

Monitoring Quality and Supporting Clinical Effectiveness

What evidence do we need for Safety and Quality improvement?

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Has anyone used this medicine lately?

Consider the scenario..

- Treating a patient
- Tried red pills with “250” on one side
- Seemed to work OK, then another patient comes up and you have run out of these pills...

Question: will red pill with “100” on side be okay?

OR

should you use white pill with “250” on side?

The science of putting research into practice

- Evidence-based Medicine
 - Explicit use of best-available evidence to inform decisions about care of (individual) patients
 - Hypotheses undergo rigorous evaluation
- Quality Improvement (the story so far)
 - Implement best practice for processes and outcomes of care in routine practice, based on best available evidence
 - Implementation however is based on... intuition, anecdotes, low level studies

Evolution of Quality Improvement and Implementation Research

- Passive diffusion
 - *“publish it: they will come”*
- Guidelines and systematic reviews
 - *“read it for them: they will come”*
- Industrial style QI
 - *“TQM/QI it: they will come”*
- Systems (Re-)engineering
 - *“completely rebuild it (around them): they will come”*

Designs for evaluating QI Research

- Systematic Reviews (published) research:
 - Weak study designs: susceptible to bias
 - Expediency vs. rigor: “just do it”
 - RCT’s needed: what factors determine successful QI interventions??
- Before and after
 - Can’t control for confounding/ co-interventions/baseline change
- Time series
 - More time points: greater precision of estimates of effect
- Controlled before and after
 - E.g. study of critical pathways effect on surgical LOS in Boston used comparator sites: data collected but no intervention


Evidence of Effectiveness of specific QI strategies

- Systematic reviews remain superior
 - Multi-faceted interventions
 - Active vs passive implementation
 - Modest impact
- Targeting provider behaviour
 - Active/multifaceted
 - Modest impact: mean effect size marginally greater than single factor
 - Passive distribution of educational leaflets
 - Modest positive benefits

AHRQ Review: QI strategies targeting organisational change

Focus on diabetes and hypertension

- Strategies that work for diabetes may not work for hypertension
 - Context is important
 - Everything works for diabetes
 - Publication bias?
 - Confounding by co-interventions??
- Regression analysis: 3 QI strategies work:
 - Case management is the “red pill” but what ingredients and instructions for use??



*Knowing is not enough; we must apply.
Willing is not enough; we must do.
— Johann Wolfgang Von Goethe (1749-1832)*

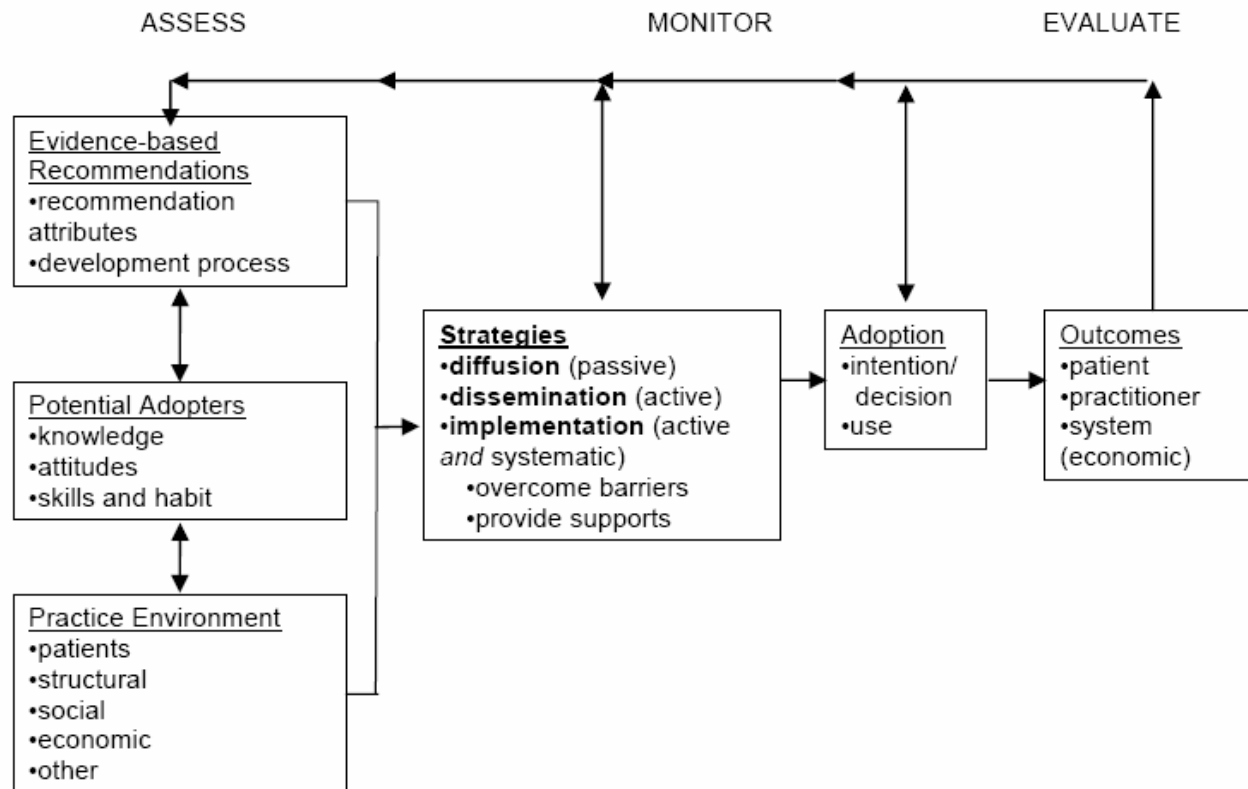
Quo Vadis?

- QI literature is poor quality
 - Evaluations of interventions fail to reach basic standards
 - Choices behind interventions lack a theoretical framework (Culture of research??)
 - Poor Quality reporting
 - Omit pre-intervention values (1 in 3)
 - Omit number of subjects or providers participating
 - Need better understanding of factors driving organisational and provider behaviour change

There is no Red Pill

- Wonder drugs unlikely to exist
- Quackery abounds
- Challenges will be met in standards of publication
- Good news:
 - Davidoff F Batalden P. Toward stronger evidence on quality improvement. Draft publication guidelines: the beginning of a consensus project. *Qual Saf Healthcare* 2005;14:319-325.
 - Ottawa model

Ottawa model of research use



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Clinical indicators as a measure of patient safety

A literature review

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Patient safety

- A priority for providers, particularly in hospital settings
- Public concerns reinforced by recent scandals
 - E.g., Bundaberg Hospital (2005).
 - Common characteristic: compromised patient safety not detected by sentinel event reporting.

Efforts to promote safe and effective health care have lead to development and reporting of performance indicators

- increased attention to measures of patient safety at an organisational level in the hospital setting.

Measurement of patient safety enables health care providers to assess the safety and quality of their service.

Clinical indicators

A summary of research evidence on use of clinical indicators.

- Aim to identify hospital wide clinical indicators in use
 - Most effective as a measure patient safety and
 - Have potential to be modified for the Australian context.
- Users will need to assess ease of full implementation in their organisation's health care setting.
- Use of indicators for performance measurement
 - Prerequisite towards quality improvement but not a goal in itself.
- Indicators alone do not provide judgement
 - Need to be compared to reference points and related to other performance indicators, clinical review, practice improvement programs and program evaluation.

Measurement of patient safety

Many patient safety problems are uncommon :

- demonstrating success of safe practice is not possible in a conventional statistically meaningful way.

Measurement of patient safety requires:

- Multiple data collections and
- Consistent methodologies for collection and analysis.

Rate based indicators:

- Do not provide definitive answers
- Are designed to indicate potential problems in organisational or clinical performance by highlighting statistical outliers or variations.

Measuring time between events:

- More effective for detecting changes and verifying improvements.

Generic indicators measure aspects of care that are relevant to most patients.

Use of clinical indicators as a measure of patient safety at a hospital wide level

Base on rigorous scientific evidence *if possible*.

A mix of process and outcome measures is the best strategy for impact on safety and quality of care.

In the absence of evidence in health care:

- Use development methods including
 - consensus techniques which combine expert opinion and available evidence
 - indicators based on clinical guidelines.

Performance indicators may be used as:

- single and isolated measures
- in a core set of integrated and interdependent measures
- in a core set of diverse and independent measures or
- as a comprehensive program.

There is considerable use of clinical indicators in the US, UK, Australia, Europe and Canada.

Strengths and weaknesses of clinical indicators as a measure of patient safety at a hospital wide level

- CI's flag potential problems that require closer investigation, analysis and understanding of factors that influence them.
- Development and use of CI's should be subject to rigorous evaluation.
- Well developed measures:
 - Based on strong clinical evidence
 - Depict uncontroversial clinical practices that have broad consequences among clinicians, and
 - Incorporate agreed-upon standards for determining satisfactory performance.
- Clinical process interventions have strong evidence for reducing the risk of adverse events related to a patient's exposure to hospital care.

Strengths and weaknesses of clinical indicators as a measure of patient safety at a hospital wide level

- Indicators based on administrative data sets:
 - cannot provide definitive measures of health care quality but
 - can provide *indicators* of health care quality that can serve as a starting point for further investigation.
- Some clinical indicators, and dimensions of care, tend to be based primarily on empirical evidence or expert judgement.
- The most widely used measures define explicit criteria against which performance is judged.
- Good evidence exists that certain clinical interventions will improve patient safety in the acute health care setting.
- Further research into the construction of core sets of indicators and indicator programs is needed.

Summary

- A mix of process and outcome measures is the best strategy for having an impact on the safety and quality of care.
- Indicators based on administrative data sets
 - cannot provide definitive measures of health care quality but
 - can provide *indicators* of the quality of health care that serve as a starting point for further investigation.
- Experience from existing clinical indicator programs indicates
 - need a process of review to modify and improve established indicators
 - need to maintain their relevance to clinical practice as it consistently changes
- AHRQ has identified 11 patient safety practices based on the strongest supporting evidence:
 - clinical interventions that if implemented more widely, would decrease risk associated with hospitalisations, critical care and surgery.

Recommendations



Adoption of the following clinical indicators as a measure of patient safety at a hospital wide level

- Monitor outcome variables:
 - In-hospital and neonatal mortality for specific procedures
 - Unplanned readmissions to intensive care unit
 - Unplanned returns to the operating theatre
 - Unplanned returns to hospital as an inpatient
 - Unplanned admissions following day procedures
 - Unplanned readmissions to higher level care within 48 hours

Adoption of the following clinical indicators as a measure of patient safety at a hospital wide level

- **Implement a set of clinical indicators:**
 - **Hospital acquired infections** including central and peripheral line associated bloodstream infections, catheter associated urinary tract infections and surgical site infections for procedures which are performed at least 100 times a year. Procedures should include hip and knee replacement, coronary artery bypass grafts, other cardiothoracic and colorectal procedures.
 - **Patient falls** per 1000 bed days.
 - **Pressure ulcers** per 1000 bed days.
 - **Medication errors** (prescribing, dispensing, administration and documentation processes) per 1000 bed days.
 - **Post-operative deep vein thrombosis / pulmonary embolism** per 1000 bed days for the following conditions; hip and knee replacements, hip fracture, general surgery, orthopaedic trauma and medical patients. Consider monitoring these for acute spinal cord injury and neurosurgery patients.
 - **Obstetric and birth trauma**

Consider implementing

- Monitoring administration of **prophylactic antibiotics**
 - particularly pre-operative use for surgical patients (cardiothoracic, abdominal, orthopaedic, and colorectal), specifically timing of administration of first dose and choice of antibiotic concordant with national guidelines.
- Monitoring adherence to **clinical pharmacist reconciliation of patient medications**
 - prescribing, dispensing, administration and documenting processes for the use of medicines.
- Monitoring administration of **DVT/PE prophylaxis**
 - particularly for surgical patients focusing on timing of administration of first dose and choice of antibiotic concordant with national guidelines.
- Monitoring use of **maximal sterile barriers** while placing central intravenous catheters.
- Monitoring use of **real time ultrasound guidance during central line insertion**.
- Use of **antibiotic impregnated venous catheters**.
- Use of **pressure relieving bedding** materials.

Recommendations

- Agree on benchmark standards based on published results.
- Consider implementing a process control reporting tool such as CUSUM analysis and develop “stop and review” rules.
- Develop and implement a clinical audit tool to collect relevant process level data.
- Establish a process of review of established indicators to maintain their relevance to clinical practice.