

Powerful Reporting: Spreadability in Action

Jay Wish, MD
Quality Improvement Redesign Meeting
August 25, 2009
Baltimore, MD

3 Key Attributes of Successful QIPs

- Attribution
- Sustainability
- Spreadability

Intelligent QIP Design is Congruent with Powerful QIP Reporting

- Background
- Project description/problem
- Goal
- Project design & methodology
- Root cause analysis
- Barriers
- Interventions
- Start and stop dates
- Indicator(s), numerator(s), denominator(s)
- Measurement frequency
- Evaluation of effectiveness
- Sustainability

Why Publish a QIP?

- Disseminate successful practices/interventions for others to emulate
- Despite over 3 decades of ESRD Network QI activities, there is a dearth of publication in this area
- There is an increasing demand for published QIP guidance as regulatory oversight bodies require QIPs of providers

QIP Friendly Journals

- American Journal of Kidney Diseases (published by NKF www.ajkd.org)
- American Journal of Medical Quality (published by the American College of Medical Quality www.amcq.org)
- Journal of Quality and Patient Safety (published by JCAHO www.jcrinc.com)
- Quality and Safety in Healthcare (published by the British Medical Journal qshc.bmj.com)

Institutional Review Board: The New Rules (OHRP)

- Most quality improvement efforts are not research subject to the HHS protection of human subjects regulations and therefore do not require IRB review
- HHS research definition: “*A systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge*”

For Example

“If 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, that quality improvement project may also constitute nonexempt human subjects research under the HHS regulations.”

Quality Improvement Activities (1)

1. Quality improvement activities conducted by organizations whose purposes are limited to:
 - a) *Implementing a practice* to improve the quality of patient care and
 - b) Collecting patient or provider data regarding the *implementation of the practice* for clinical, practical, or administrative purposes

Do Not satisfy the definition of “research”

Quality Improvement Activities (2)

2. Quality Improvement activities for the purposes of:

- a. Delivering healthcare
- b. Measuring and reporting provider performance data for clinical, practical and administrative use

Do Not satisfy the definition of “research”

Data Analysis & Publication

- Data that are not individually identifiable can be analyzed for quality improvement activities without having to apply the HHS protection of human subjects regulations (i.e., IRB approval)
- Intent to publish is an insufficient criterion for determining whether a QI activity involves research

For more information visit

www.hhs.gov/ohrp/qualityfaq.html#q1

Other IRB Issues

- Local rules (university, hospital) may be more restrictive than those of the OHRP
- When in doubt, check with the local IRB to be sure the QI activity is exempt
- Non-exempt activities involving multiple institutions can choose local or systemic IRB approval

The SQUIRE

- Standards for Quality Improvement Reporting Excellence
- Developed by a working group for Quality and Safety in Health Care chaired by Dr. Greg Ogrinc of Dartmouth Medical School
- Analogous to reporting guidelines already developed for
 - ◆ Randomized controlled trials (CONSORT)
 - ◆ Studies of diagnostic accuracy (STARD)
 - ◆ Epidemiological observational studies (STROBE)
 - ◆ Meta-analyses (QUOROM and MOOSE)

SQUIRE Elements

- Title and abstract
- Introduction
 - ◆ Background knowledge (same as QIWP)
 - ◆ Problem description (same as QIWP)
 - ◆ Intended improvement (same as goal in QIWP)
 - ◆ Study question
- Methods
 - ◆ Ethical issues
 - ◆ Setting

SQUIRE Elements (cont'd)

■ Methods (cont'd)

- ◆ Planning the intervention (includes RCA and interventions from QIWP)
- ◆ Planning the study of the intervention (includes evaluation of how effectively intervention was implemented from QIWP)
- ◆ Methods of evaluation (includes evaluation of how effective was intervention from QIWP)
- ◆ Analysis (includes quantitative data from QIWP: indicator(s), numerator(s), denominator(s), measurement frequency and dates)

SQUIRE Elements (cont'd)

■ Outcomes

◆ Nature and setting of improvement intervention

- ☞ Elements of setting and structures of patterns of care that provided the context (P)
- ☞ Actual course of the intervention (D)
- ☞ Degree of success in implementing the intervention (C)
- ☞ Evolution of initial plan and lessons learned (A)

SQUIRE Elements (cont'd)

■ Outcomes (cont'd)

- ◆ Changes in care processes and clinical outcomes associated with the intervention
 - ☞ Data
 - ☞ Benefits, harms, unexpected results, problems, failures
 - ☞ Evidence on strength of association between outcomes and intervention (ATTRIBUTION)
 - ☞ Summary of missing data

SQUIRE Elements (cont'd)

- Discussion (this is the hard part)
 - ◆ Summary of key successes and difficulties
 - ◆ Relation to other evidence (will require literature search)
 - ◆ Limitations (confounding, bias, imprecision, generalizability (SPREAD), likelihood that observed gains will weaken over time (SUSTAINABILITY), plans for monitoring and maintaining improvement)

SQUIRE Elements (cont'd)

■ Discussion (cont'd)

◆ Interpretation

- ☞ Reasons for differences between observed and expected outcomes
- ☞ Inferences about strength of evidence
- ☞ Causal mechanism and size of changes
- ☞ Modifications to improve future performance
- ☞ Opportunity costs and actual financial costs

◆ Conclusions

- ☞ Overall usefulness of intervention
- ☞ Other settings in which intervention is likely to be effective
- ☞ Implications for further studies

QIWP vs. SQUIRE

QIWP	SQUIRE
Background	Introduction/background
Project description/problem	Introduction/problem
Goal	Introduction/intended improvement
Project design & methodology	Methods
Root cause analysis	Methods/planning
Barriers	Methods/setting
Interventions	Methods/planning & studying
Start & stop dates	Methods/analysis
Indicator(s), numerators(s), denominator(s)	Methods/analysis
Measurement frequency	Methods/analysis
Evaluation of effectiveness	Outcomes
Sustainability	Conclusions/limitations

SQUIRE is Challenging

- Including all the elements of SQUIRE may put the manuscript over the journal's word limit (3500 in AJKD)
- A robust discussion section is key to SPREAD which makes the article attractive to journals and readers
- Efficient use of tables and graphs may satisfy elements of methods and results so that more space can be used for discussion

Summary & Conclusions

- There is a need for more QIPs to be published in the nephrology literature
- Networks have the resources (internal and voluntary) to convert successful QIPs into manuscripts for publication
- The QIWP provides an easy cross-walk to the elements of SQUIRE. Just add discussion!
- The publication of QIPs by Networks is a priori evidence of spreadability