Report of the

Canada-Italy Workshop on Patient Safety

May 3-4, 2018, Carleton University,

Ottawa, Ontario, Canada

October, 2018

Executive Summary

Overview:

This patient safety workshop was organized to identify major issues related to technology-based aspects of patient safety and examine approaches and strategies that could help to reduce adverse events, medical errors, and other unsafe occurrences. The workshop's intended outcomes are to propose policies and provide hospital administrators, clinical personnel, clinical engineers and technologists with a series of implementable actions. These actions define what can be done by each of these groups to improve patient safety in aspects related to clinical engineering. In addition, the effective use of information technologies that could help minimize potential risks for patients is explored and discussed.

The workshop was held at Carleton University in Ottawa, Canada, on May 3-4, 2018. Experts from Canada and Italy were invited from several professional groups: physicians, clinical and biomedical engineers, nurses, epidemiologists, regulators, and health care administrators. Fifteen stakeholders attended from Canada and five from Italy to share their knowledge and approaches on how to optimize patient safety.

This summary provides an overview of the key aspects of this workshop and a summary of the recommendations for action. Readers seeking further information on the detailed aspects of this work are encouraged to review the complete report.

The participants in this workshop are all keen to encourage and support the adoption of the actions identified here, and this report will be widely circulated to interested parties and participants are encouraged to present it at relevant meetings and share it freely.

Individual Presentations:

Each attendee presented their perspective on this topic under a series of six headings; The Current State of Patient Safety in Healthcare, Patient Safety Issues from a Clinical Engineering Perspective, Human Factors Approaches to Patient Safety, Technological Tools to Help Minimize Patient Safety Issues, The Role of Health Technology Assessment in Promoting Patient Safety, and Building a Commitment to Patient Safety in Healthcare Systems.

Small Group Discussions:

In the afternoon of Day 2, four discussions groups were held, with four to five members each. Each group was asked to reflect on the presented materials and discuss a series of questions on patient safety:

- What are the current issues?
- What needs to be done to address them?
- Who needs to be involved to make these changes?
- How can they be implemented?
- What would be the impact of the proposed changes?

At the end of the discussions, a member of each group was asked to report the results of each discussion to the larger group. All groups then sent their written notes to the workshop organizers who were tasked with reviewing and combining the notes into this report.

Summary of Group Discussions:

Please note that for each of these issue statements, the full report contains a series of proposed actions in response:

Safety must be made much more prominent in the commitment to health care quality, and part of the solution to better marrying safety as part of quality.

A top down and across the board effort compelled by legislation, standardization, accreditation, recommendations and guidelines as well as investment in resources can help to make sure that safety is embedded in the entire healthcare system by design.

Clinical engineers should play a more central role in implementing Safety by Design to both resolve issues at the frontline as well as reduce the complexity of healthcare technology. Moreover, they should be involved in the assessment and procurement of implantable technology and not just equipment.

There are numerous opportunities to strengthen regulations or recommendations should these regulations not be in place, specifically with regards to the post-market surveillance of medical devices, including human factor engineering and health technology assessment.

Patient safety can be improved with increased collaborations among health care providers and decision makers across all levels of the health care system that also involve patients and their families.

Proposed Resolutions:

- To improve the commitment to patient safety it is important to demonstrate that these systems-based approaches are making a difference. Making safety a leadership priority, implementing safety improvement projects, showing policy impact, and creating alliances and networks to encourage sharing of successes and benchmarking outcomes are all strategies that should be utilized.
- Environmental conditions need to be made conducive to educate and incentivize physicians, nurses and other clinicians to report on adverse medical device events. More research is needed to investigate how to better design and implement post-market surveillance systems for medical devices, to assess the impact of various constraints on clinical outcomes, and to develop interventions that optimize decision-making about device choice.
- A collaborative approach needs to be taken and expertise from other disciplines leveraged, including clinical and human factors engineering, to assist in appropriate device selection, to learn how to ensure safe use of medical devices, and to identify system and device vulnerabilities to proactively address them.

- Time and resources need to be dedicated to not only use new health information technologies safely and effectively, but to also acquire data on harms prevented and errors caused by the implementation of HIT. This information should be used to inform future changes to system design and implementation.
- Hospital leadership needs to solicit and act on feedback from front-line healthcare teams after implementation of HIT. Healthcare teams need to continue being educated about competencies that are now being automated by the HITs, and training that promotes resilience and effective team functioning needs to be embraced.
- With the increasing amount of technology and devices being introduced to improve the way healthcare is delivered to patients, frontline staff need to be provided with the resources and support to continue listening to patients and their families while providing bedside care for patients. Patients and families need to be actively engaged and included when designing and troubleshooting patient safety systems. Collaborations with other healthcare organizations are important to find shared solutions to common problems, harmonize practices, and reduce variation in systems and practice.

Conclusions

Healthcare institutions continue to struggle to reduce harm despite advancements in health care technologies. Patient safety efforts in the last decades have emphasized the need for better device design, but broader resolutions are required to reduce preventable adverse events. Resolutions need to effect system change, including consideration of interacting elements that influence performance: people (e.g., physical and cognitive limitations) tasks (e.g. difficulty or complexity of the task), tools and technologies (e.g. usability and accessibility), organization (e.g. resources), environment (layout, lighting). Furthermore, patient safety efforts must not only focus on why adverse events occurred, they must also proactively identify how they might be prevented. To do so, feedback about risks must be communicated across various health care sectors, such as ministries of health, health regions, institutions, organizations, and the community. The resolutions presented in this report highlight the various ways clinical engineers can and need to be engaged to create safer health care systems for patients and clinicians.

The proposed resolutions to the identified current issues can increase the effectiveness of both health care delivery and clinical outcomes; thus enhancing the overall quality of patient care. Further, the resolutions may result in positive changes to the workplace environmental and culture due to less staff burnout and better staff engagement and workforce self-image, such as having the clinical engineers play a more prominent role in patient safety.

It is clear that there are a number of promising approaches available. The key to success will be encouraging their broad uptake within healthcare systems. To help to initiate this, the findings of this workshop will be widely circulated and shared, to initiate discussions on how best to initiate the actions that have been identified here.

Full Report of the Canada-Italy Workshop on Patient Safety (May 3-4, 2018), Carleton University, Ottawa, Ontario, Canada

INTRODUCTION

Patient safety in healthcare institutions has not improved despite the significant attention that has been focused on this topic in the past twenty years, advancements in healthcare technology, and the increasing cost of healthcare. Although different regions have different needs and available resources, a 2030 goal of reducing incident-related deaths by 20% could be adopted by governments, to help to focus attention on this important concern. The proliferation of technology in healthcare provides many benefits but also brings with it increased complexity, placing additional demands on healthcare providers and the healthcare system. There is a growing awareness of these healthcare technology issues and the steps that can be taken to address them, and focusing on them is likely to lead to significant improvements in overall patient safety outcomes.

The issue of patient safety has become extremely important in the 21st century. Consider that in the USA alone, 251,454 patients died in 2013 as a result of medical errors or adverse events in that one year! This is the third leading cause of death in the USA[1]. This figure, published in 2016, must be under-estimated since it derives from identified cases, and it is well-known that not every adverse patient outcome is reported and tracked. Extrapolating these numbers for Canada based on relative population size, the figure would be around 25,000, and for Italy; 50,000 patients.

Clinical engineers who manage medical devices and train users on the safe use of technology can play a critical role in helping to minimize these occurrences. Moreover, it is vital that administrators, physicians, nurses and all clinical staff understand how these errors occur and how to minimize them.

[1] Medical Error – the third leading cause of death in the US. Makary M and Daniel M. BMJ 2016; 353 doi:https://doi.org/10.1136/bmj.i2139 (Published 03 May 2016).

PATIENT SAFETY WORKSHOP

A patient safety workshop was organized to identify major issues related to technology-based aspects of patient safety and examine approaches and strategies that could help to reduce adverse events, medical errors, and other unsafe occurrences. The workshop's intended outcome was to propose policies and provide hospital administrators, clinical personnel, clinical engineers and technologists with a series of implementable actions. These actions would define what can be done by each of these groups to improve patient safety in aspects related to clinical engineering. In addition, the effective use of information technologies that could help minimize potential risks for patients was explored and discussed.

The workshop was held at Carleton University in Ottawa, Canada, on May 3-4, 2018. Experts from Canada and Italy were invited from several professional groups: physicians, clinical and biomedical engineers, nurses, epidemiologists, regulators, and health care administrators. Fifteen stakeholders attended from Canada and five from Italy to share their knowledge and approaches on how to optimize patient safety. See Appendix A for the list of participants and Appendix B for the program.

Organisers from Canada:
Monique Frize: Distinguished Professor, Systems and Computer Engineering, Carleton University, 1125 Colonel By Drive, Ottawa, ON, Canada, K1S 5B6; Chair Council of Societies, International Federation of Medical and Biological Engineering CoS-IFMBE)
Anthony Easty: Adjunct Professor, Institute of Biomaterials & Biomedical Engineering (IBBME), University of Toronto, Rosebrugh Building (RS), 164 College Street, Room 407 Toronto, Ontario M5S 3G9 Canada; Member, Clinical Engineering Division (CED-IFMBE)
Patricia Trbovich: Associate Professor and Badeau Family Research Chair in Patient Safety and Quality Improvement, Institute of Health Policy, Management and Evaluation, University of Toronto, 155 College, Suite 425, Toronto, Ontario, M5T 3M6 Canada; Member, Health Technology Assessment Division (HTAD-IFMBE).

Organisers from Italy:
Ernesto Iadanza: Adjunct Professor of Clinical Engineering, Department of Information Engineering, Università degli Studi di Firenze, Via di Santa Marta, 3, 50139 FIRENZE, ITALY; Chair, Clinical Engineering Division (CED-IFMBE).
Leandro Pecchia: Assistant Professor, Biomedical Engineering, School of Engineering, University of Warwick, Coventry, CV4 7AL, UK (But family home is in Rome); Chair Health Technology Assessment Division (HTAD-IFMBE).

FORMAT

Individual Presentations:
On Day 1 and on the morning of Day 2, attendees presented on topics related to patient safety and health technologies in which they have expertise.

There were six main topics to be addressed by speakers in their presentations. They were as follows:

1. **The Current State of Patient Safety in Healthcare:** Where are we at now with safety related to technology and processes in health care? What is the current state and why is it proving to be such a difficult problem to address systemically?
2. **Patient Safety Issues from a Clinical Engineering Perspective:** Types of technology-focused patient safety issues (electrical, EMI, adverse events and medical errors, mechanical failure, radiation hazards, use-errors associated with medical devices, etc.)
3. **Human Factors Approaches to Patient Safety:** Human factors engineering and other approaches to identify potential risks and their elimination.
4. **Technological Tools to Help Minimize Safety Hazards:** The impact of Physician Order Entry Systems, Clinical Decision Support Systems, Health Information Systems, access to information at point-of-care, etc.
5. **The Role of Health Technology Assessment in Promoting Patient Safety:** Defining clearly all stages of ensuring technology-based patient safety, from equipment design, regulation, user-training, and proper management by clinical engineering specialists, etc.
6. **Building a Commitment to Patient Safety in Healthcare Systems:** Examining the organizational commitment to safety. What strategies can be brought to bear to make safety a top priority across each organization with clear leadership from the top.

Small Group Discussions:
In the afternoon of Day 2, four discussions groups were held, with four to five members each. Each group was asked to reflect on the presented materials and discuss a series of questions on patient safety:

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- Who needs to be involved to make these changes?
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SUMMARY OF PRESENTATIONS

Topic 1: The Current State of Patient Safety in Healthcare

Making a Difference! Progress, gaps and frontiers in patient safety – Gordon Wallace

- There are three key messages that need to be conveyed:
    - Errors can be reduced.
    - For effective solutions, we need to think in terms of individuals, teams and systems.
    - A new era focused on quality is required.

- We must consider the dimensions of quality (as defined here by the Institute of Medicine):
    - Safe.
    - Effective.
    - Patient-centred.
    - Timely.
    - Efficient.
    - Equitable.
- To accomplish these we need supporting systems and we need to improve provider and team performance.
- Across developed nations, the incidence rates of patient harm among hospitalizations are estimated to be between 6% and 17%, according to the Canadian Patient Safety Institute (CPSI). We thus have a burning platform for change.
- Patient, provider and team stories are very powerful and can help to mobilize action.
- Healthcare is not that safe overall and there are multiple causal factors. For example, in reviewing harm, 60% of cases are associated with a problem in communication.
- After harm and error have occurred, it is very important that there is disclosure to patients and families, apologies, and commitments made to improve.
- CPSI training on Patient Safety Competencies[2] and CanMEDS Competency by Design[3] are important efforts to provide training on patient safety issues.
- Diagnostic delay and error is a contributing factor, as are common cognitive biases.
- Aviation has improved safety through crew resource management, situational awareness, communications, checklists and simulation.
- Encouraging patient engagement in their care is also very important, and tools such as Electronic Health Records help to facilitate this.
- The traditional workplace culture regarding errors has been to "blame, shame and retrain", and this has not proven effective. We need to apply systems thinking to systems-based errors.
- Professor James Reason's Swiss cheese model of system failure has been widely applied in health care and is a powerful tool for viewing errors in a systems framework.
- We tend to "drift" into failure by cutting corners and using workarounds. These behaviours are not necessarily bad but need to meet safety thresholds. We need to differentiate between human error, at-risk behaviour and reckless behaviour and respond to each accordingly.
- Unprofessional behaviour should not be tolerated – courage should not be a prerequisite to coming to work.
- We should push toward consistency and decrease unwarranted variation in care.
- The Safer Healthcare Now Lives Campaign[4], Bundles of Care[5] and Choosing Wisely[6] are helpful guidance tools.

[2] http://www.patientsafetyinstitute.ca/en/toolsResources/safetyCompetencies/Pages/default.aspx
[3] http://www.royalcollege.ca/rcsite/cbd/rationale-why-cbd-e
[4] http://www.patientsafetyinstitute.ca/en/toolsResources/Pages/Interventions-default.aspx
[5] http://www.ihi.org/Topics/Bundles/Pages/default.aspx
[6] https://choosingwiselycanada.org

- We need to measure quality wisely and avoid the trap of being awash in indicators and excessive measurement, much of which is useless.
- Tools such as forcing functions (e.g., uniquely keyed connectors for lines carrying different gases) are highly effective since they prevent issues such as dangerous misconnections by making it physically impossible for these misconnections to occur. The hierarchy of effectiveness of interventions should also be considered, with priority given to more effective solutions such as constraints and forcing functions where possible.
- Excessive alarms in ICUs can lead to fatigue and overload, making critical events less detectable.
- The Black Box project[7] in the operating rooms currently championed at St. Michael's Hospital in Toronto can help to reveal the details of procedures and how they can be made safer in future.
- The digitization of medicine is generally a positive trend but it must be done in a way that supports patients and healthcare providers and should be designed to meet their needs.
- Generally, we need the people doing the work to be involved in the redesign of the system for safer outcomes. "The people affected by the work need to be the people who change the work".
- Knowledge transfer for safety improvement must be active and multifaceted if it is to be effective.
- Are we safer? Currently:
    - Better understanding of the extent and origins of the safety problem.
    - Specific clinical issues and processes have improved.
    - Patients are more involved.
- However:
    - We are still more reactive than proactive, and mainly hospital focused.
    - Spreading innovation is still a struggle.
    - We do not yet have safety at a population level.
- In Canada according to a study by Risk Analytica in 2017[8]:
    - In the next 30 years, patient safety incidents could average 400,000 cases annually at an additional cost of $2,75 billion in 2017 dollars.
    - Every 13 minutes and 14 seconds a Canadian patient will die from preventable harm.
- To mitigate this, we need to move toward Era 3 for Medicine and Health Care[9]:
    - Transparency.
    - Improvement science.
    - Empowered patients.
    - More civility.
- Many professions need to work together to accomplish change and we need to innovate, to do valued things better.

[7] http://www.stmichaelshospital.com/media/detail.php?source=hospital_news/2014/20140708_hn

[8] http://www.patientsafetyinstitute.ca/en/About/Documents/The%20Case%20for%20Investing%20in%20Patient%20Safety.pdf

[9] ERA 3 for Medicine and Health Care. Berwick DM. JAMA 2016; 315(13):1329-1330. doi:10.1001/jama.2016.1509

- Three final messages:
    - Errors can be reduced!
    - For effective solutions, think individuals, teams and systems.
    - A new era focused on quality is required.

Topic 2: Patient Safety Issues from a Clinical Engineering Perspective

IFMBE/Clinical Engineering Division Global Role in Improving Patient Safety - Ernesto Iadanza

- Main topics discussed:
    - Education
        - Body of knowledge and body of practice surveys have been undertaken, which provide useful insights into the distribution of technology management responsibilities currently undertaken by clinical engineers in various countries.
    - Training
        - The Clinical Engineering Division is developing a series of online training courses on the support and safe use of a range of technologies.
    - Recognition
        - Biomedical/Clinical Engineers are still not classified as a distinct healthcare profession under the International Labour Organization. Efforts are underway to try to achieve this classification. The World Health Organization and IFMBE have joined forces on a worldwide survey of Biomedical/Clinical Engineers.
    - Certification
        - The CED has produced a white paper on the international state of certification for Clinical Engineers, which is currently somewhat fragmented around the world[10].
    - Awards
        - The CED helps to build the profile of the Clinical Engineering profession by offering a series of awards for exceptional contributions to the field[11].
    - Publications
        - The IFMBE/CED has commissioned a series of texts on topics that are relevant to clinical engineers. Many of these are available as free downloads from the IFMBE/CED website[12].
    - Communication
        - The CED participates strongly in international meetings and collaborates closely with organizations such as the World Health Organization[13].

Smart Pumps: The Canary in the Coal Mine – Scott Olsen

[10] http://cedglobal.org/ced-certification-white-paper/
[11] http://cedglobal.org/awards/
[12] http://cedglobal.org/ced-books/
[13] http://cedglobal.org/ernesto-iadanza-ced-chairman-plenary-talk/

- Main topics discussed:
  - Alberta Health Services (AHS): Consistency (e.g.,Toyota)
    - The AHS is the largest fully integrated health system in Canada, which offers the opportunity to share information and help to develop best practices.
  - AHS: Standardization of Infusion Pumps
    - The AHS decided to reduce the variety of infusion pumps across its system and standardize on just two products.
  - AHS: Collaborative approach (Provincial Infusion Pump Quality & Safety Committee)
    - Recognizing the complexity of modern medication deliveries, the AHS pulled together staff from a wide range of disciplines to devlop this approach.
  - Infusion Pumps: evolution grows together with complexity (smart pumps)
    - The advent of smart pumps that contain drug libraries and drug error reduction software holds much promise but brings new levels of complexity that need to be understood and managed.
  - Management of recalls
    - As in many other institutions, the AHS has been very busy monitoring and acting on infusion pump recalls, since this technology has been particularly prone to problems, in part as a result of the new features associated with smart pumps.
  - Cybersecurity
    - As more and more devices are connected to the internet, issues of device vulnerability and data security have come to the fore.
  - Mistakes in programming the drug libraries in the devices (new source of complexity)
    - While smart pump technology offers the potential for improving the safety of drug infusions, it also brings with it the potential for new errors to occur based on issues such as programming errors. The AHS tracks and trends reported problems with infusion pumps.

Clinical Engineers' Strategies to Ensure Safety at CHEO – Marie-Ange Janvier

- Main topics discussed:
  - Paediatric versus adult hospitals
    - Children have special vulnerabilities as patients, such as inability to communicate with care providers, small body size, etc.
  - Health Technology Assessment (HTA) and its impact on patient safety. Examples were provided on the selection of large volume infusion pumps and electronic beds; two different technologies with significant potential to cause patient harm if not appropriately selected, implemented and operated. The process followed included:
    - Needs assessment.
    - RFP (request for proposal) sent to the market.
    - Evaluation strategies (bench testing, simulation, pre-implementation test on one patient).
  - Clinical Engineers can enhance patient safety by working with manufacturers and clinical users during the technology assessment process.

Incident Investigations for High Performing Clinical Engineering Service – Andrew Ibey

- Main topics discussed:
  - Incidents and investigation
    - Important to have processes in place for capturing incidents in a consistent manner. These are important learning experiences for the healthcare system, and a tool that can help us all to improve in the long-term.
  - Importance of documentation
    - Impartiality and a non-judgemental approach coupled with capturing a record of the circumstances surrounding an incident is of great importance.
  - Chain of custody, evidence preservations, scientific rigour, personal observations.
    - These issues all form important components of the overall process.
  - Reporting
    - Sharing the outcomes with manufacturers, regulators, and other healthcare systems are key, to promote widespread learning and benefit.
  - Example of over-infusion
    - Wrongly programmed (loading dose).
    - Clinical Engineering contributed, because there were three different software versions used in the hospital.

Topic 3: Human Factors Engineering Approaches to Patient Safety

Using Human Factors to Assist in the Proper Alignment between Corrective Actions and Causal Factors – Patricia Trbovich

- Despite a growing understanding of the patient safety threats, we continue to struggle to reduce preventable adverse events. Improving safety requires the following:
  - A mix of system-level changes and enhanced resilience
    - System-level interventions should focus on automating safety checks and forcing functions to decrease unwanted variation in care.
    - Resilience-based interventions are required to help individuals and teams anticipate threats so that they can respond effectively.
  - Alignment of corrective actions to causal factors to identifying effective interventions
    - Application of Human Factors and safety science is needed to assist hospitals with analysis of incidents to uncover and resolve deep system problems by generating evidence about which corrective actions should be implemented.
  - New methods to study safety
    - Traditional methods of incident reports, chart reviews and mortality and morbidity rounds can be enhanced with simulation testing and video review that allow for more detailed understanding of system factors impacting safety.
- Goals of human factors for Medical Technologies and Processes
  - Improve patient safety.

- Improve efficiency.
- Decrease the need for training.
- Accelerate adoption.
- Create an enjoyable experience.
- Decrease need for instructions.

- We must recognise the diverse roles of clinical engineers within our health care system
  - Selection and procurement of medical devices.
  - Installation and integration with other devices.
  - Incident investigation: uncovering the root causes of the problem (technical failures versus no fault found human-technology interaction issues).
  - Operations monitoring.
  - Managing maintenance and repairs.

Medical Device Risk Management from a Human Factors Perspective – Tony Easty

- The application of human factors methods to the core activities of a Clinical Engineering Team opens up some interesting opportunities for clinical engineers to make a worthwhile contribution to moving forward the patient safety agenda.
  - Clinical Engineering can assist with better technology procurement by shadowing users to more fully understand the work environment, conducting heuristic analyses of potential equipment purchases to uncover human factors deficiencies in their design, and in extreme cases, conducting full usability tests to determine how safely users interact with prospective technology purchases.
  - Clinical engineering can help investigate incidents through the application of tools such as root cause analysis, failure mode and effect analysis, and the Canadian Incident Analysis Framework[14].
  - Clinical Engineering can identify no fault found repairs. These are situations where a piece of equipment is sent for repair and on investigation it is found that it is working to specification. This is often an indication that users are confused by the operation of the device, and further investigation can delve into the specifics of each case.
  - The application of these tools can significantly improve the safety of complex technologies in healthcare environments.

Topic 4: Technological Tools to Help Minimize Safety Hazards

Improving Patient Safety through Engaging Patients and Family Members in Health Information Technology Adoption – Gillian Strudwick

[14]http://www.patientsafetyinstitute.ca/en/toolsResources/IncidentAnalysis/Documents/Canadian%20Incident%20Analysis%20Framework.PDF

- Two case studies were presented
- Case 1: Efforts to engage patients and health professionals resulted in improvements to medication and patient identification scanning rates, as part of barcode medication administration
    - Number of potential errors prevented through the identification of scanning mismatches decreased.
    - Medication error incident reports also decreased.
    - Efforts involved a Peer Support Worker who interviewed over 50 patients about their experience with the technology used to support medication administration safety, as well as a set of knowledge translation activities.
- Case 2: Engaging with patients, family members and Peer Support Workers in the design, implementation and evaluation of a mental health patient portal.
    - Peer Support Worker conducted five focus groups with these important groups, as well as conducted over 100 interviews with individual patients and family members.
    - Findings were used to identify design considerations, implementation strategies, as well as specific outcome indicators to measure during the patient portal evaluation.
    - Patients have been engaged in usability testing of the patient portal which has informed design changes as well as educational materials.

Information Technology and Patient Safety - Monique Frize

- Several types of adverse events (AEs) can occur: adverse drug events and improper transfusions, surgical injuries and wrong-site surgeries, restraint-related injuries or death, falls, burns, pressure ulcers, and mistaken patient identities.
- Factors that interfere with cognitive or technical performance of providers are: insufficient use of information technologies (ITs) for decision-making, fatigue, sleep deprivation, supervision of junior staff, and a culture that portrays errors as individual failure.
- ITs that can help reduce errors are: practice guidelines and protocols at the point-of-care; automated reminders for patients and providers for tests or follow-up; adequate patient outcome information that can be benchmarked to identify unacceptable variations.
- AE tracking systems and online clinical information systems can be a solution. There exist pharmacy and nursing information systems and computerized physician order entry systems (POES) for medication management, electronic medical records, automatic and biometric identification technologies; clinical decision-support systems (CDSSs).
- Training users on the safe and effective use of medical devices and on their limitations is critical to maintain patient safety at the highest level possible.
- On the flip-side of safety, the following problems can arise: An over reliance on the device and its output; a malfunction (software or hardware); poor design; lack of updates when soft funding runs out; or require too much time from caregivers to use.

UBORA (Euro-African Biomedical Engineering e-Platform): Safety by Open Design - Arti Ahluwalia

- Patient safety is the number one priority in medical device design.
- Today, there are examples of open source medical devices (OSMD); this refers to sharing ideas and concepts with other professional designers on: design files, documentation, source-code, blueprints and prototypes, testing results and data.
- While they are not yet accurate or safe enough to be inserted in the clinical environment, OSMDs possess intrinsic advantages due to accessibility, sustainability, lower costs and, under ideal conditions, improved performance and safety because everyone can review the design file.
- Open-source means no IP protection, Open data on device performance and blueprints.
- UBORA platform is an open environment for collaborative design of innovative biomedical devices supported by a framework based on European medical device regulations.
    - Process begins with innovators and designers creating a profile. The design must be compliant with EC Medical Device Regulation; there is peer-to-peer review and mentoring from experts and from Academia and Industry to ensure the designs comply to the highest technical standards at all steps.
    - E-infrastructure allows open access to all reviewed designs.
    - UBORA leads engineers through a design process which is underpinned by attention to safety and current EU regulations, and peer-to-peer evaluation of the design, before submitting the documentation for the formal certification route: this double check should lead to safer medical products.
    - Although UBORA's focus is Africa, the approach and conclusions can be generalised to a global context.

Patient Safety in Medical IT Networks - Francesca Satta

- Increased connectivity of medical devices to computer networks technologies has introduced new hazards that require the implementation of a risk management process of complex systems.
- Integration must be managed throughout lifecycle, starting with planning and budgeting phase, then in the procurement phase with interoperability requirements; the installation and final testing are crucial to verify that the information flow is correct;
- Daily use aspect must be managed well to avoid incidents due to unevaluated changes in configuration, as well as hardware and software upgrades.
- Field Safety Corrective Actions (FSCAs) are increasingly related to software and security issues.
- New Regulation (EU) 2017/745 on medical devices strengthens these aspects, with the introduction of new requirements and the reformulation of some requirements already present in the old directive.
    - Opportunity, either for manufacturer or for Health Delivery Organization to reduce hazards related to complex systems.
    - Some of the current international standards (e.g., EN 80001-1:2010) can be confusing; thus, can be hazardous for patients.
- Necessity to quickly and effectively tackle the issue of enhancing patient safety by inviting hospital administrators to provide multidisciplinary team with competencies and skills in the domains of project management, information communication technology, health technologies and to appoint a medical IT network risk manager.

Topic 5: The Role of Health Technology Assessment in Promoting Patient Safety

Real-World Evidence to Assess Patient Safety in a Health Technology Assessment (HTA): Julie Polisena

- It is becoming increasingly recognized that a wealth of real-world data and evidence (RWD/RWE) covering the medical device experience exists and is routinely collected in the course of treatment and management of patients. These data can provide new insights into the performance, safety, and clinical outcomes associated with medical device use.
- RWE has always underpinned the HTA processes to an extent, because HTAs often rely on outcomes that are not always measured or available from a systematic review or clinical trial.
- The role of RWE includes:
    - RWE can provide estimates of effectiveness rather than efficacy in various clinical settings.
    - RWE analysis can help expedite the generation of hypotheses that sharpen the focus of clinical research, including the design of studies.
    - RWE analysis can also augment conventional clinical data with data from patients whose diversity reflects real world practice, resulting in better insight on safe and effective use of health technologies.
    - Analyses of patient outcomes from the use of health technologies in real world settings can generate further insight on their safety and effectiveness.
- The challenges with RWE include:
    - Non-randomized study designs need to be evaluated rigorously to identify sources of bias and confounding factors, and adjusted for them before estimating the impact of interventions on health outcomes.
    - Multiple data sources can come from multiple institutions in multiple formats, and may require data sharing agreements. Gaps and inconsistencies can exist across these data sources.
    - Privacy and security of patient data could stifle the willingness of institutions to invest in RWE applications, if patients do not consent to the use of their data.
    - Cost of generating and maintaining data sets from non-traditional sources is uncertain.
    - Researchers often have to clean RWD since most of it is not collected for research purposes.
- Future uses with RWE include:
    - RWE can support the expansion of the population or indications for which a device is approved, and help to identify relevant comparators and outcomes to be measured.
    - RWE from high-quality sources could supplement the adverse event reporting process, and might be able to replace numerous post-approval studies that are currently required; thus, saving cost and time and help to better understand how medical devices are used in a standard care setting.
    - Insights generated from RWE can impact decisions across the entire product lifecycle
    - RWE can expedite an assessment when there is limited time or money to conduct a clinical study.

Strengthening the Use of Real-World Evidence and Regulations for Medical Devices - Patrick Fandja

- The Canadian healthcare system is changing rapidly. A regulatory system that adapts to changes in healthcare delivery while giving people faster access to the medical devices they need is necessary.
- Our current regulatory system is in need of some improvements to make it more efficient, support timely access to therapeutic products and build better linkages within the health care system as a whole.
- Health Canada plans to enhance the use of RWE to support regulatory decisions across a medical device's life cycle, and to modernize medical device surveillance to align more closely with the risk level type of medical devices.
- Objectives for the Regulatory Reviews for Drugs and Devices (R2D2) project include:
    - Enhance the use of RWE across the product life cycle for regulatory decision making
    - Increase awareness on the post-market aspect of medical devices to improve regulatory oversight throughout the product life cycle
    - Establish a more proactive surveillance model for monitoring the safety and effectiveness of medical devices throughout their life cycle
    - Improve ability to manage identified safety risks for medical devices
- Drivers for this initiative include the international landscape for medical devices to increase post-market surveillance (e.g., changes in FDA with the establishment of National Evaluation System for Health Technology Coordinating Center and the 2018 medical device safety action plan, and the new European medical device regulations)
- Protecting Canadians from Unsafe Drugs Act (Vanessa's Law) includes new rules that strengthen the regulation of therapeutic products and improve the reporting of adverse reactions by healthcare institutions. As well, these measures are intended to improve Health Canada's ability to collect post-market safety information and take appropriate action when a serious health risk is identified.
- In June 2018, Health Canada published the proposed regulations that will require some healthcare institutions to report serious adverse drugs reactions and medical devices incidents to Health Canada. The final regulations are anticipated for June 2019.
- Ultimate goal of the R2D2 project is to improve the accessibility, affordability and appropriateness of drugs and medical devices for the patients.

Patient Safety and Health Technology Assessment of Medical Devices: Where are We? - Leandro Pecchia

- There are important differences between drug therapies and medical devices that can impact HTA methods. These differences can be categorised as follows: product lifecycle, clinical evaluation, user issues, costs and economic evaluation, and intellectual property.
- Factors related to the use of medical devices involve the people (e.g., patients, health care providers, and public), and structural, technological and organizational pillars, minimum requirements, and international standards.
- Technologies are not always resilient to extreme environments: For example, if a device requires very pure, filtered air, is this available in the intended location of use?

- Medical Device safety depends on complex and dynamic interactions among several factors, including: physical locations, users, maintenance, servicing, etc..
- Does HTA capture those factors and their interactions? Based on the literature, not entirely.
- Some of the reasons reported in literature are:
    - Traditional HTA is based on secondary data analysis, therefore, it suffers from lack of standardised terminology (e.g. Patient Safety MeSH (Medical Subject Headings) search term was only introduced in 2012).
    - Randomized Controlled Trial timing not sufficient to capture patient safety issues.
    - Inadequate outcomes.
    - Limited evidence on HTA of medical devices.
- In 2018, the International Federation of Medical and Biological Engineers-HTA Division published their first manuscript on the HTA of medical devices: Polisena J, Castaldo R, Ciani O, Federici C, Borsci S, Ritrovato M, Clark D, and Pecchia L. "HTA Methods Guidelines for Medical Devices: How can We Address the Gaps?" The International Federation of Medical and Biological Engineering Perspective. (*Int J Technol Assess Health Care. 2018 Jun;34(3):276-289*)
- The study objectives aims were to: i) review and identify gaps in the current HTA guidelines on medical devices, ii) propose 30 recommendations to optimize the impact of HTA for medical devices, and iii) reach a consensus among biomedical engineers on these recommendations.
- The proposed recommendations aimed to address the gaps in the HTA guidelines and to provide a more integrated and improved approach to HTAs on MDs. According to the scores from the Delphi survey responses, consensus was achieved for all recommendations among 32 international panelists in one round.
- Next steps:
    - How to move from the recommendations to HTA practice?
    - What should we do, in order to facilitate proper consideration of "patient safety" issues in HTA?
    - Is this part of an ongoing discussion on HTA of medical devices?

One Health System's Approach to Medical Device Risk Management and Patient Safety, through the Lens of the Medical Devices Life Cycle: Current Issues and Hope for the Future - Holly Meyer

- In the early 2000s, a centralized workflow was introduced and established by the Alberta Health Service (AHS).
- AHS also developed a patient safety strategy that outlines the AHS expectations related to the immediate and ongoing management of clinical adverse events.
- Key relationships with AHS include Health Canada, industry, and speciality groups.
- Three challenges by the AHS were proposed: i) adverse event reporting; ii) identification of good outcomes; and iii) Electronic Medical Record (EMR) transformation with EPIC[15].

[15] EPIC Systems Corporation, Verona, Wisconsin, USA, 53593

- Connect Care[16] intends to remove barriers to reporting by connecting most of the independent clinical information systems together to create a common system to manage patient information.

Critical Aspects and Best Practices on User Training on Medical Devices - Stefano Bergamasco

- International statistics in terms of adverse events, as well as the analysis of the main causes of medical equipment failure, show that human errors are one of the most important factors for patient safety.
- In addition to proper design and selection of devices, training of the clinical staff is a process of fundamental importance to ensure that complex health technologies are used safely.
- This process involves:
    - Identification of training needs, choice of themes, identification of participants.
    - Choosing the training method.
    - Planning, design and implementation of the training.
    - Evaluation of results in a given period of time.
- Why is user training difficult?
    - Are all users present when a new equipment is introduced and training occurs?
    - How do you cascade training from one person to the next, to achieve a train-the-trainer approach?
    - Is training performed every time a new type of equipment is introduced?
    - How do you manage training for new employees?
    - What if users move to a department where there are different devices?
- Action items to improve user training on medical devices:
    - 1: establish a clear policy on user training (and then implement it!).
    - 2. manage users' manuals.
    - 3.link user training to equipment inventory in the Computerized Maintenance Management System and Human Resources database.
    - 4. consider ease of use when purchasing new equipment.
    - 5. increase equipment uniformity (standardization).
    - 6. consider training tools based on new technologies for more effective user training.
- In summary:
    - Use errors are a significant component in patient safety issues.
    - User training and clear instructions for use are critical.
    - Laws and regulations make user training mandatory.
    - The implementation of user training is not an easy task.
    - A systematic approach to user training is required, along with tracking and recording of this activity.
    - Instructions for use must be available when and where required.
    - User training should be linked to equipment inventory in the CMMS.
    - Ease of use should be considered when purchasing new equipment.
    - Equipment standardisation make things easier to manage.
    - New technologies are available for more effective user training.

[16] https://www.albertahealthservices.ca/info/cis.aspx

Topic 6: Building a Commitment to Patient Safety in Healthcare Systems

Strategies to Maximize the Safety in Health Care Systems – Erika Bariciak

- Medical errors in high risk areas of hospitals are common and most are believed to be systems-based and preventable.
- Errors can be due to unique vulnerabilities of various patient populations, the types of highly specialized technology being used, the high-risk nature of procedures being done, and may even be due to the health information technology being introduced to help decrease the occurrence of adverse events.
- Health information technology (HIT) in high risk areas of the hospital is being widely implemented and although it is helping to identify and reduce adverse events, few studies show an actual reduction in patient harm.
- Evidence exists in the literature that new patient technology has resulted in new types of errors related to human-computer interface, workflow and communication issues, incorrect use of HIT, malfunction or non-availability of the HIT, and systems not interacting properly with other system components.
- Unintended consequences of HIT include more work for clinicians, never-ending system demands, paper persistence, negative emotions of the healthcare team, over-dependence on technology, and reduced vigilance due to mental task handover.

Multiple Factors Influence and may Compromise Decision-making about Implantable Medical Devices and Associated Adverse Events – Anna Gagliardi

- Rigorous processes are in place for pre-market research and approval of medical devices in Canada.
- Minimal data available regarding the safety and efficacy of medical devices post-marketing and rudimentary data exists on medical device recalls in Canada.
- Choice of device most suitable for a given patient can be compromised, due to personal preference bias or limitations in hospital inventory availability, potentially leading to sub-optimal clinical outcomes.
- Patient engagement in discussions and decisions about devices can also be biased.
- Adverse medical device event (AMDE) reporting is non-standardized and inconsistently acted upon.
- There is a recognized conflict of interest with industry representatives' presence during the selection and implantation process, requiring physician vigilance about patient safety.
- There is often a reactive, siloed approach to device safety.
- Important changes to local protocols for device preparation and insertion have resulted in significant improvements in patient outcome, but these changes have been made after adverse events have occurred rather than being done systematically and proactively.

Safety of Emerging Health Technologies: The Learning Curve from the Perspective of a Front-line User and its Impact on Adoption/Implementation – Harindra Wijeysundera

- Current framework for medical device assessment in Canada
    - Canada is a federal system that is highly decentralized.

    - Regulatory approval for a medical device to enter the marketplace is conducted federally by Health Canada – There is a special access/compassionate use category that expedities approval and bypasses normal requirements.
    - Once in the marketplace, funding for devices is provided at the Provincial/Territorial level with a single third-party payer system.
    - Administration of health care delivery is done regionally within provinces.
- Currently the approach/framework for incorporation of safety into practice is largely reactive, and there are limited incentives or motivation for front-line users to engage.
    - Many clinicians have limited knowledge of clinical engineering or human factors methods and so the system is facing the problem of siloed expertise.

- Case Study – Transcatheter Aortic Valve Implantation (TAVI)
    - Five-year survival rates for severe inoperable aortic stenosis are extremely poor (3%).
    - Traditionally, 50% of aortic stenosis patients are inoperable due to excessive peri-operative risk. TAVI offers a less invasive alternative approach.
    - Majority of patients are awake, valve delivery is fully percutaneous, median length of hospital stay is 2 days.
    - Some good outcomes; clear, structured patient selection process, sophisticated pre-procedural planning, smaller procedure team required, post-procedure registries linked to vital statistics database, wait-times coming down. Strong focus on safety practices.
    - Some not-so-good outcomes; device available typically through special access/compassionate use process, proctored process, training generally "dry-land" with possible animal model training.
    - In summary, this is a generally positive story, but concerns remain about missed opportunities to leverage expertise of other disciplines due to siloed knowledge.
    - Main incentive for adopting safety practices was the provision of conditional funding, requiring teams to focus on optimizing the safety and effectiveness of the procedures.

Moving Patient Safety from a Clinical Focus to a System Focus: Driving Sustainable Change – Sandi Kossey

- Improvements in patient safety in healthcare are moving from a clinical focus towards system-based strategies and the commitment to patient safety in healthcare should exist at all levels in the healthcare system.
- 3rd "WHO Patient Safety Challenge" is Medication without Harm. Past themes, including hand hygiene and surgical checklists, have resulted in significant improvements to patient safety in healthcare on a global scale.
- Global patient safety alerts is a publicly available database of evidence informed alerts, advisories, and recommendations from around the world.
- Canadian Patient Safety Institute (CPSI) was funded by Health Canada in 2003, and receives funding from the federal government. Health Quality Ontario (HQO) is an agency mandated by the Excellent Care for All Act to advise and report on the quality of healthcare to hospitals and the public.

- Changing conversations and culture in Canada due to discussions around boardroom tables with a shift to focusing on patient harm, reliability, sensitivity to operations, anticipation and preparedness, and learning and integration.
- By presenting the economics of patient safety, it can be shown that most of the burden is associated with a few common adverse events such as healthcare associated infections and medication errors.
- Patient safety culture "bundles" for CEOs and senior leaders provide established practices that have been proven successful in fostering a commitment to a culture of safety and reduction in patient harm.
- At the local hospital level, leadership teams are committing to becoming a highly reliable organization and making safety a top key performance indicator for their Quality Improvement Plans.
    - Implementing new safety-focused practices at the leadership, management, and frontline levels.
    - New health information technologies are being introduced and collaborations are being formed with other institutions in Ontario and across North America to improve the safety culture and the care being provided.
- Patients and families are being actively engaged to take part in the efforts to improve the safety of our healthcare system. An example of this is Patients for Patient Safety Canada[17], which is an advocacy group made up of individuals who have been touched personally by adverse medical events.

SUMMARY OF SMALL GROUP DISCUSSIONS

GROUP 1

Problem: Lack of Appreciation that Safety is an Important Component of Health Care Quality

Safety must be made much more prominent in the commitment to health care quality, and part of the solution to better marrying safety as part of quality.

Solutions:

- Apply a "top-down" leadership approach to address the problem, at least in part.
- Emphasize that proactive safety measures are required, although learning from events is important.
- Use more training and tools are required to identify potential problems before harm occurs.
- Build expectations by patients and families that care will be safe and communicate with them the potential risks and involve them better in the safety of their care.
- Conduct appropriate training and education, again across the different levels. Both pre- as well as post-employment training and follow up and monitoring are necessary, especially with the adoption of a new technology.
    - Monitor and change management phases.
    - Evaluation phase.

[17] http://www.patientsafetyinstitute.ca/en/About/Programs/PPSC/Pages/default.aspx

Problem: Lack of Prioritization of Patient Safety by Leadership
A top down and across the board effort compelled by legislation, standardization, accreditation, recommendations and guidelines as well as investment in resources can help to make sure that safety is embedded in the entire healthcare system by design (e.g., Safety by Design [SbyD]).

Solutions:
- Establish the organization's values and strategy and allocate of resources (money and people) at the front line.
- Align an "up and down" strategy with the requirement for safety across the various health care sectors, such as ministries of health, health regions, institutions organizations, and the community.
- Help individual staff members to understand why their job and efforts are important to safe care and optimal outcomes for patients.
- Health ministries must require that organization strategy and actual operational plans must reflect safety efforts in a fulsome way.
- Educate providers on the value of involving expertise from multidisciplinary teams.
- Give frontline workers access to safety expertise that is embedded at the department/unit level.
- Build in incentives for health care staff (e.g., promotion based on safety work).
- Include requirements in all career paths for physicians working in academic centres to contribute to safety as a component of quality.
- Introduce an additional clinical path with a focus on safety (e.g., academic preparation for Physician and Nurse Safety Officers.
- Implement policy regarding patient safety has to be made at institutional/governmental/management levels before it filters down to the frontline across the board.

GROUP 2

Problem: Lack of Awareness of Clinical Engineering and its Potential Role in Patient Safety
Clinical engineers should play a more central role in implementing Safety by Design to both resolve issues at the frontline as well as reduce the complexity of healthcare technology. Moreover, they should be involved in the assessment and procurement of implantable technology and not just equipment.

Solutions:
- Create partnerships with international and national groups of Clinical Engineers.
- Use top down approach to participate at nursing and medical conferences.
- Form strategic alliances with international, national, provincial groups of clinicians and researchers at teaching hospitals.
- Include clinical engineers at the C-Suite level to advocate for patient safety.
- Invite clinical engineers to provide input in procurement (operational + capital budget), resources to support new devices, and funding for the adoption of new technology

- Use existing lifecycle costs, key performance indicators, Total Cost of Ownership, and adopt standards to measure performance (e.g., measuring downtime).
- Share information and experiences with international clinical engineering networks.
- Provide clinical engineers with appropriate training in methods of embedding SbyD into the system through process, systems, resilience and reliability engineering (or human factor engineering), be part of frontline and clinical safety review and resolution teams and interact with other health care providers.

GROUP 3

Problem: Insufficient Regulation and Surveillance of Medical devices
There are numerous opportunities to strengthen regulations or recommendations should these regulations not be in place, specifically with regards to the post-market surveillance of medical devices, including human factor engineering and health technology assessment.

Solutions:
- Integrate medical device experts into the healthcare team and daily work.
- Decrease the impact of medical device defects, failures, and poor usability on patients, personnel/clinicians, and health care systems:
  - Improve pre-market and post-market safety and effectiveness requirements for medical devices, without delaying their market authorization (EU's new regulation [745 and 746] requires more robust data and evidence by the manufacturer for market authorization).
  - Incorporate Real World Data/Real World Evidence in the regulatory and reimbursement processes to contribute to the safety and effectiveness evidence of medical devices throughout the lifecycle (e.g., Health Canada's Regulatory Review of Drugs and Devices[18]).
  - Establish data sharing agreements and sharing usability testing results among organizations and jurisdictions.
- Design the interface of the device to be more intuitive and involve the end-users.
- Add end-users to the equipment selection process.
- Simplify reporting problems and incorporate it in the daily routine.
- Improve the balance between standards versus resilience:
  - Consider all relevant staff, medical devices and systems and physical location to better understand the management of the unknown and unexpected possible events and outcomes
  - Standards are usually developed in silos and standards for staff, medical devices and systems, and location can be disconnected from one another.
  - Staff may not always be compliant with standards; some jurisdictions (e.g., Italy) require minimal requirements by law.
  - As technologies are constantly evolving, standards can quickly become outdated.
  - Establish communication among technological experts (e.g., clinical and civil engineers, and human factor and IT specialists) and across disciplines (e.g., technical experts and health care providers) to help harmonize the standards.

[18] https://www.canada.ca/en/health-canada/corporate/transparency/regulatory-transparency-and-openness/improving-review-drugs-devices.html

- Determine and apply appropriate mechanisms to foster resilience in devices, systems and people, to improve management of the unexpected, when standards don't necessarily apply.

GROUP 4

Problem: Insufficient Integration and Information Sharing

Patient safety can be improved with increased collaborations among health care providers and decision makers across all levels of the health care system that also involve patients and their families.

Solutions:

- Establish a forum for regular daily interactions on patient safety of all professions.
- Incorporate the patient-family perspective in the provision of healthcare as their insights often trigger consideration of better ways to do things.
- Facilitate the sharing of best practices across organizations and geographic locations.
- Develop and implement a centralized national or regional platform for reporting both successes and non-successes.
- Create a registry of databases, possibly managed by the WHO
- Establish a standardized ontology for reporting and identifying protocols, risks, adverse events and other safety-related outcomes. There is a need to identify benchmarks for quantifying improvements in patient safety so that progress can be assessed objectively.
- Develop a harmonized nomenclature around patient safety to facilitate discussions across organizations and jurisdictions.
- Ensure the safety of integrated medical devices and IT systems (as compared to individual devices and fragmented IT systems):
  - Identify accountable role(s).
  - Obtain commitment from senior management.
  - Review and consider current regulations (e.g., standards exist in EU for healthcare organization's responsibility for integrated system risk management).
  - Involve clinical engineers, IT, risk managers, patient safety experts, clinical experts, and procurement officers in the planning for and implementation of measures for the safety of an integrated system.
  - Involve standards or accreditation organizations (e.g., Canadian Standards Association, Accreditation Canada, and Health Standards Organization) in the process.
  - Steps:
    - Planning phase: budget must account for the system integration analyses and other related costs.
    - Procurement phase: outline detailed and comprehensive requirements or tenders.
    - Implementation phase: develop specific testing protocols and user training on how to use the system and the potential hazards.

RESOLUTIONS

- To improve the commitment to patient safety it is important to demonstrate that these systems-based approaches are making a difference. Making safety a leadership priority, implementing safety improvement projects, showing policy impact, and creating alliances and networks to encourage sharing of successes and benchmarking outcomes are all strategies that should be utilized.
- Environmental conditions need to be made conducive to educate and incentivize physicians, nurses and other clinicians to report on adverse medical device events. More research is needed to investigate how to better design and implement post-market surveillance systems for medical devices, to assess the impact of various constraints on clinical outcomes, and to develop interventions that optimize decision-making about device choice.
- A collaborative approach needs to be taken and expertise from other disciplines leveraged, including clinical and human factors engineering, to assist in appropriate device selection, to learn how to ensure safe use of medical devices, and to identify system and device vulnerabilities to proactively address them.
- Time and resources need to be dedicated to not only use new health information technologies safely and effectively, but to also acquire data on harms prevented and errors caused by the implementation of HIT. This information should be used to inform future changes to system design and implementation.
- Hospital leadership needs to solicit and act on feedback from front-line healthcare teams after implementation of HIT. Healthcare teams need to continue being educated about competencies that are now being automated by the HITs, and training that promotes resilience and effective team functioning needs to be embraced.
- With the increasing amount of technology and devices being introduced to improve the way healthcare is delivered to patients, frontline staff need to be provided with the resources and support to continue listening to patients and their families while providing bedside care for patients. Patients and families need to be actively engaged and included when designing and troubleshooting patient safety systems. Collaborations with other healthcare organizations are important to find shared solutions to common problems, harmonize practices, and reduce variation in systems and practice.

CONCLUSIONS

Healthcare institutions continue to struggle to reduce harm despite advancements in health care technologies. Patient safety efforts in the last decades have emphasized the need for better device design, but broader resolutions are required to reduce preventable adverse events. Resolutions need to effect *system* change, including consideration of interacting elements that influence performance: people (e.g., physical and cognitive limitations) tasks (e.g. difficulty or complexity of the task), tools and technologies (e.g. usability and accessibility), organization (e.g. resources), environment (layout, lighting). Furthermore, patient safety efforts must not only focus on why adverse events occurred, they must also proactively identify how they might be prevented. To do so, feedback about risks must be communicated across various health care sectors, such as ministries of health, health regions, institutions, organizations, and the community. The resolutions presented in this report highlight the various ways clinical engineers can and need to be engaged to create safer health care systems for patients and clinicians.

The proposed resolutions to the identified current issues can increase the effectiveness of both health care delivery and clinical outcomes; thus enhancing the overall quality of patient care. Further, the resolutions may result in positive changes to the workplace environmental and culture due to less staff burnout and better staff engagement and workforce self-image, such as having the clinical engineers play a more prominent role in patient safety.

It is clear that there are a number of promising approaches available. The key to success will be encouraging their broad uptake within healthcare systems. To help to initiate this, the findings of this workshop will be widely circulated and shared, to initiate discussions on how best to initiate the actions that have been identified here.

Appendix A: Alphabetical List of Participants

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Appendix B: Workshop Program

Program for the Special Workshop on Patient Safety (Endorsed by IFMBE)
Carleton University, Ottawa, Canada, May 3-4, 2018
1125 Colonel By Drive, Ottawa, K1S 5B6; Meeting Room Minto Case 2014 (corner of Campus Avenue and Library Road)
Campus Map: https://carleton.ca/campus/map/
Visitor Parking in Car Park P2 (Pay and display)

May 3:

8:30 – 9:00am	Welcome breakfast and registration
9:00 – 9:15	Welcome (Dean Eng Carleton); workshop background, structure, and introduction to participants – Monique Frize and Tony Easty
	Topic 1: The current state of patient safety in health care
9:15 – 9:45	Making a difference! Progress, gaps and frontiers in patient safety – Gordon Wallace
9:45 – 10:00	Questions and discussion on topic 1
10:00 – 10:15	Refreshment Break
	Topic 2: Patient safety issues from a clinical engineering perspective
10:15 – 10:35	IFMBE/Clinical Engineering Division global role in improving patient safety – Ernesto Iadanza
10:35 – 10:55	Smart pumps: The canary in the coal mine – Scott Olsen
10:55 – 11:15	Clinical Engineers' strategies to ensure safety at CHEO – Marie-Ange Janvier
11:15 – 11:35	Incident investigations for high performing clinical engineering service – Andrew Ibey
11:35– 11:50	Questions and discussion on topic 2
11:50 – 12:30	Lunch
	Topic 3: Human factors engineering approaches to patient safety
12:30 – 12:50	Using human factors to assist in the proper alignment between corrective actions and causal factors – Patricia Trbovich

12:50 – 13:10	Medical device risk management from a human factors perspective – Tony Easty
13:10 – 13:25	Questions and discussion on topic 3
13:25 – 13:40	Refreshment Break
	Topic 4: Technological tools to help minimize safety hazards
13:40 – 14:00	Improving patient safety through engaging patients and family members in health information technology adoption – Gillian Strudwick
14:00 – 14:20	Information technology and patient safety – Monique Frize
14:20 – 14:40	UBORA (Euro-African Open Biomedical Engineering e-Platform): Safety by open design – Arti Ahluwalia
14:40 – 15:00	Patient safety in medical IT networks – Francesca Satta
15:00 – 15:15	Questions and discussion on topic 4
15:15 – 15:30	Refreshment Break
	Topic 5: The role of Health Technology Assessment in promoting patient safety
15:30 – 15:50	Real-world evidence to assess patient safety in a health technology assessment – Julie Polisena
15:50 – 16:10	Patient safety and health technology assessment of medical devices: Where are we? – Leandro Pecchia
16:10 – 16:30	One health system's approach to medical device risk management and patient safety, through the lens of the medical device life cycle: Current issues (and hope for the future) – Holly Meyer
16:30 – 16:50	Critical aspects and best practices on user training on medical devices – Stefano Bergamasco
16:50 – 17:05	Questions and discussion on topic 5
17:05 – 17:20	Brief summary of the day, announcements and adjournment – Monique Frize and Tony Easty
18:00	Reception and Dinner (Place to be determined)

Day 2: May 4, 2018

8:30 – 9:00	Breakfast, meeting room Minto Case 2014, Carleton University
	Topic 6: Building a commitment to safety in health care systems
9:00 – 9:20	Strategies to maximize the safety benefits of a range of technologies in health care – Erika Bariciak
9:20 – 9:40	Multiple factors influence and may compromise decision-making about implantable medical devices and associated adverse events – Anna Gagliardi
9:40 – 10:00	Safety of emerging health technologies: The learning curve form the perspective of a front-line user and its impact on adoption/implementation – Harindra Wijeysundera
10:00 – 10:20	Moving patient safety from a clinical focus to a system focus: Driving sustainable change – Sandi Kossey
10:20 – 10:40	Questions and discussion on topic 6
10:40 – 11:00	Break
11:00 – 12:30	Review of speakers' top prioities for action, break out into group discussions: establish recommendations
12:30 – 13:15	Lunch
13:15 – 14:00	Group presentations in plenary session and comments, questions
14:00 – 15:00	Prioritizing the recommendations
15:00 – 15:30	Identifying the stakeholders and writing of report. Disseminating the outcomes of the workshop
15:30 – 15:45	Closing remarks

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Workshop Participants Celebrating "STOP! Clean Your Hands Day", May 4, 2018