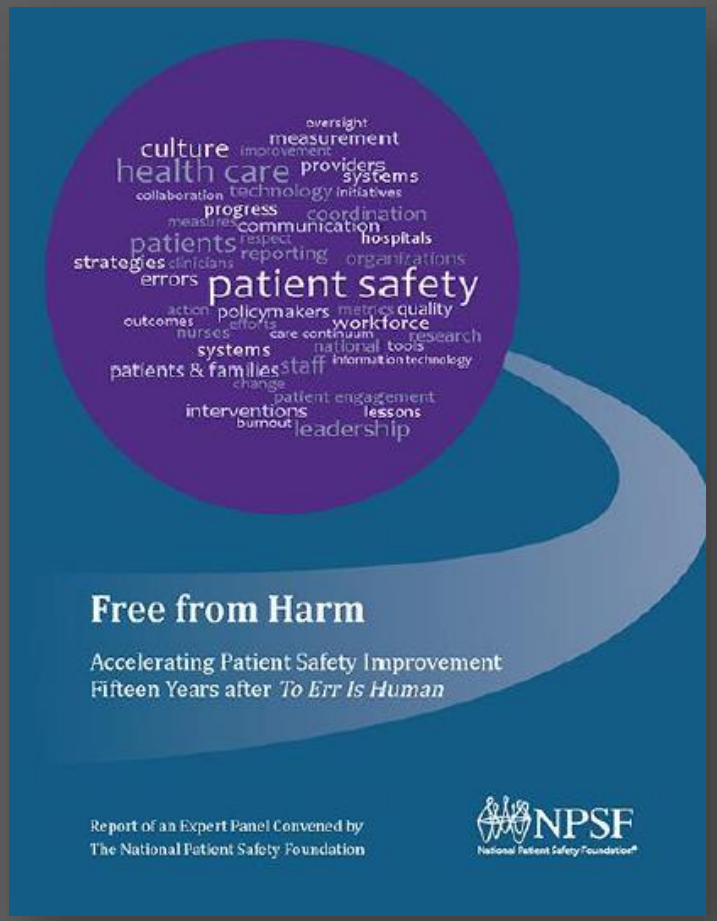
Application of Research in QI

Shorouq Zakariya, *BSN, MRM, CPPS, IHI-NPSF Patient Safety Leadership Fellowship*

Director, Quality Management



EIGHT RECOMMENDATIONS FOR ACHIEVING TOTAL SYSTEMS SAFETY

1. ENSURE THAT LEADERS ESTABLISH AND SUSTAIN A SAFETY CULTURE

Improving safety requires an organizational culture that enables and prioritizes safety. The importance of culture change needs to be brought to the forefront, rather than taking a backseat to other safety activities.

2. CREATE CENTRALIZED AND COORDINATED OVERSIGHT OF PATIENT SAFETY

Optimization of patient safety efforts requires the involvement, coordination, and oversight of national governing bodies and other safety organizations.

3. CREATE A COMMON SET OF SAFETY METRICS THAT REFLECT MEANINGFUL OUTCOMES

Measurement is foundational to advancing improvement. To advance safety, we need to establish standard metrics across the care continuum and create ways to identify and measure risks and hazards proactively.

4. INCREASE FUNDING FOR RESEARCH IN PATIENT SAFETY AND IMPLEMENTATION SCIENCE

To make substantial advances in patient safety, both safety science and implementation science should be advanced, to more completely understand safety hazards and the best ways to prevent them.

5. ADDRESS SAFETY ACROSS THE ENTIRE CARE CONTINUUM

Patients deserve safe care in and across every setting. Health care organizations need better tools, processes, and structures to deliver care safely and to evaluate the safety of care in various settings.

6. SUPPORT THE HEALTH CARE WORKFORCE

Workforce safety, morale, and wellness are absolutely necessary to providing safe care. Nurses, physicians, medical assistants, pharmacists, technicians, and others need support to fulfill their highest potential as healers.

7. PARTNER WITH PATIENTS AND FAMILIES FOR THE SAFEST CARE

Patients and families need to be actively engaged at all levels of health care. At its core, patient engagement is about the free flow of information to and from the patient.

8. ENSURE THAT TECHNOLOGY IS SAFE AND OPTIMIZED TO IMPROVE PATIENT SAFETY

Optimizing the safety benefits and minimizing the unintended consequences of health IT is critical.

Our Goal is to Increase Attention to Patient Safety Research and Publications

- Quality Management Department's collaboration with Research.
- A strategic priority

Mission: KFSH&RC provides the highest level of specialized healthcare in an integrated educational and research setting

Vision: To be a world leader in healthcare through excellence and innovation

PRIORITIES (THEMES)	STRATEGIC OBJECTIVES
Medical, Research and Academic excellence	1. Drive Culture and Process redesign to pursue Zero Harm and improve Quality
	2. Become a global role model in our core specialties
	3. Leverage research & innovation to improve clinical outcomes & set standards for Med.care
	4. Optimize the education of the next generation of healthcare professionals & leaders
KFSH&RC experience	5. Provide excellent patient experience throughout the patient journey
	6. Improve access to KFSH&RC healthcare services
	7. Promote a conducive environment
	8. Provide a rewarding career experience that attracts and retains the best talent
	9. Promote transparent and objective performance management
Organizational Sustainability	10. Optimize efficiency, productivity and accountability to reduce cost and improve delivery
	11. Deliver effective generation and management of revenue
	12. Develop a high-performing and sustainable healthcare endowment fund
	13. Leverage innovative technology and information to deliver high quality healthcare
Community Relations	14. Establish workflows that include external entities
	15. Strengthen external collaboration and partnerships
	16. Promote social responsibility activities

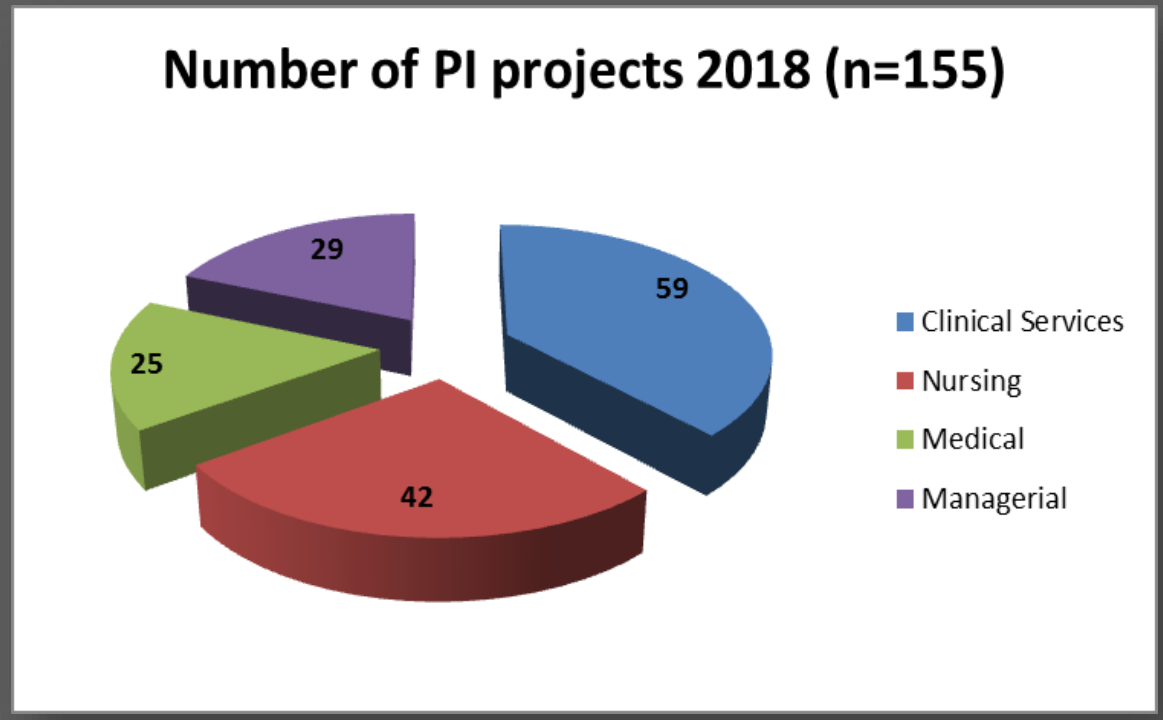
Frequent Issues Related to QI

- Publishing the results of a successful PIP in an academic journal can boost our hospitalist's prestige and chance of promotion. But how do I know if my PI project is a candidate for publication?
- Examples of activities that begin as QI and Become Research
- Examples of Activities that are likely QI and Research
- Why doesn't the IRB review PI activities?
- How to publish my PI Project?
- What are the ethical requirements for the protection of human participants in PI activities?
- What are the major Quality & Safety Journals?

All Commit to Improve 2018

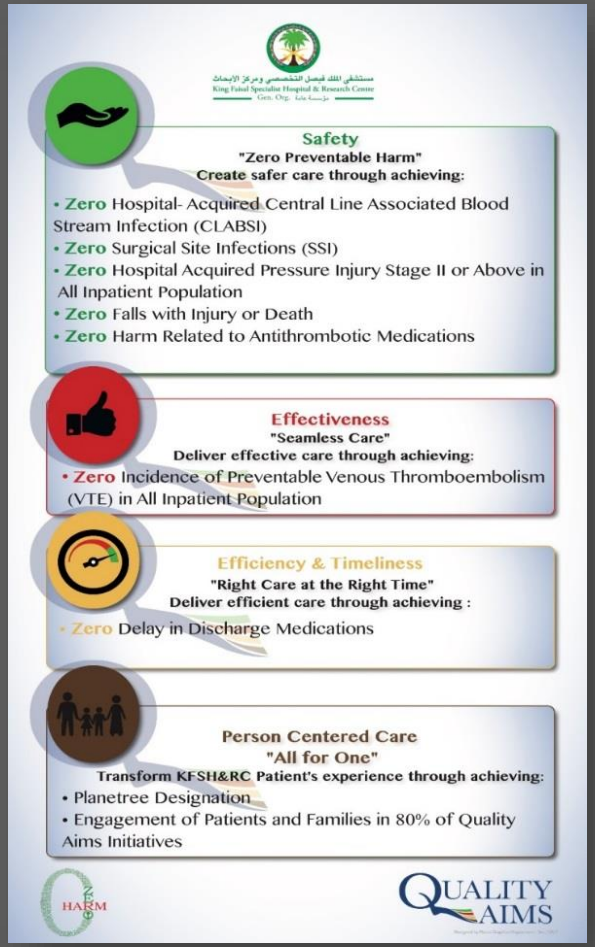
"Performance Improvement Projects"

- 155 Initiated
- **94** Completed
- **24** Were presented during the Quality Day 2018.



Quality Aims Jeddah 2018

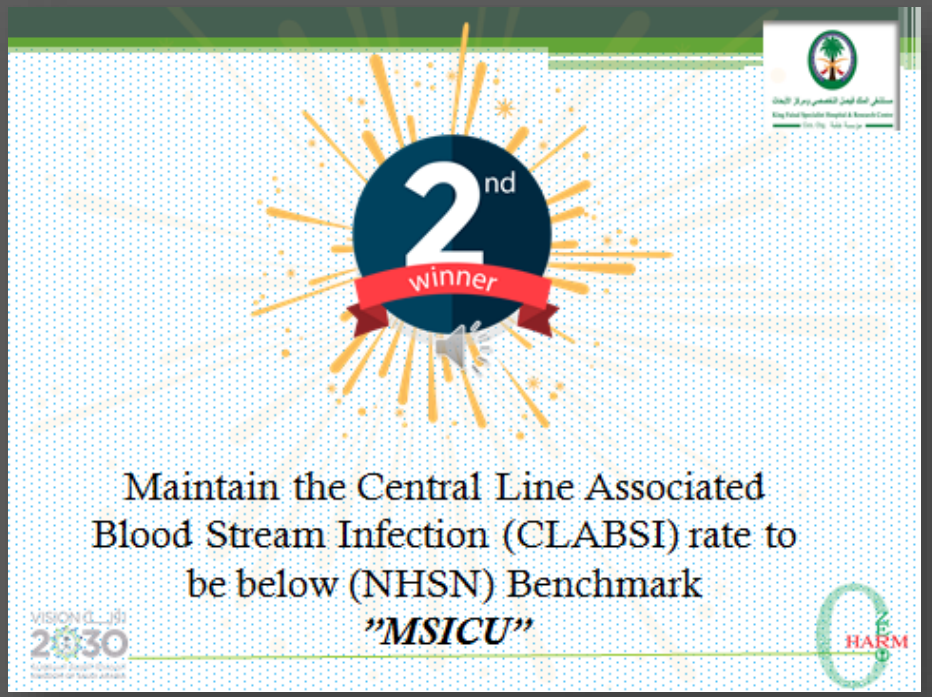
Safety		Team Leader	QM Facilitator
1	Zero Hospital Acquired Central line Associated Blood Stream Infection (CLABSI)	Hanadi Alsalmi	Nour Al-attas
2	Zero Surgical Site Infection (SSI)	Hanadi Alsalmi	Nour Al-attas
3	Zero Hospital Acquired Pressure Injury Stage 2 or above in all inpatient population	Gillian Sedgewick	Ohood Al-Hadad
4	Zero Fall with Injury or Death	Gillian Sedgewick	Ohood Al-Hadad
5	Zero Harm Related to Antithrombotic Medications	Merryland Abdeljawad	Rola El-Khateeb
Effectiveness		**Team Leader**	**QM Facilitator**
6	Zero Incidence of Preventable Venous Thromboembolism.	Dr. Bassim Albeirouti	Sarbonza Meera
Efficiency and Timeliness		**Team Leader**	**QM Facilitator**
7	Zero Delay in Discharge Medication	Dr. Muntazar Bashir	Rola El-Khateeb
Person Centered Care "All for One"		**Team Leader**	**QM Facilitator**
8	Planetree Designation	Ghaddah Al-Sarraf (Pending)	
9	Engagement of Patients and Families in 80% of Quality Aims Initiatives.	All	



No.	PI Title	Unit/ Department
1	Reduce Energy Consumption in The Main Hospital Parking Areas	EU&M
2	Decrease Catheter Associated Urinary Tract Infection (CAUTI) in Adult Oncology Unit None Bone Marrow Transplant Service.	Oncology
3	Improve KFSHRC-J Patient and Visitor Experience	Nursing Affairs
4	Improving Ward Rounding on The Surgical Unit	Surgery
5	Prevention Strategies to Achieve Zero-Harm in Catheter Associated Bloodstream Infection (CLABSI) based on evidence based practice in Renal Transplant Unit.	Renal Transplant Unit
6	Decrease Turnaround Time from the Time of Lab Results Available Complete Blood Count (CBC) in ICIS to Faxing Medication Protocols to Pharmacy on each Sunday.	Oncology
7	Reduce Tube Feeding Process Turn Around Time (TAT).	Clinical Nutrition
8	Reducing The Number of Environmental Pollution Incidents.	Food Services
9	Improve Clean Linen Delivery Turn Around Time (TAT)	Laundry
10	Reduce Percentage of Vitamin D re-testing	Family Medicine
11	Reduce Number of Non-Chemotherapy Patients in Chemo Treatment Area	Oncology
12	Optimize efficiency of utilization of antibiotic discs in the microbiology section.	DPLM
13	Improving the Pregnancy Rate in In-Vitro Fertilization (IVF) Patients Who Supposed to Have Fresh Embryo Transfer.	DPLM
14	Improve Appointment Turnaround Time For Sleep Deprived EEG (SDE) Patients in 2018.	Neurosciences
15	Improve the quality Control process of Motor Evoked Potential (MEP) test to be in line with international standards of normative data.	Neurosciences
16	Improve Nutritional High Risk Screening Compliance.	Protocol Unit
17	SEHATY Guidelines Barcode	Nursing Affairs
18	Improve staff documentation compliance related to General Consent Form	Registration, Appointments & Admission Services
19	Maintain the Central Line Associated Blood Stream Infection (CLABSI) Rate in MSICU	MSICU
20	Reduce Reported Pressure Injury Incidents (CAPI)	Nursing Practice and Research
21	Enhancing Turn Around Time for Tuberculosis (TB) Chest x-ray screening for employees	Radiology
22	Improving the safety of insulin pens and reduce the overutilization for inpatient.	pharmacy
23	Reduction of Central line associated blood stream infection(CLABSI)in PICU at National healthcare safety network benchmark	PICU
24	Improve compliance with eligible IV Stat orders turnaround time to be processed within 30 minutes	Pharmacy

For more Information , please contact :
Quality Management Department
Ext: 62312, 62325, 62315

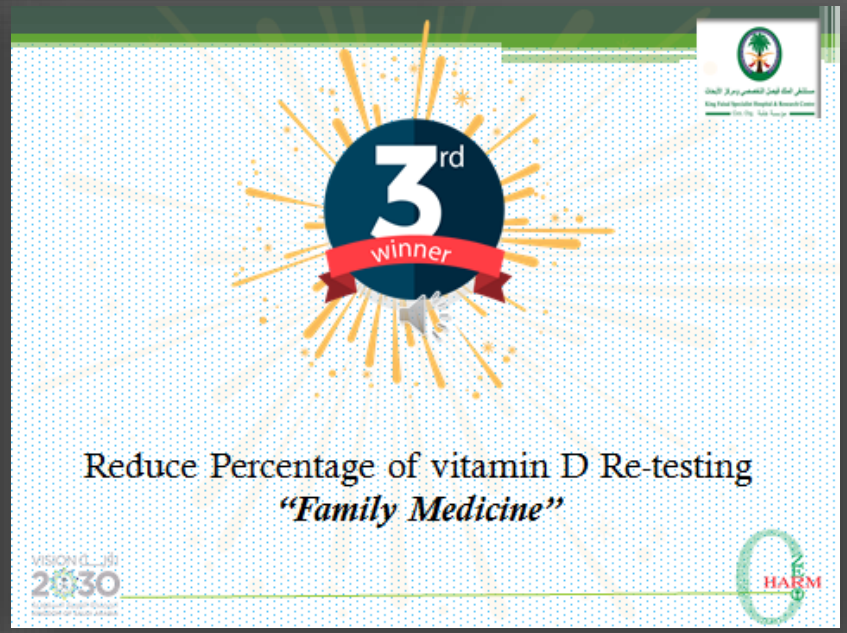
competition
* Great Catch Award
* And more


2nd
winner
Maintain the Central Line Associated Blood Stream Infection (CLABSI) rate to be below (NHSN) Benchmark
"MSICU"
0
HARM


1st
winner
Improving Safety with Insulin Pens and Reduce the Overutilization for Inpatient-
"Medication Safety"


5th
winner
Improve (EEG) Appointment Turnaround Time
"Neurosciences"
0
HARM


4th
winner
Reducing Number of Environmental Pollution Incidents
"Food Services"
0
HARM

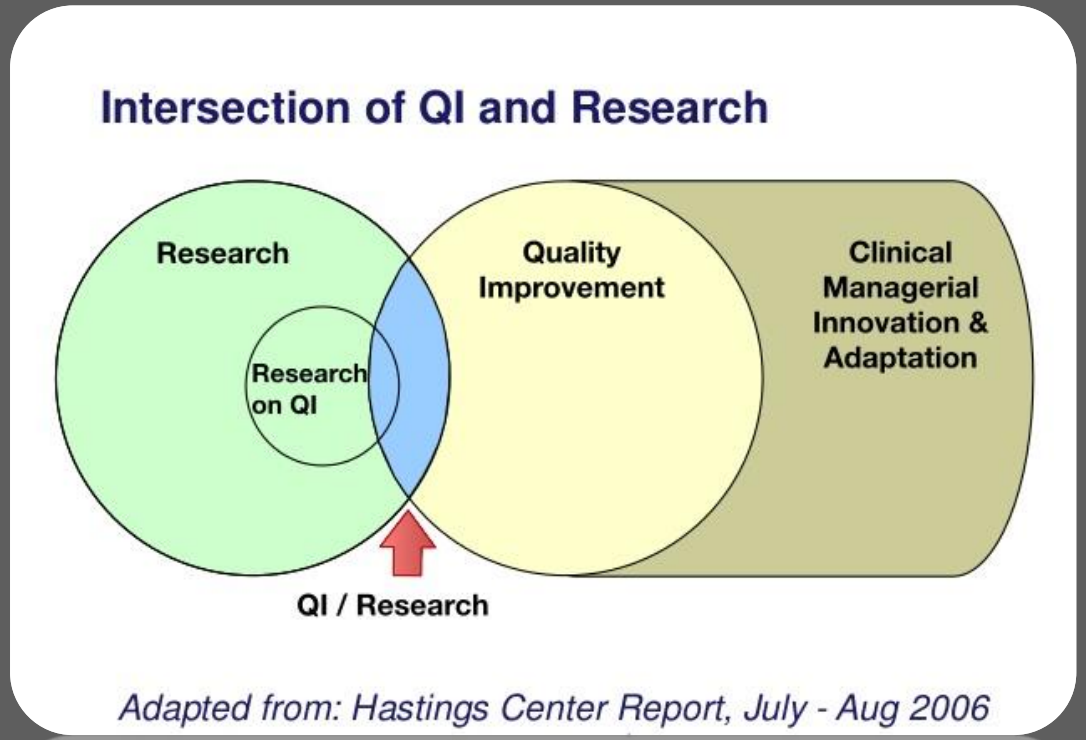

3rd
winner
Reduce Percentage of vitamin D Re-testing
"Family Medicine"
0
HARM


You are our future Champions


Quality Day 2018
12 - 13 November
2 0 1 8
HARM
Together Towards Zero

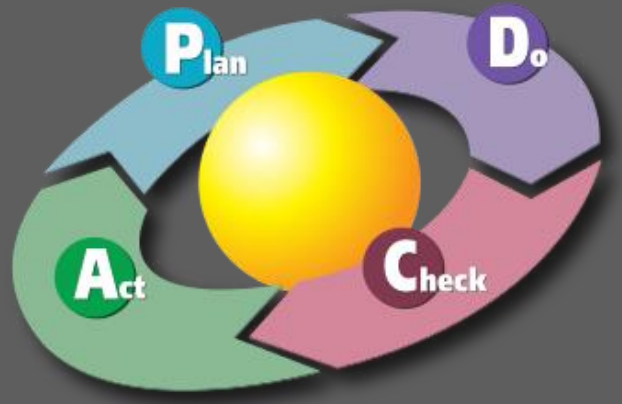
Intersection of QI & Research

- Quality improvement (QI) activities are an important component of KFSH&RC's operations.
- QI activities are **data-driven** and involve **human participants**.
- Determining if an activity is **Research** or **Quality Improvement** can be challenging.
  - Human subject research must be re reviewed and approved by the IRB, while strictly QI activities do not require IRB oversight. However, some QI activities may also be research and therefore need IRB approval.



What is Quality Improvement (QI)?

- QI is an activity where the primary purpose is to monitor or improve a process, program or system delivered by an institution.
- A systematic, data-guided activities designed to bring about immediate improvements in health delivery in particular settings.
- QI projects generally aim to determine if a particular treatment or procedure at an institution is meeting expected standards.
- If deficiencies are detected changes might be made to clinical practice, local guidelines updated or staff training provided.
- QI findings are typically specific to the hospital in which the activity was conducted and so the results are usually only disseminated within that hospital.
- QI activities include analyzing routinely obtained data to capture current practice and comparing this to existing best practice standards.



Types of QI activities can include:

PI projects Selection Criteria's:

1. High Risk.
2. High Volume.
3. High Cost.
4. Problem Pron.
5. Feedback from customers.
6. Accreditation.
7. Departmental Scorecards.

Clinical Audit:	A quality improvement process that seeks to improve patient care and outcomes through systematic review of care against explicit standards and the implementation of changes in practice if needed.
Practice Review:	The systematic assessment of current practice, without comparison against set criteria or of one therapy against another and may also be known as a baseline assessment.
Satisfaction/Knowledge Survey:	The systematic collection of data from a sample of patients or staff to determine levels of satisfaction or knowledge about a service.
Service Improvement:	Implementing an initiative to promote change or maintain good practice in order to enhance care and may be known as practice development.
Program Evaluation:	Evaluation is the systematic collection and analysis of information about a specific program or intervention in order to allow its critical appraisal.

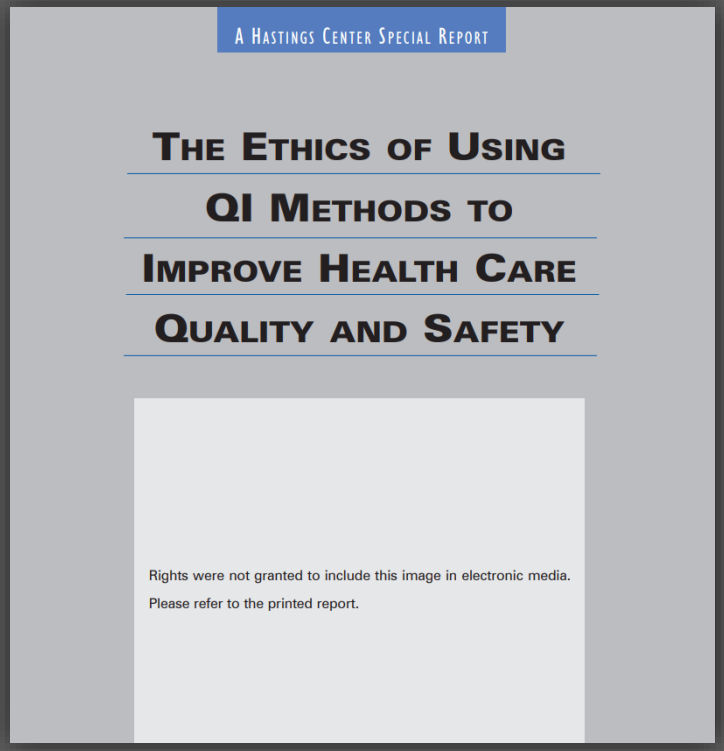
What is Research?

- Research is a systematic **investigation of phenomena** for the purposes of **generalizing findings to a population.**
- Researchers aim to **add to the current body of knowledge** about a particular subject, and **results are often published** in academic journals.
- Researchers **must follow strict policies**, **obtain consent** from subjects, **and report any deviation** from the protocol.
- An Institutional Review Board **(IRB) must approve the research** project before it starts.

How Does QI Differ from Research?

- Both research and quality improvement are systematic investigations that may involve human participants but they differ in important ways.

Reference: The Ethics of Using QI Methods to Improve Health Care Quality and Safety



Research vs. Quality Improvement Comparison

	RESEARCH	QUALITY IMPROVEMENT
INTENT	Develop or contribute to generalizable knowledge (e.g., testing hypothesis)	Improve a practice or process within a particular institution or ensure it conforms with expected norms; not designed to contribute to generalizable knowledge
DESIGN	Systematic; follows a rigid protocol that remains unchanged throughout the research; may involve randomization	Adaptive, iterative design; may or may not be systematic; generally does not involve randomization
MANDATE	Activities not mandated by institution or program	Activity mandated by institution or clinic as part of its operations
EFFECT ON PROGRAM OR PRACTICE EVALUATED	Findings are not expected to directly affect institutional or programmatic practice	Findings are expected to directly affect institutional practice and identify corrective action(s) needed
POPULATION	Usually involves a subset of individuals; no obligation to participate; may involve statistical justification of sample size to achieve endpoints	Responsibility to participate as a component of the program or process; information on all or most involved in the practice or process is expected to be included; exclusion of some individuals significantly affects conclusions
BENEFITS	Participants may or may not benefit directly; often a delayed benefit to future knowledge or individuals	Directly benefits a process, program, or system; may or may not benefit participants
RISKS	May place participants at risk	Does not place participants at risk with the possible exception to risks to privacy or confidentiality of data
ANALYSIS	Statistically prove or disprove hypothesis	Compare program, process or system to established standards
DISSEMINATION OF RESULTS	Intent to disseminate results generally presumed at outset of project as part of professional expectations, obligations; results expected to develop or contribute to generalizable knowledge by filling a gap in scientific knowledge or supporting, refining, or refuting results from other research studies	Intent to disseminate results generally not presumed at outset of project; dissemination often does not occur beyond the institution evaluated; when published or presented to a wider audience the intent is to suggest potentially effective models, strategies, assessment tools or provide benchmarks rather than to develop or contribute to generalizable knowledge

Adapted in part from University of Wisconsin-Madison Health Sciences IRBs Comparison of the Characteristics of Research, Quality Improvement, and Program Evaluation Activities

Examples of Activities that Begin as QI and Become Research

- A QI project is implemented, and upon completion, the investigator realizes they want to do research about the project, and interview clinicians. The data they will collect from the interviews will be used for research.

- A surgeon believes that a certain technique will improve their own practice, so they implement it and record results as part of clinical practice. They then decide that this practice would help others, so they go back to their data to systematically analyze and generalize outcomes and results.

- It is important to note that *the intent to publish is an insufficient criterion for determining whether a QI activity constitutes research.*

Examples of Activities that are likely QI and Research

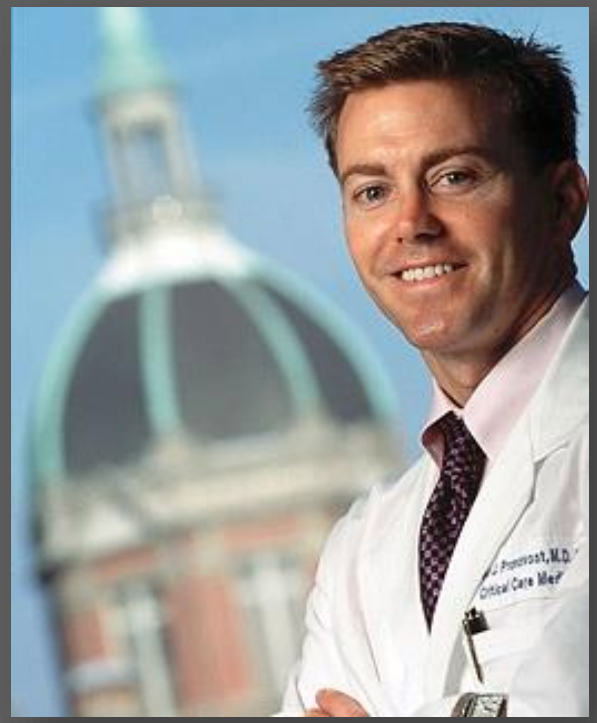
- A project involves introducing an untested clinical intervention for purposes which include not only improving the quality of care but also collecting information about patient outcomes for the purpose of establishing scientific evidence to determine how well the intervention achieves its intended results.

- Collaborative (multi-site) – All the sites are trying to improve some aspect of clinical care (ex. implementing an application to help improve making clinical decisions). The whole department decides this app will improve care, and implement the app. They collect data as the app is implemented, and in addition, analyze this data for generalizable knowledge.

Publishing your QI project

"Even though most QI activities aren't research, there is much to be learned from sharing descriptions of these non-research activities"

- The Keystone ICU project, published in the Dec. 28, 2006 *New England Journal of Medicine* is an example of a QI project well-suited to publication.
- Researchers on that project were able to demonstrate that adherence to 5 basic evidence-based steps, such as hand washing, by clinicians in over 100 Michigan ICUs led to a significant reduction in catheter-related bloodstream infections.
- That study is notable not only because the intervention was successful but because the authors meticulously described their process, which enabled other hospitals to reproduce their results.
- Lead author **Peter Pronovost, MD, PhD, of Johns Hopkins University School of Medicine**, led a similar study in Rhode Island that resulted in catheter-related bloodstream infections falling by 74% in 23 ICUs. The results were published in the December 2010 issue of *Quality and Safety in Health Care*.



The NEW ENGLAND JOURNAL of MEDICINE

ESTABLISHED IN 1812 DECEMBER 28, 2006 VOL. 355 NO. 26

An Intervention to Decrease Catheter-Related Bloodstream Infections in the ICU

Peter Pronovost, M.D., Ph.D., Dale Needham, M.D., Ph.D., Sean Berenholtz, M.D., David Sinopoli, M.P.H., M.B.A., Haitao Chu, M.D., Ph.D., Sara Cosgrove, M.D., Bryan Sexton, Ph.D., Robert Hyzy, M.D., Robert Welsh, M.D., Gary Roth, M.D., Joseph Bander, M.D., John Kepros, M.D., and Christine Goeschel, R.N., M.P.A.

ABSTRACT

BACKGROUND

Catheter-related bloodstream infections occurring in the intensive care unit (ICU) are common, costly, and potentially lethal.

METHODS

We conducted a collaborative cohort study predominantly in ICUs in Michigan. An evidence-based intervention was used to reduce the incidence of catheter-related bloodstream infections. Multilevel Poisson regression modeling was used to compare infection rates before, during, and up to 18 months after implementation of the study intervention. Rates of infection per 1000 catheter-days were measured at 3-month intervals, according to the guidelines of the National Nosocomial Infections Surveillance System.

RESULTS

A total of 108 ICUs agreed to participate in the study, and 103 reported data. The analysis included 1981 ICU-months of data and 375,757 catheter-days. The median rate of catheter-related bloodstream infection per 1000 catheter-days decreased from 2.7 infections at baseline to 0 at 3 months after implementation of the study intervention ($P \leq 0.002$), and the mean rate per 1000 catheter-days decreased from 7.7 at baseline to 1.4 at 16 to 18 months of follow-up ($P < 0.002$). The regression model showed a significant decrease in infection rates from baseline, with incidence-rate ratios continuously decreasing from 0.62 (95% confidence interval [CI], 0.47 to 0.81) at 0 to 3 months after implementation of the intervention to 0.34 (95% CI, 0.23 to 0.50) at 16 to 18 months.

CONCLUSIONS

An evidence-based intervention resulted in a large and sustained reduction (up to 66%) in rates of catheter-related bloodstream infection that was maintained throughout the 18-month study period.

From the School of Medicine (P.P., D.N., S.B., S.C., B.S.), the School of Professional Studies in Business and Education (D.S.), and the Bloomberg School of Public Health (H.C.), Johns Hopkins University, Baltimore; and the University of Michigan, Ann Arbor (R.H.); William Beaumont Hospital, Royal Oak (R.W.); Ingham Regional Medical Center, Lansing (G.R.); Harper University Hospital, Detroit (J.B.); Sparrow Health System, Lansing (J.K.); and the Michigan Health and Hospital Association Keystone Center for Patient Safety and Quality, Lansing (C.G.) — all in Michigan.

N Engl J Med 2006;355:2725-32.

What is an Institutional Review Board (IRB)?

- An IRB is a committee of health professionals and a community member that reviews and approves research proposals to ensure human rights are protected.
- The IRB assesses appropriate consent of subjects, design of the study, and maintenance of confidentiality, among other factors.
- Researchers must sometimes revise the research protocol before it is approved.
- Most researchers are required to complete a short education program before they can submit a research protocol to the IRB.
- Evidence of IRB approval is often required for publication of articles related to the research project

Why Doesn't the IRB Review PI Activities?

- The IRB Process can take weeks to months to obtain approval.
- By its very nature, PI is an iterative, adaptive process that often requires rapid action.
- To force all QI activities into the IRB system would impose such a heavy overhead that many worthwhile projects wouldn't be feasible.
- QM & Research collaboration.

Worksheets for Assessing Whether a QI Activity is Also Research

1. Developed by Rachel Nosowsky, Esq. and is based on The Hastings Center Report The Ethics of Using QI Methods to Improve Health Care Quality and Safety.

Quality Improvement or Research Worksheet

Rachel Nosowsky, Esq.

SEQ	Issue and Guidance	Rating
1	Are patients randomized into different intervention groups in order to enhance confidence in differences that might be obscured by nonrandom selection? *Randomization done to achieve equitable allocation of a scarce resource need not be considered and would not result in a "yes" here.*	☐ Yes ☐ No
2	Does the project seek to test issues that are beyond current science and experience, such as new treatments (*i.e.*, is there much controversy about whether the intervention will be beneficial to actual patients – or is it designed simply to move existing evidence into practice?). *If the project is performed to implement existing knowledge to improve care – rather than to develop new knowledge – answer "no".*	☐ Yes ☐ No
3	Are researchers who have no ongoing commitment to improvement of the local care situation (and who may well have conflicts of interest with the patients involved) involved in key project roles? *Generally answer "yes" even if others on the team do have professional commitments. However, where the project leaders with no clinical commitment are unaffiliated with the project site, it may be that the project site is not engaged – and does not require IRB approval/oversight – even if the project leaders' roles do require IRB oversight at their institutions.*	☐ Yes ☐ No
4	Is the protocol fixed with a fixed goal, methodology, population, and time period? *If frequent adjustments are made in the intervention, the measurement, and even the goal over time as experience accumulates, the answer is more likely "no."*	☐ Yes ☐ No
5	Will there be delayed or ineffective feedback of data from monitoring the implementation of changes? *Answer "yes" especially if feedback is delayed or altered in order to avoid biasing the interpretation of data.*	☐ Yes ☐ No
6	Is the project funded by an outside organization with a commercial interest in the use of the results? Is the sponsor a manufacturer with an interest in the outcome of the project relevant to its products? Is it a non-profit foundation that typically funds research, or internal research accounts? *If the project is funded by third-party payors through clinical reimbursement incentives, or through internal clinical/operations funds vs. research funds, the answer to this question is more likely to be "no."*	☐ Yes ☐ No

Adapted from Hastings Center, "The Ethics of Using Quality Improvement Methods to Improve Health Care Quality and Safety" (June 2006)

If the weight of the answers tends toward "yes" overall, the project should be considered "research" and approved by an IRB prior to implementation. If the weight of the answers tends toward "no," the project is not "research" and is not subject to IRB oversight unless local institutional policies differ. Answering "yes" to sequence #1 or #2 – even if all other answers are "no" – typically will result in a finding that the project constitutes research. *It is important to consult with your local IRB if you are unsure how they would handle a particular case, as the analysis of the above issues cannot always be entirely objective and IRB policies and approaches vary significantly.*

Worksheets for Assessing Whether a QI Activity is Also Research

- Developed by the CHOP Quality Improvement Committee (QIC) Ethics Subcommittee.

Quality Improvement Committee (QIC) Ethics Subcommittee

Children's Hospital of Philadelphia

CHOP Screening Checklist for Quality Improvement (QI) Projects

This checklist will help you determine whether a proposed project is in fact QI or potentially human subjects research.

Consideration	Question	Yes ✓	No ✓
PURPOSE	Is the primary aim or motive of the project either to: • Improve care **right now** for the next patient seen? **OR** • Improve operations or efficiency?		
RATIONALE	Is there sufficient evidence for, or acceptance of, this mode or approach to support implementing this activity or to create practice change, based on: • literature, • consensus statements, or • consensus among clinician team?		
METHODS 1	Are the proposed methods flexible and customizable, and do they incorporate rapid evaluation, feedback and incremental changes?		
METHODS 2	Do the methods include any of the following? • Control group • Randomization • Fixed protocol		
RISK	Is the risk related to the project minimal and no more than usual care (including the unavoidable minimal risk in implementing any changes made in processes of care)?		
PARTICIPANTS	Will the activity only involve participants (patients, parents, or CHOP staff) who are ordinarily seen, cared for, or work in the setting where the activity will take place?		
FUNDING	Is the project funded by any of the following? • An outside organization with an interest in the results • A manufacturer with an interest in the outcome of the project relevant to its products • A non-profit foundation that typically funds research, or by internal research accounts		
If all of the check marks are inside the shaded gray boxes, then the project is very likely QI and not human subjects research. Projects that are not human subjects research do not need review by the IRB. For more guidance about whether the activity meets the definition of Human Subjects Research see https://irb.research.chop.edu/not-human-subjects-research			

Last Revised: 09.20.18

KFSH&RC
DRAFT Worksheet
for Assessing Whether You Need IRB Approval for Your PIP or not

Does my quality performance improvement project need IRB approval?

Please answer the following:

1. Are you considering publishing this project in a journal? (Y / N)
2. Is the project funded through a grant or any other source? (Y / N)
3. Dose the project involve human subjects?(Y / N)
4. Does the project use a fixed clinical protocol that may not be altered by caregivers or staff ?(Y / N)
5. Does the project compare 2 or more outcomes based on an intervention or observation? (Y / N)
6. Dose the project involves an intervention that poses any risks other than those presented by routine clinical care? (Y / N).

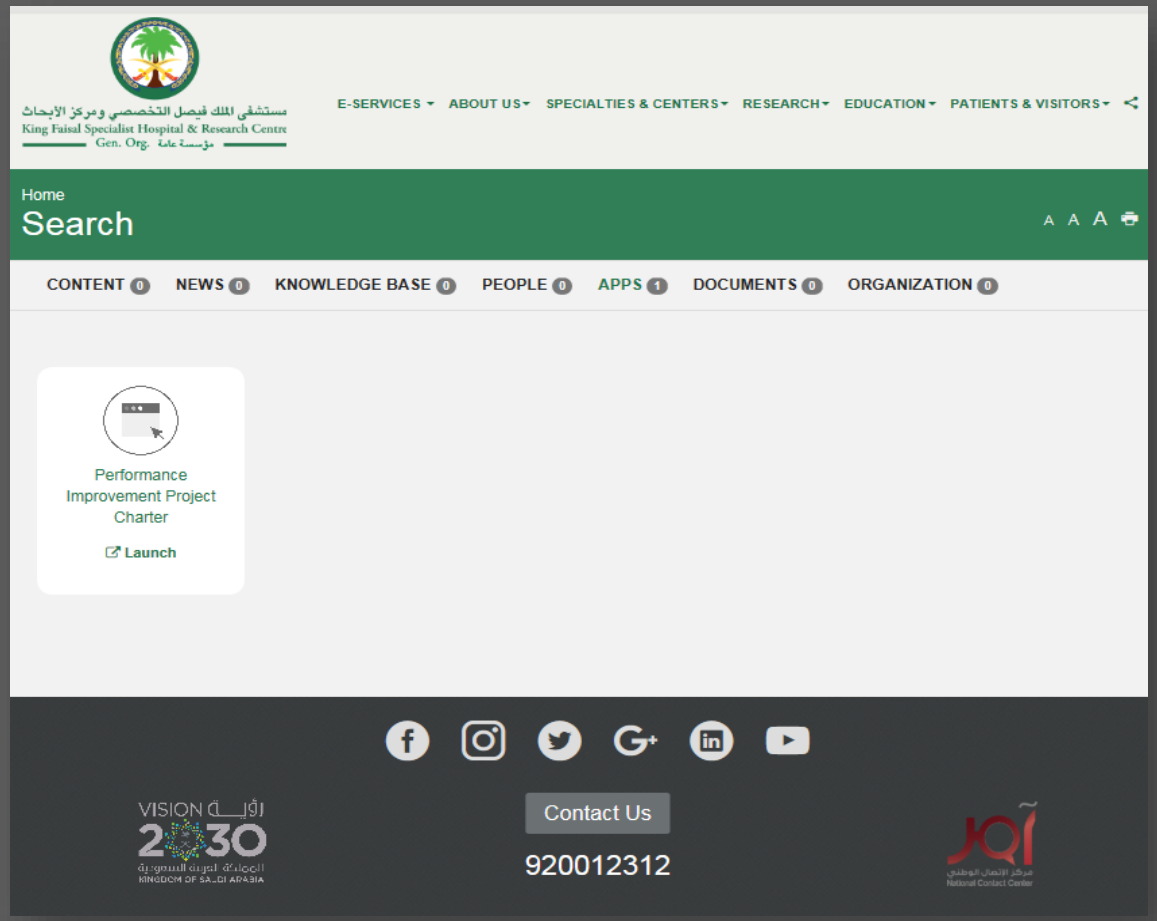
If any of the above is yes an IRB submission might be required, please forward the application for the IRB Processing officer to be reviewed at: HawazinA@kfshrc.edu.sa .

- PI Project Title:
- PI Project #:
- PI project Director / Leader:

Tips for getting your PI published

- Focus on innovative, and relevant topics to hospital strategic priorities.
- Complete a PI initiation form
- Complete the Assessment worksheet once you receive it and return it to QM.
- Form your team and follow the PI Methodology adopted by KFSH&RC
- Review literature /evidence based practices
- Investigate journals suitable to your project in advance.
- Please note that while QI activities typically involve minimal risk, they must still be conducted in a way that is ethical.
  - Staff conducting the activity should consider whether the people involved (patients or staff) will be exposed to any harm,
  - How consent will be obtained (if applicable) and privacy protected.
  - Staff should explicitly identify ethical issues arising and include a plan to manage them.

Performance Improvement (PI) Project Charter



Ethical Requirements for the Protection of Human Participants in QI activities

Hospital departments and divisions should review all proposed PI projects to ensure ethical requirements are met

Requirement	Explanation
Social or scientific value	The gains from a QI activity should justify the resources spent and the risks imposed on participants.
Scientific validity	A QI activity should be methodologically sound (i.e., properly structured to achieve its goals).
Fair participant selection	Participants should be selected to achieve a fair distribution of the burdens and benefits of QI.
Favorable risk–benefit ratio	A QI activity should be designed to limit risks while maximizing potential benefits and to ensure that risks to an individual human participant are balanced by expected benefits to the participant and to society.
Respect for participants	A QI activity should be designed to protect the privacy of participants and the confidentiality of their personal information. Participants in a QI activity should receive information about findings from the activity that are clinically relevant to their own care. All patients and workers in a care delivery setting should receive basic information about the program of QI activities. The QI results should be freely shared with others in the health care system, but participant confidentiality should be protected by putting results into nonidentifiable form or obtaining specific consent to sharing.
Informed consent	Consent to inclusion in minimal-risk QI activities is part of the patient's consent to receive treatment. Patients should be asked for informed consent to be included in a specific QI activity if the activity imposes more than minimal risk. The risk to patients should be measured relative to the risk associated with receiving standard health care. Workers (employees or nonemployee professionals who provide care in an organization) should participate in minimal-risk QI activities as part of their job responsibilities. Workers should be asked for their informed consent to be included in a QI activity that imposes more than minimal risk. The risk to workers should be measured relative to the risk associated with the usual work situation. This does not include any risk to economic security (for example, if a QI activity reveals that the worker is incompetent or that the organization can provide quality care without that worker).
Independent review	Accountability for the ethical conduct of QI should be integrated into practices that ensure accountability for clinical care. Each QI activity should receive the kind of ethical review and supervision that is appropriate to its level of potential risk and project worth.

Major Quality & Safety Journals to Consider

- The Joint Commission Journal on Quality and Patient Safety
- BMJ Quality and Safety
- PLoS Medicine
- Top medical journals also publish some QI work:
  - New England Journal of Medicine
  - Annals of Internal Medicine
  - Journal of the American Medical Association

- **The American Journal of Medical Quality**: *The American Journal of Medical Quality* is the official Journal of the American College of Medical Quality. The journal publishes original work in the entire field of quality measurement and improvement.
- **BMJ Quality**: BMJ Quality is an online workspace that supports individuals and teams to work through quality improvement ideas, make an intervention, and publish their results while developing their knowledge and skills. Projects are published in BMJ Quality Improvement Reports journal and, as of January 2015, we accept over 85%* of submissions.
- **Health Care: The Journal of Delivery Science and Innovation**: *Health Care: The Journal of Delivery Science and Innovation* is a quarterly journal invested in promoting cutting edge research on innovation in health care delivery, including improvements in systems, processes, management, and applied information technology.
- **The International Journal for Quality in Health Care**: *The International Journal for Quality in Health Care* (IJQHC) is a leading international peer-reviewed scholarly journal addressing research, policy, and implementation related to the quality of health care and health outcomes for populations and patients worldwide.
- **Journal for Healthcare Quality:** *The Journal for Healthcare Quality* (JHQ) welcomes submissions by writers from all sectors in the field of health care quality. The journal publishes articles on a broad range of topics including administration and management, performance measurement and improvement, and global and international issues.
- **The Journal of Clinical Outcomes Management**: *The Journal of Clinical Outcomes Management*® (JCOM®) is an independent, peer-reviewed journal offering evidence-based, practical information for improving health care quality.
- **The Journal of Healthcare Risk Management**: The *Journal of Healthcare Risk Management* is published quarterly by the American Society for Healthcare Risk Management (ASHRM). The purpose of the journal is to publish research, trends, and new developments in the field of healthcare risk management with the ultimate goal of advancing safe and trusted patient-centered healthcare delivery and promoting proactive and innovative management of organization-wide risk.
- **PLoS One**: *PLOS ONE* is an international, peer-reviewed, open-access, online publication. PLOS ONE welcomes reports on primary research from any scientific discipline
- **Patient Safety and Quality Healthcare**: This online and print magazine reaches a readership of about 20,000 people, and has published Open School student work on several occasions. Please note *PSQH* is not a peer-reviewed journal.
- **Pulse Voices**: It publishes work from all people involved in giving and receiving health care. It seeks high-quality original nonfiction, first-person stories, poetry, artwork, and photographs by patients and providers who want to share their experiences of health care.
- **Quality Management in Health Care**: *Quality Management in Health Care* (QMHC) is a peer-reviewed journal that provides a forum for readers to explore the theoretical, technical, and strategic elements of health care quality management. The journal's primary focus is on organizational structure and processes as these affect the quality of care and patient outcomes.

References

SQUIRE

Promoting Excellence in Healthcare Improvement Reporting

SQUIRE stands for Standards for QUality Improvement Reporting Excellence. The SQUIRE guidelines provide a framework for reporting new knowledge about how to improve healthcare. They are intended for reports that describe system level work to improve the quality, safety, and value of healthcare.

Read More!

Latest News

2018 SQUIRE Writing Conference - November 13 -14, 2018 Dallas, TX

This year's conference was held in Dallas, Texas at the Meadows Conference Center. More info on next year's conference coming soon!

SQUIRE Introduced at EQUATOR Seminar

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INDUSTRY SPONSORED RESEARCH

GUIDANCE ON RESEARCH VS. QUALITY IMPROVEMENT AND PROGRAM EVALUATION

Version Date: April 2016

Determining whether a project constitutes human subjects research rather than quality improvement or program evaluation involves multiple factors. The federal definition of research is "a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program which is considered research for other purposes." This is an important distinction to make because it determines whether IRB review and oversight of a project is needed because IRB oversight is limited to human subjects research.

The Health Sciences (HS) IRBs Office are frequently asked to make a formal determination that a project falls outside of the federal definition of research. Often, IRB review of these projects isn't required; however, formal IRB determinations that the projects do not require IRB oversight are requested in anticipation of such documentation being required for journals, conferences, funding sources and others.

The materials below are intended to assist study teams in determining whether a project requires submission to the IRB as a research project involving human subjects. If the project involves some characteristics of a research project, submission to the IRB for review is expected. To address the issue of documentation, the HS IRBs Office also has developed a tool that can provide self-certification that the project does not require IRB review and oversight.

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AAHRPP
Association for the accreditation of Human Research Protection Programs, Inc.
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Welcome to BMJ Open Quality, an expanded and rebranded version of BMJ Quality Improvement Reports. The journal is dedicated to publishing high quality, peer reviewed healthcare improvement work. Articles covering original research, local, national and international QI projects, value-based healthcare improvement initiatives and educational improvement work are all considered. BMJ Open Quality adheres to the highest possible industry standards concerning publication ethics. To read the journal's detailed guidelines please see our policies.

Our website provides resources to support you in your quality improvement work such as templates to help you run and write up quality improvement projects.

BMJ Open Quality operates a fast submission process with continuous publication online, to ensure timely, up-to-date knowledge is available worldwide. The journal adheres to a rigorous and transparent peer review process and papers are considered on the basis of methodological soundness rather than priority or novelty.

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HIPxChange

Publishing Quality Improvement Work

This site contains several resources to help clinicians publish the results of their quality improvement work within healthcare organizations. UW Health and the Health Innovation Program partnered to create the site based on the SQUIRE (Standards for Quality Improvement Reporting Excellence) Guidelines, Maintenance of Certification requirements, and A3 guidelines for conducting quality improvement projects.

The materials on this site will walk you through the manuscript writing and publication process to help ensure that your final manuscript is high quality and contains all of the information required in a quality improvement publication. Please note that this site does not replace the MOC program in place at UW Health; it is a set of additional resources that you can use if you are interested in publishing your QI project.

The tools currently on the site are most useful if you review them as soon as you start thinking about

View the Materials

To access the materials, we ask that you register on our website and answer a few short questions about your QI project.

Register or Log In

Health Innovation Program
Integrating healthcare research and practice

School of Medicine and Public Health
UNIVERSITY OF WISCONSIN-MADISON

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Institute for Healthcare Improvement's (IHI) Collection of Publications

- IHI's collection provides QI publications to expand your knowledge and/or to provide examples of what has been published. As you browse the publications, you can take note of where they were originally published for context.

Refernece: http://www.ihi.org/education/IHIOpenSchool/resources/Pages/Publications/default.aspx

Thank You