

Synthesising qualitative and quantitative evidence

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How can reviews accommodate diversity of primary evidence?

- Crucially linked to the *nature of the research question*
- And to the *aim of the review*
- Review questions are of different types and demand different forms of answers
- Review methods need to be matched to the type of questions
- Broadly, review methods are either *interpretive* or *integrative*, though most contain elements of both
- Many published reviews currently do not adequately match questions & methods

Systematic reviews

- Conventionally understood to be characterised by:
 - An explicit study protocol
 - Pre-specified, highly focused question
 - Explicit methods for searching
 - Explicit methods for appraisal
 - Explicit methods for synthesis of studies

Aggregative syntheses - conventional systematic review

- Starts with tightly defined question
- Focus on <u>summarising data and testing</u> <u>hypotheses about causality</u>
- Categories under which data are to be summarised are assumed to be secure and well-specified
- Aim is to assess strength of evidence in favour of causality

Systematic reviews are excellent

- If you want to know "does it work?"
- And you can measure what "it" is
- And you can measure "working"
- So it's theory testing in particular, testing theories/hypotheses about causality



Macular degeneration



Macular degeneration







And a very helpful systematic review

• There is accumulating evidence that taking vitamin E or beta-carotene supplements will not prevent or delay the onset of AMD. There is no evidence with respect to other antioxidant supplements, such as vitamin C, lutein and zeaxanthin, or any of the commonly marketed multivitamin combinations. Although generally regarded as safe, vitamin supplements may have harmful effects and clear evidence of benefit is needed before they can be recommended.



Implicit requirements for conventional systematic review

- 1. You have a decent theory about pathogenesis, so you know what you are targeting.
- 2. You have a decent theory about the intervention, so you know what your intervention is.
- 3. You have a decent theory about causal mechanisms that link the intervention to the outcomes you seek.
- 4. You can measure the outcomes.



Conventional SR

- Much more problematic when you have a messy question or messy forms of evidence, or the things you are looking at can't be measured easily.
- Claim that proceduralisation of method confers scientific credibility is not defensible for all types of question

Some types of questions

- Listing
- Estimating
- Identifying causal chains
- Identifying conditions of causality
- Finding factors implicated in relationships
- Creating taxonomies
- Describing and characterising
- Theorising and explaining



Deciding on questions

- Reviewers should decide on the types of answers they want first.
- For example: What are the maternal psychosocial outcomes of caesarean birth?
- This is could be a LISTING question: we could list measures of outcomes that are currently used.
- Or it could be a TAXONOMIC question: we could use a wider literature to identify outcomes that are currently unmeasured but nonetheless important.



Conventional systematic reviews may not be the best approach

- When you want to:
- Characterise the problem and pathogenesis of the problem, so you can design an appropriate intervention
- Characterise the intervention
- Explain the causal mechanisms of the intervention

The importance of the type of question

 For some types of question, emphasis on procedure produces a method that is robust to "the author", but stifles necessary elements of creativity, insight, and flexibility





A quality improvement programme in action



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.

Success of Michigan project

- infection control in insertion and management is major factor in CVC-BSIs
- Programme in 103 ICUs in Michigan; included checklist for CVC insertion and management
- Sustained reduction of CVC-BSI rate:
 <u>Baseline</u>: mean 7.7 CVC-BSIs per 1000 catheter days
 <u>18 months</u>: mean 1.4 CVC-BSIs per 1000 catheter days

ANNALS OF MEDICINE

THE CHECKLIST

If something so simple can transform intensive care, what else can it do?

by Atul Gawande

DECEMBER 10, 2007

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If a new drug were as effective at saving lives as Peter Pronovost's checklist, there would be a nationwide marketing campaign urging doctors to use it.

T he damage that the human body can survive these days is as awesome as it is horrible: crushing, burning, bombing, a burst blood vessel in the brain, a ruptured colon, a massive heart attack, rampaging infection. These conditions had once been uniformly fatal.

KEYWORDS

Intensive-Care Units (I.C.U.s); Pronovost, Peter; Checklists; Hospitals; Infections; Johns Hopkins Hospital; Sinai-Grace Hospital

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 Subscription Info. Permissions 	<u>"Explaining Michigan: Developing an Ex Post Theory of a Quality Improvement Program"</u> Mary Dixon-Woods, Charles L. Bosk, Emma Louise Aveling, Christine A. Goeschel, and Peter J . Pronovost June 2011 (Volume 89, Number 2)
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Michigan

- **Clinical community** approach, led by community insiders
- Flexible, evolved over time
- Became a "learning community"
- Impetus and momentum came from within the community
 - role of peer pressure
 - importance of social network
 - redefinition of problem as more than technical
 - symbolic functions of activities
 - judicious use of harder edges
- Gradually more participant-led
- Best understood as a <u>culture change intervention</u> that made patient safety a priority and helped destabilise unhelpful hierarchies

We need

- Small theories of phenomena (what are they and what explains what's going on?)
- Small theories of treatment (what are they and what are their mechanisms of change?)
- Theories of outcomes (what are they and how should they be characterised)?

Programme theory

 "Nothing improves research design so much as having a clear idea about what is being investigated. An important function of theory in research design is to help researchers ensure that they are playing in the right ballpark to begin with— that is, to help them avoid studying the wrong thing" (Lipsey, 1993)

What is programme theory?

- Plausible model of how the programme works
 - Identifies the desired outcomes
 - Identifies the activities and resources, and who will undertake them
 - Identifies the <u>mechanisms</u> that link those activities and resources to the desired outcomes
 - Identifies conditions likely to be favourable or unfavourable to functioning of the mechanisms
 - Identifies possible unwanted outcomes (the side effects)

To design a programme theory

• You need to understand the phenomenon and environment in which you are intervening



Foot care in England

- There are over 70 amputations of feet a week in England, of which 80% are potentially preventable.
- In 2007/8, nearly a quarter of people with diabetes did not have a foot check.
- You are twice as likely to have your foot amputated if you live in the Southwest compared with the Southeast.





So – improvement is needed!

- But how do we intervene? Should we:
 - Send an email around to remind GPs to do foot checks?
 - Train GPs in doing foot checks?
 - Pay them to do the checks?
 - Fine them if they don't do them?
 - Give them a goal they have to meet for their annual performance review?
 - Give them feedback every month on how they compare with others?
 - Publish a league table of amputations by GP?
 - Tell patients they should ask their GP for a foot check?

Well...

- It would be better to start with a good theory about what is causing the problem in the first place
- Then we can design and evaluate our intervention



For some kinds of review questions

- We need methods that more interpretive
- More oriented towards theory-building
- Allow us to answer a broader range of important questions
- Build on the range of methods we have available in primary research

Interpretive syntheses

- Start with a review topic; formulate the question more precisely after scoping stage and remain open to possibility of modification
- Sees the generation of the concepts of the analysis as one of its tasks - category specification therefore deferred til end of process
- Oriented towards theory generation, though may also be primarily descriptive

Examples of primarily qualitative and interpretive approaches

- Meta-ethnography
- Critical interpretive synthesis
- Narrative summary
- Realist synthesis
- Meta-narrative mapping
- Grounded theory
- Miles & Huberman's techniques

Primarily quantitative and aggregrative

- Content analysis
- Case survey
- Qualitative comparative analysis
- Bayesian meta-analysis

Syntheses of qualitative research

- Found 42 papers published between 1998 and 2004
- Many papers lacked explicitness about methods for searching, appraisal and synthesis
- Most commonly used method was meta-ethnography (19 papers)
- Some evidence of inappropriate use of techniques
- Important that appeals to the particularist nature of qualitative research are not used to legitimate or obscure poor practices or faults of execution
 - Dixon-Woods M, Booth A, Sutton AJ (2007) Synthesizing qualitative research: a review of published reports. *Qual Res* 7: 375-422

Meta-ethnography

- Noblit and Hare (1988)
 - Reciprocal translational analysis
 - Refutational synthesis
 - Lines of argument synthesis



Reciprocal translational analysis

- Key "metaphors" are identified.
- Attempt to translate the concepts into each other.
- Judgements about the ability of the concept of one study to capture concepts from others are based on the attributes of the themes themselves, and concept that is most adequate is chosen.

Refutational synthesis

 Contradictions between the study reports are characterised and an attempt made to explain them



Lines of argument synthesis

- Involves building a general interpretation grounded in the findings of the separate studies.
- Themes or categories that are most powerful in representing the entire dataset are identified by constant comparisons between individual accounts.

Meta-ethnography

- Modified and developed by Campbell, Britten et al
 - Quality appraisal (CASP) used to exclude papers
 - Idea of second and third order constructs



Reciprocal translational analysis

- Similar concepts grouped together; "index concepts" generated, usually (!?) based on terminology used in the original papers.
- Procedurally like CONTENT ANALYSIS.
- Possible to compare papers systematically according to key concept.

Lines of argument synthesis

- Key concepts treated as the building blocks of a lines of argument synthesis
- Key concepts examined for patterns
- The you generate themes that have higher explanatory value across the concepts and could integrate the concepts



LOA synthesis

- LOA synthesis is interpretive
- Procedurally, this process is like the CONSTANT COMPARATIVE METHOD



Meta-ethnography

- RTA procedurally fairly straightforward but how to choose index concept is not clear
- Rather messy 2nd/3rd order distinction
- Not clear how to sample
- Refutational syntheses rarely done
- Method specified for qual studies only
- Actually quite difficult to execute

An alternative?

- Critical interpretive synthesis (CIS)
- Sensitised to issues raised by conventional systematic review methodology
- But rooted firmly in qualitative tradition of inquiry and evolved from interpretive synthesis methods such as metaethnography – clear genaeology
- Suitable for messier questions with messier literatures



Critical Interpretive Synthesis

- Aim is the generation of a synthesising argument
 A theory
- Sampling involves constant dialectic process concurrently with theory generation; highly iterative
- Development of theoretical categories is based on analysis of conceptual similarities and differences that identified in the literature, and constant comparison across these
- Synthesising argument synthesis of synthetic and "found" constructs = mid-range theory

Critical interpretive synthesis

- Focused on generating theory
- As part of this, adopts a critical stance
- Questions how the literature defines its problems
- What assumptions does the literature draw on?



Formulating questions in critical interpretive syntheses

- Start with a review topic; formulate the question more precisely after scoping stage and remain open to possibility of modification
- Sees the generation of the concepts of the analysis as one of its tasks - category specification therefore deferred til end of process
- Iterative approach- question as compass rather than anchor
- Question emerges from analysis
- Very demanding and has implications for other aspects of SR methodology



Sampling

- Conventional reviews attempt to be exhaustive in identifying body of literature
- Good if you are doing an aggregative review where you have fixed concepts at the beginning and need to produce reliable estimates
- Not so good if you are doing an interpretive review
- Need to "sample"

Sampling

- Theoretical sampling is conducted with a view towards the evolving development of the concepts
- Sampling continues until theoretical saturation is reached (if that's possible)
- Safety measures (e.g. search for disconfirming cases) built in

Searching

- Has to proceed hand in hand with sampling
- Difficult to demonstrate explicitness, reproducibility and comprehensiveness of searching
- CIS recognises relevance of literatures not directly concerned with phenomenon under review
- Impossible to be exhaustive



The debate about sampling

- Theoretical sampling approach mirrors what happens in primary research
- Some have expressed concern that this is inappropriate in synthesis
- Safety measures (eg search for disconfirming cases) can be built in but difficult to do in practice



CIS: critique not critical appraisal

- Embraces all types of evidence (qual, quan, theoretical) and is attentive to procedural defects in primary studies
- CIS conducts critique rather than critical appraisal treats literature as an object of inquiry
- Questions taken-for-granted and "normal science" conventions and what influences choice of proposed solutions



Appraising

- No hierarchy of evidence in qualitative research
- Debates about whether to exclude research on grounds of quality
- How to appraise qualitative research deeply and bitterly contested
- Dixon-Woods et al (JHSRP) not clear that structured approaches offer any advantage *in terms of consistency*



Conventional critical appraisal

- Not clear what to do with quality appraisals
- Need more work on impact of appraisal decisions on synthesis
- What if procedurally poor but conceptually great?
- How to adjust synthesis once paper has made its conceptual contribution?
- Can you conduct sensitivity analyses?

Quality assessment

- Prioritisation of relevance
- Excluding only "fatally flawed" studies



Quality screening questions based on NeLH guidance for qual literature

- 1. Are the aims and objectives clearly stated?
- 2. Is the design clearly specified and appropriate?
- 3. Do the researchers provide a clear account of the process through which the findings were produced?
- 4. Do the researchers display enough data to support their interpretations and conclusions?
- 5. Is the method of analysis appropriate and adequately explicated?

Data extraction

- Very difficult to do formal data extraction across large numbers of qualitative papers
- Not clear exactly what is to be extracted



Synthesising argument

- Integrates evidence from across the studies in the review into a coherent theoretical framework comprises a network of constructs and relationship between them
- Provides more insightful, formalised and generalisable ways of understanding a phenomenon
- Can link **synthetic constructs** and second order constructs already extant in the literature

A CIS of access to healthcare

- Construct of "candidacy" generated through synthesis of the literature
- Describes how people's eligibility for healthcare is determined between themselves and health services
- Continually negotiated property of individuals, subject to multiple influences
- Health services are continually constituting and seeking to define the appropriate objects of medical attention and intervention, while at the same time people are engaged in constituting and defining what they understand to be the appropriate objects of medical attention and intervention. Access represents a dynamic interplay between these simultaneous, iterative and mutually reinforcing processes
- Dixon-Woods et al. Conducting a critical interpretive synthesis of the literature on access to healthcare by vulnerable groups in the UK BMC Medical Research Methodology

The claim to credibility

Alternative accounts of the same evidence might be possible using different authorial voices, but....all accounts should be grounded in the evidence, verifiable and plausible, and that reflexivity will be paramount".

Dixon-Woods, Bonas, Booth et al, 2006

Critical Interpretive Synthesis

- Cannot defend it as an inherently reproducible method of systematic review
- Does produce coherent and illuminating theory of a body of evidence that is based on detailed critical study of that evidence
- Puts "the author" back in
- Is explicit about the authorial voice at work
- Recognises the partial nature of any account of the evidence but is explicit and reflexive about this



CIS

- Full transparency not possible because of intepretive process
- Dynamic, recursive and reflexive
- Requires skill and expertise, use of intuition and tacit knowledge
- Many similarities with traditional literature review



CIS

- CISis not for faint-hearted! Involves creative processes of discernment, judgement, and interpretive skill
- Extremely hard work
- Only suitable for experienced and competent researchers
- Many issues remain to be resolved
- But need to avoid descent into proceduralism

Conclusions

- Conventional systematic reviews are essential, and are the most appropriate way of answering many important questions
- Some kinds of questions may need different approaches
- We need methods of synthesis that reflect the diversity of ways of knowing in primary research
- We are still figuring out what these methods should be, but examples are now emerging

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