med Rec within 24 hours</td>
<td>Extend timeframe for Med Rec to ≤ 48 hours</td>
<td>Not approved. Australia will collect own data on Med Rec completed within 48 hours in addition to MR 1-4.</td>
</tr>
<tr>
<td>MR 2-4</td>
<td>Definitions of discrepancies were unclear and there was concern about inter-rater reliability</td>
<td>Definitions be more descriptive and include inclusions/ exclusions and provide examples, particularly in relation to PRN and complementary, medicines</td>
<td>Table of discrepancy examples created and added to Volume 4 – “Getting Started” kit. A local “How to guide” was also developed.</td>
</tr>
</tbody>
</table>

* Approved by High 5s Steering Group
In addition to the evaluation plan another challenging aspect of the SOP implementation was changing the organizational culture from one where medication reconciliation was regarded as being only “pharmacy business” to one involving medical and nursing staff in the process (Box 13).

**Box 13: A quote on sharing ownership of medication reconciliation**

**Hospital 1.** ‘...another challenge we have faced is in engaging staff to share ownership of medication reconciliation. While we have tried to increase awareness of medication reconciliation with posters, competitions, staff education, etc., pharmacists still have ownership of the process, and are the only ones formally doing and documenting medication reconciliation’.

Despite the difficulties engaging disciplines other than pharmacy in the medication reconciliation process sites reported that the initiative was accepted and valued by other staff (Box 14).

**Box 14: A quote on the value of medication reconciliation**

**Hospital 2:** The implementation of the High 5s Project in the Emergency Department has seen increased cohesion among ED nursing staff, ward nursing staff and pharmacy staff with the initiative being welcomed by the ED staff.

**Sustainability**

Sites with weekend pharmacy services reported the SOP was sustainable.

The five sites interviewed suggested sustainability of the SOP was dependent on a number of factors including:

- reducing the requirement for hospital staff to provide ongoing education and including training within university curricula;
- availability of electronic tools to support the medication reconciliation process that are integrated with electronic-prescribing/medication management systems;
- continued engagement and support from stakeholders;
- extending pharmacy services to 7 days a week; and
- provision of ongoing/additional funding to continue collection of performance measure data.

**In summary**

It was feasible to implement the medication reconciliation SOP in Australian hospitals. It is a complex process, and successful implementation requires support from the hospital executive and senior clinicians, adequate resources and a commitment to ongoing training.

**France**

**Experiences implementing the Correct Site Surgery SOP**

This SOP was fully implemented in four out of eight participating hospitals, and among these four hospitals at full implementation, three have a computerized High 5s checklist which is extremely useful.

- The most common strategy used to facilitate implementation was initially to begin with one or two surgical specialties for implementation. Three of the four hospitals, having chosen this option, encountered two kinds of difficulties: existence of multiple verification tools and no sense of urgency for change.

- All participating French hospitals except one (having no out-patient surgery in the in-patient area) adapted the SOP to permit the delegation of site-marking to nurses, after training by the surgeons. This adaptation was necessary because of the high number of out-patients having surgery in in-patient ORs (was allowed by the SOP) or of in-patients who are admitted on the morning of their surgical interventions.

- The most challenging aspects of the SOP were:
  - Data collection for all the hospitals except for one who integrated the High 5s checklist
into its electronic record from the beginning. The workload was heavy, and no resources were dedicated to support this effort most of the time. Currently, five of the eight hospitals are working on integrating the High 5s checklist into their electronic record projects.

- Site-marking faced resistance from surgeons in six out of the eight hospitals. Working together with the LTA to create a High 5s site-marking guide was helpful. Each hospital has developed procedures for site-marking in accordance with the requirements of the SOP. Site-marking, as a new practice in France not included in the WHO Surgical Safety Checklist promoted by HAS and mandated in the accreditation process since 2010, has raised many organizational, cultural, and technical questions, as well as debates on the legality of a surgeon delegating the marking responsibility to a nurse.

- Lack of involvement of anesthesiologists in the pre-op verification process was a common challenge.

**Box 15: Interview findings in two French hospitals**

**Nurses working in a surgical ward:** ‘At the beginning of the project, site marking looked like an additional task and responsibility. I was against the delegation of this task by surgeons, but then I understood that we are one of the links in the chain.’

**Project coordinator:** ‘Marking was intended for all patients admitted to a surgical unit starting April 2012. However, the majority of patients are admitted on the same day or for ambulatory surgery; very few are admitted the day before. The marking procedure was put in place. The task was delegated to a resident and then a nurse, under the surgeon’s responsibility. In approximately 70% of cases, the task was delegated to a nurse. The borderline between what can be delegated and what cannot was not always clear to the teams.’

**Some lessons learned**

- The importance of contextual conditions, such as team instability and reduced cohesion, lack of leadership, and physician resistance.
- The critical role of an organization approach to safety and the emergence of credible opinion leaders who are seen as influential in effecting changes in clinical practices.
- The need to include surgeons who are willing to be champions.
- The importance of achieving full implementation within a reasonable timeline in order to impact a sufficient number of health-care professionals.

**Experiences implementing the Medication Reconciliation SOP**

At the beginning of the project and after having solved the first difficulties related to understanding the protocol, the teams involved in medication reconciliation started the implementation by following the protocol and respecting all of the eligibility criteria. However, the teams were quickly confronted with barriers linked to the organization of care. The main difficulties related to:

- The expectation of formal medication reconciliation within 24 hours after patient admission when most organizations strive to meet a 48-hour timeline which itself was felt to be challenging.
  – Currently, three hospitals are monitoring Med Rec with a measurement of reconciliation at 48 hours and at 24 hours.
- Questions regarding the most convenient place to reconcile the patients; should this be on the medical ward or directly in the emergency department:
  – Regarding the place where medication reconciliation has to be performed, the teams had to define whether it was more convenient in their own organization to reconcile directly in the emergency department or on the medical ward. Currently, all except one hospital are conducting medication reconciliation on medical wards. This hospital center was particularly successful in reconciling all of its patients within 24 hours.
- The difficulty in extracting the data to satisfy the Project’s performance measures:
  – Initially, the information systems did not allow extraction of the data needed for the performance measures. Currently, teams involved
with the Med Rec SOP are using an Excel file which was elaborated by the LTA. In addition, some hospitals are struggling to access the measure data for the Project measures where medication reconciliation is fully integrated into pharmaceutical care and is not easily identifiable as such in the care process. This barrier explains why a hospital does not presently send any data because the design of its process does not allow it to extract exhaustive data on the number of reconciled patients within 48 hours (see Box 16).

**Box 16: Example on how to overcome the data collection burden in Med Rec**

In order to facilitate the data collection that allows monitoring of the medication reconciliation practice, a general hospital, in collaboration with the LTA, is currently working on integration of the medication reconciliation sheet into the information systems. As the computerized physician order entry (CPOE) system does not support the iterative steps in the Med Rec SOP, the hospital developed a tailor-made application directly connected to the inpatient electronic medical record. This tool can be accessed from a reconciliation tab on the medical record screen.

Med Rec data can then be displayed across multiple medical episodes. Physicians and pharmacists can consult or change the data at any time, and a historical record of changes can be made available. Data indicators support automated calculation through a supervisor tool. To increase visibility for the clinician, a summary of discrepancies, warnings and additional information can be made available when the software is opened. Patient data can be extended to see more specific data (patient ID, compliance, sources, and author). Med Rec screens, available for admission or discharge, display only the most useful information in order to increase visibility and allow quick checking. A warning check box can be manually enabled to display warning logos (e.g., no compliance warning), and free text can be entered to describe which drug is available. Additional information about drugs stopped before hospitalization can also be entered in a free text box at the bottom of the screen.

**Medication reconciliation performed outside Med Rec criteria**

Currently, French hospitals are performing medication reconciliation beyond the eligibility criteria of the Med Rec SOP. Therefore, those patients not fulfilling Med Rec criteria who are reconciled are not included in the High 5s Project database.

For example, several hospitals have started to spread Med Rec to other medical units. In the different units, all patients are now eligible for medication reconciliation- not simply patients 65 years and older entering through the Emergency Department. From the point of view of the hospitals teams, it has helped having a better integration of the medication reconciliation process into daily medical practices. The pharmaceutical teams in three hospitals have also started to implement medication reconciliation upon discharge.

**Germany**

**To what degree was the SOP implemented in all hospitals as it was originally defined?**

A total of 14 of the 16 hospitals implementing the CSS SOP have reached full implementation. Of the two hospitals that have not reached full implementation status, one has implemented the SOP in all but one department (Ophthalmology). The other hospital is the only JCI-accredited hospital of the 16 hospitals, and it has not implemented the High 5s checklist evaluation in all departments. In one hospital which started with Med Rec implementation, the SOP has been partially implemented, but it is unlikely that full implementation will be achieved in the course of the project because of a lack of human resources.

It is difficult to reach overall conclusions regarding the feasibility of the SOPs in the German context because of the likely selection bias which exists among the German hospitals who decided to implement the High 5s SOPs. These hospitals participate in the High 5s Project on a voluntary basis and thus represent a more dedicated and
experienced group of hospitals than their counterparts.

How did in-country hospitals modify the SOP to facilitate implementation?

a) Correct Site Surgery

The adaptation of the international patient safety tools to the German hospital context involved a close collaboration between hospitals and the LTA. The surgical checklist is used in Germany for both implementation of the SOP and collection of data for evaluation purposes. After translation and reduction of the complexity and text density (e.g., by creating an instruction leaflet) a national model version of the checklist was created that contained the minimum criteria needed to adhere to the High 5s standardization requirements. Therefore, a process step that is not part of routine clinical care in German hospitals was removed from the checklist, and two adaptation requests from German hospitals relating to the site-marking process were accepted by the High 5s Steering Group: (1) It is now permissible to mark the site with an “X” (adaptation on a national level), and (2) medical professionals other than surgeons are allowed to mark the site as well.

As a further result of the joint hospital workshops it also became clear that it was necessary to incorporate the checklist into already existing preoperative processes in the participating hospitals. Furthermore, more than half of the hospitals were using surgical checklists when the project started and did not want to start using a completely new checklist. Thus 11 different hospital-individualized checklists were developed that – depending on hospital needs – contain additional elements while maintaining High 5s standardization.

The hospital-individualized checklists differ from each other with regard to:

- comprehensiveness of depicted processes (e.g., in some checklists additional items from the WHO Surgical Safety Checklist are included);
- level of detail of the instructions;
- design/structure/grouping of the items.

Furthermore, in relation to the use of the High 5s checklist as an evaluation tool, the hospital coordinators required the German LTA to remove the section “Outcomes” from the checklist because of legal concerns (e.g., documentation whether an incorrect or potentially incorrect surgery was identified, information on the degree of harm). This is the reason why the German LTA does not gather data for measure CS-7. See also Annex 16.

b) For Medication Reconciliation

Because of the fact that Med Rec is a new process in Germany, some hospitals did not wish to start with the “more difficult” population of the older (65+) emergency patients but rather wanted to begin with patients who have a planned or elective admission. The German LTA offered to conduct data analysis and produce data feedback reports on these additional cases to the hospital, while submitting only the data for the internationally targeted population to the Collaborating Centre.

On the other hand, German hospitals, especially the large university medical centers, had great interest in collecting more data than the required High 5s performance measures. Therefore, a comprehensive data set was developed which included additional information on patients (e.g., gender, age, diagnosis), type of staff involved in the SOP, and type of drug along with more detailed classification information (e.g., change of dose, discontinuation of medication) for each discrepancy.

In general, implementing the evaluation components for both SOPs is the most challenging part of the High 5s Project for all German hospitals.

Specific issues relating to the SOPs themselves

a) Correct Site Surgery

Site-marking by the person who is conducting the procedure was not feasible for the majority of the German hospitals. Because of workflow considerations, especially in larger hospitals, one person is responsible for all admission processes and has responsibilities like obtaining consent from the patient and site-marking, while a separate team performs the procedure.

Further concerns that were identified by the hospital project coordinators in relation to the site-marking process were staff hygienic concerns relating to the markers used as well as the fact that the skin mark often washes off during skin preparation.
Implementing the team Time Out was challenging for those hospitals which had no experience with this process. A process step for which many hospitals reported problems was the verification of special equipment and implants prior to the procedure. This process step does not occur in proximity to the patient and the hospitals therefore found it difficult to integrate it into the workflow of completing the checklist.

b) Medication Reconciliation

Performing Med Rec within 24 hours after admission is a great challenge for all Med Rec hospitals because of a lack of resources (staff, time). In Germany, there are only 0.3 pharmacists per 100 hospital beds, which is one of the lowest ratios in Europe. Therefore, it is very challenging to achieve 100% Med Rec in the target group. In the majority of the hospitals only a small number of the patients constitute the target population being evaluated.

The Netherlands

Dutch hospitals implemented all SOP steps of the flow chart, except for one process step of the Med Rec SOP for the targeted population. A modification was requested for the process step of consulting the patient. The SOP required asking patients for their current medication list directly after entering the Emergency Department. After receiving a current medication list from the patient, other sources had to be consulted (community pharmacist or primary care physician list). Based on implementation experiences, Dutch hospitals preferred consulting patients only once: after obtaining all possible other medication sources. The SOP was subsequently revised by the High 5s Steering Group to provide for a more generalized model for medication reconciliation that gives clinicians and facilities the freedom to define their own process to obtain the BPMH and incorporate this into their existing processes and workflow.

The most challenging aspects in the SOP implementation included:
- interview with the patient;
- a sufficient IT infrastructure;
- continuous CEO support;
- data collection for SOP evaluation and SOP monitoring;
- hospitals expected additional time for pharmacy technicians and more staff to be needed to implement and sustain the SOP, but these resources were not readily available.

Box 17: Staff quotes regarding implementation issues of the Med Rec SOP

- “We created this by pilot projects and business cases. The High 5s Project has played a role in this. We discussed business cases with the CEO of the hospital, we lobbied a lot, we shared results about the effect, and we created a sense of urgency about the implementation of the national guideline for medication accuracy at transitions in care.”
- “You really need manpower to carry out the project. For the sustainability of results you need the same budget in the end. The initial costs during implementation are based on enough time for the project leader. After implementation, these costs are free.”
- “We have chosen to implement the SOP without extra manpower from the hospital pharmacy. Departments address themselves to this.”

Issues relating to the SOP implementation

- Hospitals tried to create more time for current staff and find other solutions than demanding more capacity for reconciling medications within 24 hours after admission during nights and weekends.
- IT modifications were necessary to obtain needed information to create a BPMH. Hospitals faced challenges in obtaining licenses, workspace (for computers) and extensions for current software. When IT requirements were not met, interventions and processes had to be adjusted in order to meet the Med Rec goals.
- Although hospitals received permission for High 5s participation from their CEOs, a few hospitals could not spread the SOP hospital-wide because of budget restrictions during the financial crisis. However, most hospitals have managed to successfully spread the SOP hospital-wide.
The spreading of the SOP takes time depending on the size of the hospital, awareness of medication reconciliation, and other competing priorities.

- With increased national awareness of medication safety, some project leaders were able to restart SOP implementation and to spread the SOP to other inpatient services.

- Hospitals experienced challenges in implementing the labor-intensive data collection for the performance measures mainly because of time constraints, lack of access to medical records and lack of resources (staff, funding) to carry out the work. Performance measures have been useful in creating a sense of urgency (baseline measurement) and to show improvements (measurements after implementation). A hospital staff member said that, ‘the method of measuring was very supportive and it was great to use evidenced based tools and indicators in daily practice.’

- Although project leaders were able to use the performance results to boost implementation, the trade-off always was interviewing more patients for the SOP. Another hospital staff shared that, ‘When we have no performance measurements in our hospital it does not mean that our reconciliation process is not of good quality. Measurements to monitor the process also support the national patient safety programme. During the upcoming months, we will have internal sessions to provide feedback about how to create an effective dashboard to monitor reconciliation and to sustain the reconciliation process.’

The issues and challenges mentioned above were experienced in all Dutch hospitals. Medication interviews with patients are an ongoing challenge, which has generated difficult discussions among hospital leaders, pharmacy representatives, and physicians in participating hospitals. Annex 18 shows a summary of the implementation questionnaires after SOP implementation with participating hospitals in which issues related to the SOP implementation are investigated.

Singapore

The Correct Site Surgery SOP was intended for implementation from Jan 2011 onwards in all seven participating hospitals. Local surgical checklists were modified to conform to the SOP, and staff education sessions were conducted to familiarize hospitals with this SOP.

There were several challenges noted:

1. **Difficulty in changing conventional surgical practice**: In the initial stage of the project, the bulk of non-compliance related to resistance by surgeons in complying with site-marking requirements and Time Out drills, in part because of refusal to change from conventional practice and a lack of understanding of the rationale and requirements of the SOP. Their compliance eventually improved through hard driving by OT nurses who refused patient entry into the operating theatre without a site mark and refused to pass the instruments and proceed with the operation until the Time Out was properly conducted. However, not all nurses felt empowered to stand up to surgeons. To maintain compliance, High5 leaders have found it useful to let data drive performance by providing monthly feedback on performance data to surgical heads. In addition, regular staff education helped new staff understand the SOP.

2. **Unpredictable pre-operative scenarios not covered in SOP**: Nurses had difficulty following pre-operative verification components when complicated scenarios not covered in the SOP arose, such as language barriers when asking open-ended questions to check the correct site of surgery. To overcome this, posters and videos were used to offer alternative follow-up actions and improve compliance with the expectations of the SOP.

3. **Varied adaptation of SOP**: Almost all participating hospitals reported that if they used a surgical skin marker for site marking, the site mark invariably got washed off by Chlorhexidine solution after cleansing, making it impossible to see the site mark right before the Time Out which was to occur after draping and cleansing. It was noted that if Chlorhexidine was not used, the site mark would not be washed away; however, Chlorhexidine is the recommended choice of antiseptic for surgical cleansing in Singapore’s hospitals. It was then agreed
Collectively, it is recommended that for cases where the site mark is not visible after draping because a) the window to the operative site is too small to view the site mark, and/or b) the site mark has been cleansed off, an acceptable alternative would be to verbally confirm the laterality of the operative site with the surgeon.

One of the hospitals also chose, in the alternative, to conduct the Time Out before draping so that the whole team could visualize and confirm the site mark right before draping, even though the SOP requires this to be done just before skin incision. The above adaptations of the SOP were shared during the High 5s webinar held in Dec 2011. It was then suggested that data be collected to substantiate the evidence for or against the practice variations.

There have been no reported cases of wrong-site surgery in operating theatres since the implementation of the SOP in Jan 2011.

**Trinidad & Tobago**

The CSS SOP was piloted and is being implemented at four of the five participating hospitals in its original format. No changes have been suggested.

However, Project Team Leaders have noted the challenge staff are experiencing in coping with the perceived data collection burden given the fact that many other data collection forms were already in use within the various surgical units. A review of all of the data collection tools used in the surgical units was recognised as being urgently required.

All project team leaders agreed that the CSS SOP will have a positive impact when fully implemented. The hospitals that piloted the SOP have already identified positive impacts such as:

- increased compliance with site marking;
- increased staff awareness and vigilance for surgical safety;
- provision of an opportunity for staff to double check the information given before surgery;
- encouragement/reinforcement of the importance of teamwork; and
- encouragement of communication among members of the surgical team.

**The United States of America**

The US hospital successfully incorporated the High 5s checklist into its pre-surgical process and received Institutional Review Board approval for participating in the High 5s Project. Further, it incorporated the ‘Event Analysis’ documents into its data collection processes. The IT department at the hospital was able to build an electronic bridge from the OR electronic medical record (EMR) Centricity® to a database accessible to the data collector for both the pre-operative records and operative records. However, the hospital later switched its pre-operative EMR to another system, and the data collector had to then hand-filter the relevant records.

The only modification the hospital requested was to start sampling its cases because of the large volume of the surgeries that would need to be reviewed in accordance with the SOP. It provided the LTA with a request to the Steering Group to sample (see Annex 21 for the request), and the High 5s Steering Group approved the request. Currently, the hospital samples at least 261 cases per month.

**2. Impact**

**2.1. Overall issues**

The SOPs have had a significant impact in all participating Member States. As a result of implementation of the SOP, certain process steps were implemented. Safety components are now built into surgical and medication management workflows, and a culture of shared ideas and learning among hospitals is promoted.

**Impact of the Medication Reconciliation SOP**

Thirteen hospitals in the Netherlands that implemented the Med Rec SOP have demonstrated equally significant medication communication safety improvements. Medication inaccuracies were reduced by 90% within the first five months of the SOP’s introduction in six hospitals. The percentage of patients reconciled within 24 hours rose by 40% in nine hospitals after the first year of implementation and has been increasing to 60% and even 90% following a few years of implementation. The role of the pharmacist in the Netherlands gained more visibility and importance. The care process was unified through better communication. Electronic
prescribing systems were introduced in some Dutch hospitals and others have been able to access community dispensing records electronically, as a result of SOP implementation in an effort to reduce errors. Sites universally achieved a reduction in unintentional discrepancies.

When all of the LTAs implementing the Med Rec SOP met, the positive impacts of different models of implementation, e.g., pharmacist vs. technicians creating the BPMH, were apparent, as shown by the process measure, percent reconciled. As a result, the French LTA was encouraged to consider the use of pharmacy technicians in the Med Rec process, as had occurred in the Netherlands. Lastly, the comparison of and learning from each Member State’s data and implementation processes was felt to be beneficial by all of the Member States.

Impact of the Correct Site Surgery SOP

After several years of designing and implementing the High 5s CSS SOP, positive impacts can be seen in organizational safety cultures, process improvement, and outcomes. Clearly, among the health-care leadership in participating LTAs and in hospitals, the High 5s Project has achieved a heightened awareness of the value of standardization and the risks associated with use of non-standardized processes; of the actual level of performance of defined processes (often lower than had been assumed prior to measurement); and of the value of teamwork in achieving higher levels of performance. Comparison of culture survey results (average composite scores) with performance measure results (CS-0 through CS-4) suggests a positive influence of an organization’s safety culture on the success of its implementation and level of performance of the standardized procedures. Yet to be demonstrated is the reverse influence; that is, the impact of SOP implementation on the organization’s culture.

Precisely defined, collected, transmitted and analyzed performance data suggest an improvement in the key patient care processes: preoperative verification, surgical site-marking, and the Time Out before surgery. For example, in France, site-marking was not routinely done prior to introduction of the High 5s Correct Site Surgery SOP. Since then, performance of this step in the participating hospitals has gained traction with performance levels ranging between 52% and 89% for all eligible cases. In Singapore, a Member State recognized for its rules-based culture, site-marking performance improved from 40% to 97%. Meanwhile, compliance with complete preoperative verification and the pre-operative Time Out has been consistently in the high 90% range.

If implementation of standardized operating protocols is successful, does it have an impact on the patient safety problem that the SOP is designed to address? Measuring outcomes in patient safety initiatives is always challenging and especially so when the outcomes to be measured, in this case, incorrect surgeries, are relatively infrequent.

The small sample of hospitals, the limited timeframe for the Project, and the uncertainty of complete reporting of all wrong-site surgery cases all add to the difficulty of demonstrating an actual decrease in the number of incorrect surgeries. By the end of the Project, there may be sufficient data to answer this key question.

However, in the meantime, a surrogate measure is available by considering the results of CSS performance measure No. 4: Proportion of Cases with Discrepancy Noted at Final Time Out and performance measure No.5: Proportion of Cases Undergoing Surgery with Unresolved Time Out Discrepancies. Together, these measures indicate cases at risk for incorrect surgery because of identified discrepancies that remain unresolved when the surgical procedure is begun. Certainly not all of those cases would have resulted in wrong site surgeries, but some of them may well have. The relative proportion of the types of unresolved discrepancies—factual, procedural, or documentary—is, at this time, unclear but it is reasonable to assert that a decrease in the number of unresolved discrepancies is a proxy for a reduction in the number of incorrect surgeries. However, this approach is limited in that these measures apply only to discrepancies identified during pre-operative Time Out. Ideally, any discrepancies that arise throughout the process of preparing patients for surgery would be identified and reconciled long before the patient gets to the operating room.

Unfortunately, these “good catches” are not routinely measured as part of the High 5s evaluation strategy. Recently France has recognized this deficiency and instituted a supplemental measurement activity designed to identify cases in which discrepancies have been identified and reconciled at all stages of the preoperative process. Data showing types of discrepancies, steps in the
process where they most frequently occur, categories of health professionals who identify them, and other useful data are emerging along with compelling stories of individual cases that were impacted by performance of the standardized procedures of the SOP. Other participating Member States have been encouraged to emulate this measurement approach initiated by the French LTA in hopes that the database for assessing impact on surgical outcomes as a result of the High 5s Project will be enhanced in time for the final project report.

2.2. Summary of Member State experiences

Australia

Impact of SOP implementation or participation in this Project

a) Leadership
At some sites, the performance measure data has proven useful in obtaining executive and senior clinician engagement with the SOP.

b) Hospital
Several sites have reported a change in the hospital culture, with medication prescribers actively looking for and responding to the pharmacist’s BPMH and recommended actions in the medication management plan (see Box 18).

Box 18: Medication reconciliation culture change across the organization
“The successful implementation of medication reconciliation in an organization requires an entire culture change across the organization involving all disciplines. Implementation is complex and difficult and it’s hard not to get discouraged. However the positives have been a much greater awareness of medication safety across the organization.”

c) Hospital processes
Eight sites integrated the medication reconciliation SOP into their existing processes to some extent.

Box 19: Raising awareness about best practice of medication reconciliation

Hospital 7: Raised awareness of the process of obtaining a BPMH, medication reconciliation and follow up of discrepancies ultimately resulted in better processes.

Hospital 2: The High 5s Project has resulted in an increased awareness of best practice medication reconciliation throughout the hospital.

Several hospitals chose to use the national Medication Management Plan (MMP) to standardize the documentation of medication reconciliation. This enabled pharmacists to record outstanding discrepancies requiring resolution in a standard place in the patient’s notes and readily available when medicines were prescribed. Since implementing the SOP the MMP has been viewed as a multidisciplinary tool for communication rather than a pharmacy document, as had been the case prior to the High 5s Project (see Box 20).

Box 20: MMP for reconciliation of medications

Hospital 5: The medical specialties within the hospital now look for the MMP for reconciliation of the medications when reviewing the patient and completing the medication discharge summary. It has enabled the doctors to provide complete medication summaries to the primary care providers, including documenting the status of medications, e.g., continued, dose increased/decreased, ceased. This has led to improved communication in the transitions of care and also with the patient.
One hospital reported implementation of the SOP had effects beyond the medication reconciliation process (see Box 21).

### Box 21: SOP impact beyond the medication reconciliation process

**Hospital 2:** When reviewing existing processes, the hospital identified multiple problems with their current medication management processes. As a result, there has been a greater focus on standardization of medication management, prescribing and patient safety, including the introduction of the National Inpatient Medication Chart in the Emergency Department.

### d) Patient care/clinical impact

Around half of the hospitals indicated that implementation of the SOP had an impact on related or interacting activities and on patient care. Most were considered positive and included:

- having a standard and improved protocol for medication reconciliation;
- improving processes through raising awareness of the processes of obtaining a BPMH, reconciling medicines and following up on discrepancies;
- using data collected to plan interventions to follow up on discrepancies;
- collection of data not previously accessible;
- improving patient safety.

Sites reported that the implementation of the SOP has improved the quality of the medication histories obtained and documented by pharmacy staff. The low figures reported for the MR 2-4 performance measures demonstrate the benefit of having a standard process on the quality of the medication reconciliation performed. See section 5.4.5 for results.

Resolving discrepancies early in the admission allowed for timely resolution of medication issues on discharge, thus reducing delays in discharging patients. It also freed up time for pharmacists to educate patients about their medicines (see Box 22).

### Box 22: Comprehensive counseling to patients

**Hospital 5:** Having nursing staff aware that all discharge summaries must be reviewed by a pharmacist prior to discharging a patient has enabled pharmacists to provide comprehensive counselling (written and verbal) to patients with the opportunity for patients to ask questions.

A downside of increasing the quantity and quality of medication reconciliation performed when resources are limited is that it is done at the expense of other activities such as patients receiving a regular review of their medicines. One of the reasons given by hospitals for withdrawing from the Project related to competing priorities.

### e) Communication

Communication about the High 5s Project and the organization’s commitment to the Project was disseminated primarily through announcements and progress reports made at department/project specific meetings, newsletters, and information posted in public areas. Staff updates on SOP implementation are primarily provided through regular reporting of performance measures, quarterly reports, and periodic reports of specific aspects of the Project. Lack of resources and organizational support or guidance were the primary challenges to communication.

### f) Resolving discrepancies

By auditing the quality of the medication reconciliation process hospitals were able to identify that some discrepancies remained unresolved for some days and sometimes until the time of discharge. As a result, discharges were often delayed while the discrepancy was resolved. Initially identified as a problem by one hospital, other hospitals soon reported similar problems. This led to the development of two additional performance measures to assist hospitals collect data on outstanding discrepancies unresolved after
48 hours following admission. Hospitals used this data to provide feedback to prescribers, thereby reducing the number of unresolved discrepancies.

Impact of multi-pronged approach to SOP evaluation

a) Patient care /clinical impact

Hospitals reported that implementation of the SOP has resulted in a more standardized process for obtaining a BPMH, training staff, reconciling medicines and resolving discrepancies. The benefit of using a standardized approach to medication reconciliation is demonstrated in the results of the audits undertaken by the independent observer.

Hospitals have found the performance measure data useful for identifying gaps in practice and staff training needs and for further improving their processes. Overall the Australian performance measures show patients that receive medication reconciliation at admission are at low risk of having an adverse medication event as the result of a discrepancy between the medicines taken prior to admission and those prescribed during the hospital admission. This risk has continued to decrease over the duration of the project. See figures in Annex 10.

A limited number of event analysis reports have been submitted, none of them for a medication reconciliation incident causing serious harm. The four hospitals that have submitted event analyses report that the process has provided them with valuable information on their medication reconciliation processes and failures (see Box 22). This information has been used:

- to improve the medication reconciliation process;
- as case studies in education sessions to highlight to other clinicians what can go wrong when the medication reconciliation SOP is not followed.

See section 5.4.3 for further information on event analysis.

b) Engagement of frontline providers and/or senior leaders

Several sites reported that the performance data has been useful in engaging executive staff and senior leaders (see Box 23).

Box 23: Engagement of frontline providers

Hospital 1: Intermittent reporting of Med Rec rates increases knowledge and awareness, and reinforces processes. All executive staff within the facility are now aware of the MMP and its use. There is now heightened awareness of the benefits and value of obtaining a BPMH and performing medication reconciliation.

Performance measure MR-1 allows hospitals to measure the proportion of the eligible population receiving medication reconciliation and has been useful in some hospitals for making a successful case for more resources (see Box 24).

Box 24: Improving services

Hospital 1: Significant and sustained improvement in MR-1 rates was realized with the initiation of a Saturday ward-based clinical pharmacist service that provided medication reconciliation for new, high risk admissions.

The performance measure data and event analysis information has also been useful for informing frontline clinicians about the project and encouraging them to follow the SOP (see Box 25).

Box 25: Maintaining support

Hospital 1: Reporting of improving MR-1 rates maintains support and enthusiasm for the initiative.
c) In-country awareness and support for the initiative

Inclusion of medication reconciliation within Standard 4 (Medication Safety) of the National Safety and Quality Health Service Standards has raised the awareness of the process as an important patient safety activity. The need to demonstrate compliance with the Standards for accreditation will drive the widespread uptake of the process in Australian hospitals. In addition, one of five medication safety priority activities in the Australian Safety and Quality Goals for Health Care requires everyone aged 65 and over to have their medicines reconciled within 48 hours of admission to hospital. The Commission continues to support the initiative through working with the hospitals implementing the High 5s Project and leveraging off this work to advocate the process with key stakeholders and develop resources to assist hospitals with implementation.

France

Impact of the Correct Site Surgery SOP

This SOP has had significant impact on health-care facilities in terms of improving communication between health-care professionals and improving the safety culture.

a) Patient care/clinical impact

All health-care professionals interviewed by the LTA highlighted the impact of this SOP on patient safety and improved communication between team and patient.

b) Hospital processes

The High 5s Project has allowed health care organizations (HCOs) to optimize their surgical care pathway and to better distribute tasks and roles to each professional involved thus linking all of the professionals involved in the patient’s care ‘from scheduling to the intervention’.

c) Culture of safety

- Nurses feel more empowered, reflecting a real cultural shift to be able to speak up in instances of discordance which in turn can foster effective communication among members of the perioperative team.
- Standardized site-marking allows for shared responsibilities among surgeons and nurses when site-marking is delegated.
- The High 5s Project has had a positive impact on teamwork for the hospitals at full implementation.

d) Information

An ongoing process of information gathering and verification along the patient’s preoperative pathway has added value to the quality of patient records. Most of the Project teams highlighted that the use of the High 5s Checklist has led to structured information and improved communication among nurses, anesthetists, physicians, secretaries and others involved in the care pathway (Box 26).

A common and unique tool to collect information during the surgical pathway, including procedures already implemented before the High 5s Project was in place has been developed in several hospitals. It is known as the “Carnet de bloc” or “livret de parcours interventionnel”.

Box 26: How best to implement the CSS SOP

The four HCOs at full implementation wish to continue using the CSS SOP. They believe that implementing this SOP is sustainable in their hospitals provided that the pre-operative verification component is less complex and time consuming and that an electronic checklist is linked to the patient’s medical record.

Among the four HCOs at partial implementation, three are facing major barriers but are continuing to carry out the SOP despite the fact that they have not succeeded in reaching full implementation.
Impact of the Medication Reconciliation SOP

This SOP has also had significant impact in health-care facilities in the re-engineering of care, improving communication between health professionals, and improving the safety culture.

a) Process re-engineering of care to improve efficiency

To improve the efficiency of medication reconciliation and increase the number of patients who received medication reconciliation within 24 hours, one Med Rec hospital has reorganized its reconciliation process. To maintain the benefits of medication reconciliation, pharmacists involved in the process have designed a training programme for physicians and residents. This programme includes specific time to explain the flowchart and makes physicians aware of how to stop medication errors.

Physicians dedicated the same amount of time to medication reconciliation before and after the process re-engineering. However, there is no shared information system between the hospital and the community. The next challenge for this hospital is full implementation of medication reconciliation from patient admission to discharge.

b) Improvement of communication between healthcare professionals for better patient care

In another hospital, it was noticed that after 18 months of implementation, this SOP had actually contributed to increased cooperation between physicians and pharmacists. Beyond the improvement experienced in medical care, the benefits of better communication and coordination of health-care professionals can contribute to saving physician time and improvements to patient safety (Box 27).

Box 27: Improvements in the safety culture and quality of care

One Med Rec hospital used the experience of participating professionals to identify and highlight potential significance of failures of the process, to assess the risks if these failures occur and to propose preventive measures. The experience also helped to prioritize failures in terms of the potential severity of their effects, frequency of occurrence, and the risks associated with their non-detection.

This study was conducted using FMEA (Failure Mode and Effects Analysis) to evaluate potential risks emerging in the process of medication reconciliation.

The researchers used the Joint Commission worksheet adapted from the model used by Good Samaritan Hospital (Dayton, Ohio) and a predefined scale index published by Williams. This work led to a better understanding of the constraints of the process and sensitization of all stakeholders involved in the process.

To improve practice, better performance must be defined as:
- setting a fixed time every day for reconciliation and immediate correction or documentation in the computerized file;
- training for and assessing the quality of the patient interview; and
- recording the data collected by the pharmacist in the computerized medical file.

c) Measuring clinical impact of unintentional discrepancies

One university hospital took the lead in studying the clinical impact of unintentional discrepancies. Based on their experiences in monitoring practices, they developed an algorithm to assess the potential clinical impact of unintentional discrepancies. To evaluate the robustness of the algorithm, the national Med Rec group initiated a study in volunteer hospital participating in the High 5s Project in order to see if there are differences in how professional groups approach unintentional discrepancies in different hospitals.

Germany

a) Hospital culture

In some hospitals the existing culture was positively stimulated as a result of implementation of the CSS SOP. Project coordinators reported that there was heightened perception among staff that there is an active commitment to patient safety in the organization. Other hospitals did not recognize a cultural change as a direct result of the project because of its small magnitude in relation to other initiatives.
b) Hospital processes
Feedback of some hospitals: “It’s not just a checklist, it has helped us to fundamentally change the way we look at our process.” Thus the systematic implementation of the SOP radiates to other not yet standardised processes, and other projects were affected, for example in the introduction of wristbands with identification tags for patients. Hospitals experienced in the use of surgical checklists prior to the High 5s Project reported that the project provided a new impetus in their implementation efforts and that the existing processes were improved as a result.

c) Patient care/clinical impact
At this time, the overall change in patient safety cannot be described with certainty. However, the procedural steps can help to identify safety gaps in the care of individual patients through the documentation of the checklist. As a result, the risk potential for patients at certain steps of the process has been reduced. Project coordinators reported that they feel that the awareness of patient safety as a whole has improved in their organizations.

d) Communication
By way of the CSS SOP, the pre-operative processes have been defined more clearly, and a simplification has subsequently been introduced. Because of the implementation and individualisation of the checklists, there is more transparency about responsibilities (who does what and when) in the already existing communication process. It is difficult to draw conclusions about the impact of the evaluation approach at this time.

Because of the fact that the checklist data collected since mid-2012 is being fed back much more rapidly to the hospitals, it will be interesting to see whether an improvement in the process measure results is noticeable after 2012. In addition, national bi-annual benchmark reports have been provided to the hospitals since mid-2012, and their impact will be analysed later through an updated implementation questionnaire.

The Netherlands
Impact was seen in several areas:

a) Leadership
The SOP implementation makes Med Rec a multi-disciplinary process with clear steps for each professional group, including the engagement of patients. Hospital pharmacists contributed more to the treatment of the patient, patients were more involved in the process, doctors and nurses were further aware of the hospital pharmacy contribution during the Med Rec process, and nurses experienced easier access to the hospital pharmacy (Annex 19A and B).

b) Hospital culture
Implementing this SOP contributed to greater awareness regarding the:
1. patient safety culture in hospitals; and
2. the existence of discrepancies in medication lists.
Some hospital staff have stated that, “because of SOP implementation there’s more awareness about the risks of medication errors. In combination with the national patient safety programme there are lots of positive changes made. It has led to more awareness.” The SOP is part of patient safety in our organization”.

c) Hospital processes
Through implementing the SOP, it has become clear which professional group is responsible for creating the BPMH. The steps are set to identify and resolve discrepancies and assure interview of patients about their medications within 24 hours after admission in the Emergency Department. The hospital pharmacy and through it the medication reconciliation process, now becomes part of the treatment of the patient.

d) Patient care/clinical impact
Hospitals have found it difficult to demonstrate the impact of the SOP on patient safety. However, with the help of the four performance measures, it is possible to show the improvement in SOP implementation (Annex 19A and B). One hospital stated that SOP implementation had a huge impact on the reduction of discrepancies in medication accuracy during transfers, as well as an impact on medication safety (Annex 19C). Although the measured reduction in medication errors is important, the clinical relevance of the reduction measured is open to question. Broader studies are needed, such as assessment of the duration of hospitalization in order to demonstrate its clinical impact on patient safety.

e) Communication
High 5s Project hospital teams were fully aware that communication strategies were needed to implement and sustain this SOP. They used internal meetings, training sessions, newsletters, posters and lots of discussion to introduce the SOP.
interventions and to spread the new ways of working together. The commitment to identifying and resolving discrepancies within a multidisciplinary processes has become a structured way of working which, in turn, has improved Med Rec communication among pharmacists, physicians, nurses and other health-care professionals.

f) Resolving discrepancies
A greater awareness of medication discrepancies was created in the Emergency Department because of implementing this SOP. The SOP also contributed to awareness raising regarding this issue in other departments (Annex 19C). In the Netherlands, a reduction of 75%-90% in discrepancies within five months after SOP implementation has been seen. A challenge faced by most hospitals has been to increase the average percentage of patients reconciled within 24 hours because of insufficient pharmacy staff available seven days a week. More resources are needed to reconcile 100% of the patients within the 24 hour limit.

Singapore

a) Process for change
To enable effective implementation, the Ministry of Health teamed up with patient safety champions in each hospital to form a local High 5s Network. In addition, the Ministry of Health funded an additional Healthcare Performance Office (HPO) High 5s executive in each hospital to assist in data collection and gap closure. The Project was a joint collaboration between the Ministry of Health and all public hospitals, involving surgeons, anaesthetists and nurses.

Gap closures initiatives by the Ministry of Health included:

1. **Regular platforms for sharing and learning:**
The Ministry of Health hosted bi-annual sharing platforms for the High 5s Network to reach mutual consensus on changes to be effected. In addition, between January and March 2011 when data collection was first launched, fortnightly informal meetings were held to assist executives in overcoming problems encountered.

2. **Standardizing data collection:**
To standardize data collection, an excel spreadsheet was established for executives to enter data and derive compliance rates. The Ministry of Health also adapted the WHO Surgical Safety Checklist to the local context, including deriving a calculation sheet for institutions’ reference. This adaptation was a core catalyst for institutions to adopt the High 5s checklist and begin data collection.

3. **Ensuring data validity:**
The institution’s executive performed monthly observational audits of documentation submissions to ensure rigour of the collected data. In addition, SQI co-ordinated additional quarterly Cross Review Validation Exercises (CRVEs) that engaged executives from participating institutions to minimise bias. Discrepancies noted during the observations enabled the institution’s executives to identify differences in actual practice versus paper audits and suggest measures to address them.

b) Strategy for change
The High 5s champions are leaders in their professions such as head surgeons and anaesthetists. As such, initiatives were better disseminated to health-care professional participants. The institution’s executives were funded by the Ministry of Health but reported directly to the hospital management.

From January 2011 onwards, monthly compliance data were reported back to OR staff and senior management. Based on the data, staff noted areas that needed improvement and gradually showed increased compliance with the SOP. Overall, it took two years to implement the SOP and reach a steady state in data collection.
c) Impact of SOP implementation

The High 5s Network met to review and discuss the data since the Ministry’s last update in May 2012, and observed that in addition to improved hospital processes, there were other benefits of the Time Out drill that were not measured through the performance measures, such as improvement in communication between surgical team members and better coordination arising from the process of identifying themselves to each other before the procedure. These were noted to be important intangible impacts of the SOP on the communication culture in Singapore Hospitals.

The impact of the SOP on both leadership and culture of the hospitals was positive. Many hospital leaders gave positive feedback on how the collaboration had led to:

- improved communication between the Ministry and the hospitals;
- embedded a continuous learning culture in the hospitals, showing that staff were willing to change conventional practice given the right resource support (i.e., with Ministry funding support of the High 5s Executive); and
- demonstration that hospital processes can be re-designed to provide better patient care. The clinical impact was that there had been zero wrong-site surgery cases reported from major operating theatres since the SOP was implemented.

Overall, there were four key achievements in the implementation of the Correct Site Surgery SOP project:

1) Incorporated permanent improvements in the OR workflow of all hospitals, in particular:
   - establishing that site-marking should be done before the patient enters the OR;
   - standardizing the site mark as an arrow, and not a cross, circle or tick, or any other symbol;
   - instituting a Time Out to ensure a last check for site and side of the operation; and
   - design of IT solutions to help hospital staff follow the protocol. Initially, only one hospital (National University Hospital) had an OR dashboard. By the end of 2012, two other hospitals (Khoo Teck Puat Hospital and Tan Tock Seng Hospital) had similarly created electronic systems to hard-wire the checklist into their workflow.

2) Increased awareness of surgical safety issues:
   - implementing the CSS SOP resulted in increased awareness of safety components built into OR workflows. Through monthly audits, OR staffs in all hospitals were kept abreast of their compliance data and the areas that needed improvement. The High 5s Project then became a buzzword for surgical safety.

3) Established a sharing platform:
   - the setting up of the local High 5s Network to implement the project provided an avenue for staff in different hospitals to learn from each other and continuously innovate to support a patient safety culture.

4) Introduced data quality validation measures:
   - the Ministry of Health successfully initiated ‘Cross Review Validation Exercises’ (CRVEs) for hospitals to audit each other. While external audits were not required as part of the SOP, the executives found that it not only helped to validate each other’s work, but it also allowed them to reflect on each institution’s workflow designs and take the learning points back to their own institutions.

The journey for Singapore hospitals has been a positive one, and the hospitals have requested similar style collaborations with the Ministry of Health to look at other patient safety matters such as medication safety protocols, for example, Medication Reconciliation.

The United States of America

The U.S.A. hospital has found that the High 5s SOP strengthens processes and procedures. Using the High 5s CSS SOP as a springboard, they evaluated their pre-op process and are making improvements. In particular, they evaluated the patient and document flow in the pre-op holding area. Key takeaways from this improvement process were that nurses played a key role in the patient safety process, and sufficient care in the pre-op holding area is currently playing a key role in preventing significant issues from arising in the OR.
Developing networks and awareness raising for the High 5s Project
Developing networks and awareness raising for the High 5s Project

1. Developing global networks and awareness raising

This global collaboration among international organizations, agencies and WHO Member States has been very fruitful. From the onset of the Project, founding members from WHO and The Joint Commission/Joint Commission International—serving as the WHO Collaborating Centre—sought to optimize the prospect of success by reaching out to all participants and experts to agree on the following characteristics:

- Collaboration and good will: The concepts of standardization applied throughout the Project have consistently been built and based on consensus among the various networks of LTAs, associates, and experts in the participating Member States.
- Achievement of country ministerial commitments to the Project through the existing WHO networks of WHO with Ministries of Health of the participating Member States.
- Shared global vision coupled with local ownership among all those participating in the High 5s Project.
- Provision of an evidence base for all steps in the SOPs and the ‘Impact Evaluation Plan’ developed through global networks of experts.
- Project design that included engagement and continuous improvement platforms as well as the national networks of hospitals— the learning communities—which permit necessary local adaptations that do not change the given SOP, but modify the way it is implemented in ways acceptable to the hospitals and LTAs in the Member States.
- Emphasis on the role and interrelationship of the country-level networks of health care professionals and teams rather than individuals alone.
- Embodiment of the principles of patient-centered care by actively involving the patients and families in the SOP processes, particularly as most participating Member States patients are becoming more active participants in their own care.

Building networks nationally and globally was clearly one of the critical activities of this Project that underlay its success. Project participants had been actively building networks, and continue to do so, since its inception in 2006.

Raising awareness of the Project was supported by promoting its activities globally, engaging interest on the importance of standardization as a means to safety, attracting global experts and expert institutions to the Project, securing funding, and influencing public and political opinion about the importance of patient safety.

International and national approaches to addressing specific patient safety problems through extended, multi-country networks can ensure that there is true capacity-building in patient safety worldwide. From a global perspective simply seeing the implementation of standardized patient safety protocols by a small number of resource-rich countries is not sufficient. Over time, the networks that participating Member States, WHO and The Joint commission have with transitional and resource-poor countries will help to support the adaptation and implementation of these protocols within the developing world. This is one important way that the participating Member States, can share their expertise and technical resources worldwide.

Despite the many other successes in building global and national networks, implementation of standardized operating protocols across the boundaries of multiple countries was fraught with sociopolitical challenges. The inherent differences among national and international institutional
structures of governance, as well as the differing health-care systems and cultures in the Member States posed expected barriers to the development of networks and even to raising awareness about the High 5s Project.

The barriers encountered could be grouped into the following categories.

a) **Bureaucratic.** These included processes for approval and implementation of SOPs which were significantly different among Member States, thus preventing smooth ‘on time’ dissemination across all of the participants. Sharing developments with the wide base of High 5s Project participants was slow and demanding because of legal and bureaucratic restrictions. Ultimately, a lack of uniformity in rules, regulations, and timeliness of processes presented itself as one of the challenges.

b) **Norms of work and experiences.** Interpreting and agreeing upon content was sometimes challenging because of different understandings and experiences related to the issues being addressed.

c) **Technological.** Some participating Member States were more technologically advanced than others, leaving a cohort not as connected to the electronic resources that were available to all. This presented a unique challenge when deciding on some of the content of the SOPs, the evaluation process, and the mode of dissemination of the SOPs.

d) **Resources.** Lack of resources, monetary and human, was a significant barrier to spreading awareness. Sometimes, this barrier prevented the solution from being disseminated to the population who could benefit from it the most. Satisfactory training and reproduction of the High 5s resources was challenging to complete for this reason.

Raising awareness about the Project on a global level was achieved through various channels of communication. The High 5s Project published papers, presented the Project at international meetings, issued press releases and linked with country partners to support national communication and promotional activities of the Project. (See Table 10.)

Table 10: Communicating the High 5s Project globally

<table>
<thead>
<tr>
<th>Channel</th>
<th>Activity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Peer-reviewed papers</td>
<td>High 5s: Addressing Excellence in Patient Safety 2009, at World Hospitals and Health Services, 45, 2</td>
</tr>
<tr>
<td></td>
<td>Introduction to High 5s: Action on Patient Safety (submitted for publication)</td>
</tr>
<tr>
<td></td>
<td>ISQua 2012: 29th International Conference, Geneva, Switzerland</td>
</tr>
<tr>
<td></td>
<td>ISQua 2011: 28th International Conference, Hong Kong, China</td>
</tr>
<tr>
<td></td>
<td>ISQua 2010: 27th International Conference, Paris, France</td>
</tr>
<tr>
<td></td>
<td>5th Annual International Forum on Quality and Safety in Healthcare, Nice, France, 2010</td>
</tr>
<tr>
<td></td>
<td>ISQua 2009: 26th International Conference, Dublin, Ireland</td>
</tr>
<tr>
<td></td>
<td>2006 Annual Commonwealth Fund International Symposium on Health Care Policy</td>
</tr>
<tr>
<td></td>
<td>2005 Annual Commonwealth Fund International Symposium on Health Care Policy</td>
</tr>
<tr>
<td>Press release</td>
<td>2006 The WHO Collaborating Centre on Patient Safety Solutions, the World Health Organization and the Commonwealth Fund announce Action on Patient Safety (High 5s) Initiative</td>
</tr>
<tr>
<td>Global and national High 5s Project websites</td>
<td>See Annex 1</td>
</tr>
<tr>
<td>High 5s newsletter</td>
<td>Distributed to all High 5s Project participants and stakeholders worldwide</td>
</tr>
</tbody>
</table>
2. National networks and awareness raising

**Australia**

Participation of Australian hospitals in the High 5s Medication Reconciliation initiative has been used to raise awareness and promote the concept of multidisciplinary medication reconciliation at a national level. The Australian Commission published three articles on medication reconciliation in professional journals and has presented on the Australian experience with the High 5s Project at a number of national and international conferences over the period 2010 to 2012. These include the International Society for Quality in Health Care (ISQua), The Society of Hospital Pharmacists of Australia (SHPA) Conference, the National Medicines Symposium, and the Australian Association for Quality in Health Care (AAQHC) conference. For a full listing of titles of abstracts and peer-reviewed articles see Annex 11.

The Commission has developed a medication reconciliation webpage that houses a number of resources to assist hospitals to implement a formal process of medication reconciliation. [http://www.safetyandquality.gov.au/our-work/medication-safety/medication-reconciliation/](http://www.safetyandquality.gov.au/our-work/medication-safety/medication-reconciliation/) Australian High 5s hospitals contributed to the development of the resources. The national Medication Management Plan (MMP) published by the Commission in October 2010 provides health service providers with a standardised form that can be used by nursing, medical, and pharmacy staff to record the BPMH and reconcile medicines on admission. Other tools include an online training presentation on how to use the MMP, and a range of posters and brochures using the theme MATCH UP Medicines for use in hospitals to promote the process of medication reconciliation (Annex 9).

The Commission also works closely with NPS MedicineWise to have medication reconciliation messages included in initiatives to improve the quality use of medicines in the community. One of the results of this work is a consumer wallet and brochure that highlights the importance of being knowledgeable about your medicines and having an up-to-date medicines list. High 5s hospitals provide the wallet to patients on discharge from hospital with their discharge medication list, and other medication information. It has been distributed to a number of hospitals outside of the High 5s group (see Annex 9 for an illustration of the wallet insert).

The Commission has also raised awareness among the ambulance authorities of the importance of bringing the patient’s own medicines to the hospital when patients are admitted by ambulance from home.

**France**

**On the CSS SOP**

- Awareness was raised through presentations and posters presented by the High 5s teams and the LTA at national and international meetings (e.g., International Conference on Quality and Safety, French Annual National Patient Safety Week, HAS Annual Meeting, French Society for Orthopedic Surgery).
- A quarterly newsletter has been widely distributed to hospitals and institutional partners as well as within HAS.
- HAS has placed particular focus on site-marking and will soon disseminate the site-marking guide.
- A national conference is planned for 2013-2014 will disseminate High 5s Project data and present the outcomes of the Project to date, as well as lessons learned.

**On the Med Rec SOP**

- The High 5s teams have realized several opportunities to present to professional societies and health care institutions during pharmaceutical congresses to promote this practice.
- Presentations and posters presented by pharmacists and the LTA, (e.g., French Pharmaceutical Congress, French Society for Clinical Pharmacy, French Regional Workshop on Quality and Safety).
- Presentations on the High 5s Project and the Med Rec SOP at the national meetings of OMEDIT Aquitaine, part of the national OMEDIT network in collaboration with the Ministry of Health. This meeting takes place every semester and brings together stakeholders in medication safety. This activity helped to provide visibility for all of the hospitals that have been implementing Med Rec but are not involved in the High 5s Project. The LTA’s objective is to gather information from these teams in order to understand how they succeeded in setting up the medication reconciliation process and to develop a national network for sharing experiences.
Germany

The participation of Germany in the High 5s Project has fostered a strong German learning community of hospitals. The LTA organizes workshops for the hospitals with the aim of training the trainers and sharing experiences. In addition to the High 5s international news bulletins which are circulated to the German hospitals, the German LTA has set up a national mailing list. This mailing list is used to distribute SOP-specific information to the hospitals on an irregular basis. This information encompasses recent SOP-specific literature, case studies from CIRS, television programme tips or newspaper articles regarding patient safety, and conference presentations and posters, as well as other patient safety resources.

The German LTA and the High 5s hospitals regularly attend national and international patient safety and quality conferences and give High 5s presentations, thereby increasing the awareness of the Project. In addition, SOP-specific publications in several widely-read professional journals have achieved much attention for the Project in Germany. In this context, the LTA and participating hospitals have received many inquiries on SOP-specific issues.

The expert advisory committee convened by the Ministry of Health ensures strong connections between the High 5s Project and the German Society of Surgery as well as the German Association of Hospital Pharmacists. The Ministry of Health and these experts have established links between the High 5s Project and related projects being conducted in Germany. Further, they support Project implementation by making suggestions for further Project development and for ensuring its sustainability.

The Netherlands

The High 5s network started in the Netherlands in 2009. Within this network, hospitals have worked together to carry out the SOP. Hospitals collaborated with CBO to disseminate results at international/national conferences on patient and medication safety through workshops/(master) classes, (poster) presentations and site visits. Twelve hospitals took part in an extra data-collection effort on the effect of pharmacy-based medication reconciliation in the Netherlands. A list of dissemination activities from 2009 till present can be found in Annex 20. Because of a press release in February 2011 highlighting a 75% reduction in medication discrepancies following implementation of the Med Rec SOP, and because the pilot hospitals were successful in their SOP implementation and results, many more hospitals became interested in joining the Project. Even though it was difficult for them to find resources to participate during the time of financial crisis, four hospitals joined the network using their own budgets. Mental health and long-term care were enthusiastic about the Project, but unfortunately were not able to allocate budgets and manpower to become involved in the Project.

Singapore

The High 5s Correct Site Surgery project was presented at the Ministry of Health Work Plan Seminar 2012 held in August 2012 which was attended by the Singapore Permanent Secretary and Health Minister. The Work Plan Seminar is an annual event that provides a platform for the Ministry of Health to share Healthcare 2020 plans and initiatives with all of the Public Hospitals, and also serves as a forum for hospital clusters to share initiatives that they have put in place to support Healthcare 2020. The two part-time Network co-chairs were invited to present the journey and success in implementing the CSS SOP. The messages highlighted (i) how cross-cluster co-operation has brought about great success for everyone and ultimately better care for patients, and (ii) the innovations and different methods adopted in the project. Feedback by the hospital CEOs on the presentation was positive.

Internationally, Singapore efforts to implement the High 5s Correct Site Surgery SOP have been showcased via poster display at the 23rd Annual National Forum on Quality Improvement in Health Care in Florida in December 2011. An updated poster was again displayed at the International Forum on Quality and Safety in Healthcare in Paris in April 2012, and another updated poster was presented at ISQUA’s 29th International Conference in Geneva in October 2012.

Trinidad & Tobago

The piloting of the CSS SOP on the orthopaedic units has created a renewed awareness of the importance of staff communication (verbal and written) in achieving and maintaining patient safety. Project team members have recognised the need
for ongoing monitoring, and evaluation of the Project as well as continuing sensitization of both executive and clinical staff. National networks with other public and private hospitals are yet to be established.

**The United States of America**

The Joint Commission alongside a number of partners has made significant strides in raising awareness of wrong-site surgery. Through the Center for Transforming Healthcare, The Joint Commission has engaged with the Lifespan Hospital System in Rhode Island. A result of that collaboration was the Targeted Solutions Tool for Wrong Site Surgery, which allow organizations to identify, measure, and reduce risks in key processes that can contribute to a wrong-site surgery.
High 5s meetings
The High 5s Steering Group meetings and international hospital meeting

1. Steering Group meetings

The High 5s Steering Group includes participants from all LTA, WHO and Collaborating Centre leadership, experts from the fields of surgery and pharmacy, and the US Agency of Healthcare Research and Quality (AHRQ). Together, the Steering Group has created and approved the SOP content and the processes for evaluation and event analysis. All collaboration takes place either via electronic modes of communication such as emails, conference calls, and webinars or through the two face-to-face meetings every year.

Although the SOPs have been implemented in different Member States and under different conditions and cultures, it is both surprising and comforting that similar problems are found in all settings. When this happens, the Steering Group is able to assist each other in identifying solutions that work. Through collaboration, the High 5s Project team has found supportive partners in Ministries of Health and other groups who are contributing to improving the feasibility and impact of the standardized protocols.

2. International hospital meeting

A one-day ‘First International High 5s Hospitals Meeting’ took place at WHO Headquarters in Geneva in October 2012. The meeting provided a platform where High 5s hospital teams and LTAs met to discuss experiences, share best practices, compare evaluation data, and provide recommendations and best ways forward for the High 5s Project. The hospital meeting served as a hub for an inter-country exchange of knowledge and implementation experiences to strengthen and motivate hospitals’ commitment.

The meeting brought together 80 participants representing 31 High 5s hospitals from Australia, France, Germany, the Netherlands, Singapore and the United States of America. Participants included hospital technical and management staff, and LTA, Collaborating Centre and WHO Patient Safety Programme staff. Three High 5s experts from Canada and the United States of America joined the meeting. Each participating Member State had selected one hospital per SOP to share implementation experiences and lessons learned.

In addition, High 5s hospitals from Australia, France, Germany, the Netherlands and Singapore presented 30 posters. Hospital data showed that SOP implementation has had positive impacts on hospital processes and patient care. The poster jury consisting of the three High 5s experts together selected one poster per SOP for the “High 5s Achievement Award”. Singapore National University Hospital won the “High 5s Achievement Award” for the CSS SOP, and the “High 5s Achievement Award” for the Med Rec SOP went to The Netherlands Medical Center Alkmaar.

In the break-out session, meeting participants formed five Working Groups to exchange information on SOP implementation challenges, qualitative and quantitative evaluation activities, and the impact of the SOPs across diverse country cultures and settings. Hospital participants were able to discuss directly with High 5s Steering Group members their experiences and challenges, and to contribute ideas on the best ways forward. For further information see Annex 22.
Next steps
1. Overview

Implementation of the SOPs is progressing successfully in participating hospitals and Member States. A collaborative effort by WHO, the Collaborating Centre, all LTAs and experts is being made to keep the SOPs updated and to amend them as needed. Plans to disseminate the SOPs and share the evaluation methodologies with the rest of the world are also being developed. It is expected that at the last Steering Group meetings in 2014, discussions will focus on how to promote and share SOPs, methodologies, lessons learned and expertise worldwide, and on how to build networks with the developing world. The handover of the Information Management System (IMS) and the primary location of project data and analysis will be determined by the time data collection comes to a close in September 2014. The Steering Group intends to make the transfer smooth such that this utility can be used by Member States and organizations after the official close of the High 5s Project anticipated in early 2015.

The SOPs have been developed with the intent that hospitals and organizations worldwide can readily adopt them and improve patient care and safety. Cultural, bureaucratic and practical lessons that were learned by the High 5s teams and LTA staff will be shared with the world community. Barriers faced by teams were similar despite the differences in regions and cultural contexts, for that reason, the documentation of some solutions to these barriers should be useful. Paramount to all efforts will be active engagement with existing partnerships that the LTAs, WHO and Joint Commission International already have with transitional and developing countries to support the promotion, adaptation and implementation of the protocols within more countries around the world.

Some of the successes of this international collaborative have been largely the collaboration itself. From the inception of the Project, the leadership was composed of international public health experts and those interested in patient safety, along with organizations like WHO and Joint Commission International. This special relationship between organizations and individual experts has led to the successful analysis of the feasibility and impacts of the High 5s SOPs at a ‘grassroots’-level.

2. The cross High 5s medication reconciliation map

An interactive online map was developed by the Institute for Safe Medication Practices (ISMP) Canada, the Med Rec SOP lead, to profile High 5s achievements in the participating Member States which have implemented the Med Rec SOP. The map includes Med Rec implementation site information and highlights High 5’s Med Rec implementation publications and national supports such as accreditation standards. Links for all are supplied where available. Participating Member States were provided a country-specific map graphic to use for marketing and communications and to connect teams and sites. The map is available at http://www.ismp-canada.org/medrec/map/world/

3. Next steps by LTAs

Australia

SOP implementation

The next step for Australia is to spread the SOP to patient discharges. Quality improvement measures are currently being developed and will be available for hospitals (including High 5s hospitals) to collect information on discharge medication reconciliation and how to measure improvement.
Adopting new SOPs

The Commission will not be adopting any new High 5s SOP.

Expansion to additional hospitals

As of January 2013, all hospitals in Australia are required to meet the NSQHS Standards as part of the new national accreditation scheme. This requires hospitals to be assessed against two criteria in the Medication Safety Standard that relate to medication reconciliation. The model of medication reconciliation described in the Standard 4 - Medication Safety Standard Safety and Quality Improvement Guide – the resource developed to assist hospitals implement the NSQHS Standards - follows that of the High 5s Medication Reconciliation SOP. The objective is for the medication reconciliation SOP to be implemented in all Australian hospitals. The Commission will be working with the State and Territories to achieve this objective and is developing additional resources to assist hospitals to implement Medication Reconciliation and monitor their activities. These will include a MATCH UP Medicines medication reconciliation toolkit, a BPMH training tool, and performance measures to measure medication reconciliation performed on admission and at discharge.

France

Next steps are presented in Table 11.
Table 11: Next steps for French LTA

<table>
<thead>
<tr>
<th>CSS</th>
<th>Med Rec</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Full implementation of the CSS SOP in the four HCOs at partial implementation</strong></td>
<td>To support and assist seven or eight hospitals to develop full implementation of medication reconciliation. Currently, they are not fully operating within the framework of High 5s Med Rec criteria.</td>
</tr>
<tr>
<td>a) The LTA is reinforcing its support in order for the HCOs to overcome the barriers identified (visits, conference calls, and team training are going to be proposed by the CEPPRAL). The goal is to spread SOP implementation throughout the entire hospital. The standardized evaluation activities would be limited to a few units.</td>
<td></td>
</tr>
<tr>
<td>b) Advice is being developed on how to use these SOP results to help organizations ensure safety when patients are admitted on the day of the surgical intervention, as this situation will soon become prevalent.</td>
<td></td>
</tr>
</tbody>
</table>

**Engage the hospitals CEOs**

Targeted communications towards the CEOs of the participating hospitals will be conducted, e.g., for the CSS SOP, a quarterly newsletter addressing issues of leadership, culture safety, and comparative results. A workshop is planned at the end of the year in order to share experiences and results.

**Foster recognition of the contribution of the High 5s teams participating in the Project and reward their efforts.**

**Dissemination of lessons learned and results of the High 5s Project**

HAS is planning a conference with a large audience of interested stakeholders where outcomes and lessons learned will be presented. This is essential for the successful integration of the High 5s experience into the national strategy on patient safety. Publications and communications in French by the hospital High 5s teams and the LTA will also support the dissemination effort.

**Scale up the High 5s Project good practices to the national level**

**Site-marking and pre-operative verifications**

A committee including the Ministry of Health, HAS and the CEPPRAL has recently been set up to develop a strategy for spreading the learning about patient safety practices derived from the High 5s Project to the national level.

**Promoting site-marking at the national level**

- The surgical checklist is a required practice in France but does not include site markings. Spreading and adoption of site-marking practices will have a major impact on surgical safety. As a first step, HAS decided to promote site-marking in the next HCO accreditation cycle. Feedback from High 5s hospitals shows that a sense of “ownership” of this practice has developed within the teams involved in the Project. A community of “champions” has grown and will have a major role in the uptake of this good practice by other teams. Site-marking will also be extended to outpatient surgery.

- Pre-operative verification: Additional analysis of the feedback and High 5s data will be conducted on the pre-operative verification process. Data and success stories derived from this analysis will provide inputs on the HAS surgical safety programmes.

**Medication Reconciliation**

- Develop a strategy on the spreading of High 5s Med Rec outcomes and lessons learned at national level, and also take into account the experiences of the health care facilities not participating in the Med Rec project which perform medication reconciliation.

- Integrate Med Rec as a patient safety practice in the medication safety policy, working in collaboration with all the stakeholders in the field.

- Provide Med Rec guideline and toolkits adapted to the different types of HCOs.
Adopting new SOPs

The adoption of new SOPs is not being considered at present because of limited resources and funding HAS, as well as ongoing policy requirements concerning budget restrictions in the French public sector.

To conclude, a large amount of work and sharing of knowledge and experience has been undertaken since France became engaged in the High 5s Project. At present, integrating Project recommendations and conclusions into the national strategy is one of the main challenges. To this end, the French experiences and exchanges within the global learning community and the High 5s Steering Group have been invaluable.

Germany

SOP implementation

CSS: The German LTA has encouraged the hospitals to submit their data on a monthly basis for a period of at least two years. Several hospitals are eager to submit data for a longer period and to receive feedback until the end of 2013. Because the German data model is very resource-consuming (i.e., scanning of the checklists, creation of feedback reports for each hospital), the LTA will stop accepting checklists at the end of 2013 and will focus on a detailed final analysis of the checklist data during 2014. A majority of the hospitals have signaled that they will maintain the SOP processes (or modified versions of the SOP) and checklists after the High 5s Project has ended.

Med Rec: Following the translation, adaption of the implementation tools and the development of a data collection tool, the hospitals officially started implementation and evaluation of the SOP in the spring of 2013. Data collection is to continue until December 2014, with subsequent final analysis of the data.

A public workshop will be organized in June 2015 to present the final Project results.

Expansion to additional hospitals

CSS: There is no expansion of the current project planned. However, following the final analysis of the multidimensional evaluation data on the national and international levels, the German LTA plans to draft a “best implementable surgical checklist” and a clinically well-assessed SOP. These High 5s findings will be published as recommendations for German hospitals.

Med Rec: The German LTA is planning on recruiting 3 to 5 more hospitals for implementation.

The Netherlands

The Dutch Ministry of Health has been supporting participation in the High 5s Project and the pilot group since 2009. Follow up activities on the SOPs are being discussed, and other parties will be involved in planning about the spreading of knowledge and outcomes to other hospitals and facilities. The outcome of the national patient safety hospital programme (2008-2012) shows the importance of the theme of medication reconciliation for elective and discharged patients, which is still not effective enough. For the target population (65 years and greater admitted through the ED) of the High 5s SOP it is clear that implementation of the SOP is still needed after comparison of baseline and subsequent performance measurements among three different groups of hospitals between 2010 and 2012. Based on the results of the national patient safety hospital programme and the experiences with the High 5s SOP for Medication Accuracy at Transitions in Care, the Dutch Inspectorate of Health has highly recommended this SOP be continued in the Netherlands (see Box 28).
In June 2013, the High 5s SOPs were mentioned by NIVEL in the evaluation research of the national patient safety programme in Dutch hospitals (NIVEL and EMGO). Dutch High 5s Med Rec hospitals are also interested in adapting the SOP for Concentrated Injectables SOP. These hospitals have emphasized that, “the international contribution is great because of the learning community. We would also like to implement another SOP, for example, the SOP for Concentrated Injectable Medicines. This is also a theme of the national patient safety programme. If there’s any external budget available, we would like to participate in this SOP”.

In the Netherlands the Concentrated Injectables SOP could also be used to implement the national guideline on this topic which was also part of the national patient safety hospital programme (high risk medication). In 2013, the LTA has started a pilot on the Concentrated Injectables SOP in 16 hospitals in collaboration with national experts and the support of the Ministry of Health.

Singapore

The High 5s Network has expressed interest in implementing the High 5s SOP to other areas where appropriate and feasible, such as the Radiology Department and Day Surgery Operating Theatres, and the Ministry of Health is strongly supportive of this. They have also suggested stepping up the frequency of CRVEs so that more cross institutional observations can be conducted to validate practices. The Ministry of Health will continue to maintain a facilitative role for institutions to do so.

Meanwhile, the Ministry of Health has gone ahead to adopt the Medication Reconciliation SOP into the National Standards for Healthcare document for Public Hospitals in Singapore and to commence implementation. The target date to begin to collect data is currently set for April 2013.

The Ministry of Health will continue to support the High 5s initiative through funding of the headcount to support the data requirements of the Project until the end of the Project in December 2015.

Trinidad & Tobago

The Ministry of Health plans for:

- full implementation of the CSS SOP at relevant surgical units of all public hospitals by April 2014;
- expansion to the private hospitals within Trinidad and Tobago during the latter half of 2014;
- development and issuance of a National Policy on Site Marking to all health-care providers (public and private); and
- review and revision of all supportive data collection tools used by staff in the surgical units to achieve standardization.

The United States of America

In the U.S.A., there are two potential avenues for adoption of SOP components via process of care measures. In general, the benefit of the process of care measures is that they are designed to provide prima facie evidence of linking process to outcome. One avenue of leverage is through accreditation, while the other avenue is through re-imbursement.
If the accreditation approach were to be pursued, the obvious outlet would be through The Joint Commission. The Joint Commission is the accrediting body for over 20,000 healthcare organizations and programmes in the U.S.A. Accredited hospitals incur site visits every third year and are evaluated by series of criteria.

The Joint Commission currently uses “Accountability Measures” which are designed to incorporate four constructs: research, proximity, accuracy, and adverse events. According to The Joint Commission, the measure needs to be proven by research that the process being measured is closely connected to the outcome it impacts. Further, the measure should accurately assess whether the care process has actually been provided, and whether the measure, as designed, minimizes or eliminates unintended adverse effects. Most SOP measures would fit within all four of these constructs.

The second avenue would be through hospital re-imbursement from the US Centers for Medicare & Medicaid Services (CMS). Starting in FY12, hospitals are now scored on conducting certain processes (compared to a benchmark) and demonstrating their improvement. The scores are used to calculate incentive payment amounts. Hospitals risk losing 1% in Medicare inpatient payments, eventually rising to 2% by 2017. It is expected that the programme will expand in FY14, with the addition of 20 more measures.

It should be noted that The Joint Commission and CMS have worked together to develop measures in the past. If this course is chosen, an approach similar to the one taken in 2003 by CMS and The Joint Commission when they co-wrote the ‘Specifications Manual for National Hospital Inpatient Quality Measures’ could be used.