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Mixed Methods: A Paradigm for Holistic Evaluation of Health IT

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Abstract. This contribution offers an overview of the 'third research paradigm', its historical roots and its relevance for health informatics. Using illustrative studies, we explore the concepts of triangulation and integration of quantitative and qualitative data and refute common philosophical objections to mixing different types of knowledge. We consider how the mixed method paradigm relates to two programme design and evaluation frameworks that are important for health informatics: realist evaluation and Theory of Change. We discuss how to manage practical challenges to this approach and explain how mixed method studies support an evidence-based approach to real world policy, planning and investment decisions.

Keywords. Evidence-based practice, epistemology, informatics, outcome and process assessment, program evaluation, qualitative evaluation, quantitative evaluation, randomized controlled clinical trials, research design, theoretical effectiveness.

1. Introduction

Given the socio-technical nature of information systems, mixed method designs are widely regarded as essential for their holistic investigation [1]. The research locus for health information systems is a field of complex interaction, opaque mechanisms of action, contested definitions of success, context sensitivity and unpredictable unintended consequences. Hence, evaluating the 'whole picture' in health informatics surely needs a multi-dimensional synthesis [2].

What is the mixed methods paradigm? The *Journal of Mixed Method Research* defines its topic as "research in which the investigator collects and analyzes data, integrates the findings, and draws inferences using both qualitative and quantitative approaches or methods in a single study or program of inquiry" [3]. It also has been characterized as "the use of whatever methodological tools are required to answer the research questions under study" [4], thus differentiating it from solely qualitative or quantitative approaches.

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The objectives of this contribution are to:

- Give a brief overview of the mixed method paradigm, signposting the seminal literature.
- Analyze two example health informatics studies that employed mixed methods.
- Refute three philosophical objections to mixed methods: the 'incompatibility thesis', the 'disguised positivism critique' and the 'holism misapprehension'.
- Explore how the mixed method paradigm relates to two theory-driven programme design and evaluation frameworks: realist evaluation and Theory of Change.
- Consider some practical difficulties in resourcing and executing a mixed method project and reflect upon the impact of mixed method studies on real world policy and planning.

2. Mixed methods: the 'third paradigm'?

2.1 History

Although social researchers have been combining quantitative and qualitative methods in various ways since at least the 19th century [5], the formal concept of a distinct mixed methods research paradigm is contemporary. Mixed methods historians often cite the 1959 proposal for "multiple operationalism" (a validation process correlating independent quantitative variables and methods) [6] as a prototypical development.

The geodetic term 'triangulation' was reportedly first adopted in this sense in 1966, to mean the use of multiple quantitative measurement processes as a means to provide "the most persuasive evidence" about a theoretical proposition [7]. The idea of research triangulation was progressively extended, and by the end of the 1970s had gained a broader usage that included combining *qualitative and quantitative* methods and data [8]. Despite the historical record of methodological eclecticism in actual research practice and the emergence of concepts like triangulation to justify their co-existence, academic debates in the 1970s-80s were characterized as 'paradigm wars' between supposedly irreconcilable philosophies and practices of qualitative and quantitative research [9]. One response to these disputes was the explicit formulation of mixed methods as a 'third paradigm', which emerged from the 1990s onwards as a new methodological movement [4].

The 'third paradigm' quickly bloomed, gaining its own dedicated journal in 2007 [3, 10] and forming an international research association [11]. It has generated a substantial body of literature, with several handbooks and digests of key sources [4, 12, 13]. The "current orthodoxy" now recommends a multi-method approach [14]. However, as we discuss further below, recurrent objections persist to fundamental aspects of this 'movement'.

2.2 Defining characteristics

What differentiates the mixed methods research paradigm? As noted above, an essential mixed methods argument is that the research questions dictate the appropriate techniques: neither interpretivist/constructivist/qualitative nor post-positivist/ quantitative methods are privileged. Mixed methods studies are "interested in both

narrative and numeric data" [4]. The basic rationale for the mixed methods approach is holism [5, 15].

By definition, the aim of holistic research is to get 'the whole picture'. Neither an insightful thick description nor a reductive controlled trial with bounded statistical inferences is, on its own, a complete account. Countable things should be counted with reliability and validity. Unquantifiable things should be studied with authenticity and fidelity. Neither component is inherently superior to the other, though the objectives of a particular study will determine the relative contribution of each. The greater value offered by holism is that 'the whole is greater than the sum of its parts': a synergy between interpretivist/constructivist and post-positivist worldviews and between qualitative and quantitative methods and data.

Despite their association with "vile positivism" [14], randomized controlled trials (RCTs) remain necessary to answer many research questions [16] (particularly about *efficacy* or *effectiveness* – does intervention/system X actually result in outcome Y changing significantly)[2] and to provide data that can be subject to quantitative meta-analysis. Cluster RCTs can be used to evaluate complex interventions [17], where the unit of intervention is ward, practice or some other healthcare organizational entity – typically the unit of deployment for an information system.

Of course, RCTs do not guarantee 'purity of knowledge'. Industry funding and publication bias are known to contribute to conclusions that significantly favour experimental interventions both in primary research and meta-analysis [18][3] and apparently influence published opinion about whether to use systematic reviews in policy-making [19]. These significant criticisms do not invalidate the RCT as a study design, but they do demonstrate the need to incorporate qualitative findings to inform design and interpretation. In practice, many studies aim for this in the 'discussion' section of their published findings. What the mixed methods paradigm proposes is to make this explicit from the conception of the study and through each stage of its execution.

On the other hand, some research questions simply cannot be answered by a solely RCT design – when the objective is *explanation* of real-world phenomena. For example, if the purpose is to determine how aspects of organizational context affect adoption of a system and realization of planned benefits, or why error rates change seasonally in certain care services, it is clear that qualitative methods must be the principal techniques. Nonetheless, the full picture may be enhanced with quantitative data: What are the adoption rates in comparative services? What are the seasonal trends for medication errors? A mixed methods approach defends qualitative evaluation against the criticism of being mere reportage.

How can qualitative and quantitative methods and data be meaningfully combined? Common types of combination are triangulation, integration and dialectic. Mixed methods textbooks illustrate in detail how various kinds of method and data combination have been designed and executed (for instance, chapters 7 and 11 in [4]). These configurations typically use Morse's notation to indicate methodological dominance (capital letters, "QUAN" or "QUAL") and sequence ("→") or concurrence ("+"). For example, "QUAN → Qual" would denote a quantitatively driven project

[2] See also: C.R. Weir, Ensuring the quality of evidence: Using the best design to answer health IT questions, in: E. Ammenwerth, M. Rigby (eds.), Evidence-Based Health Informatics, Stud Health Technol Inform 222, IOS Press, Amsterdam, 2016.

[3] See also: C. Urquhart et al., Systematic reviews and meta-analysis of health IT, in: ibid.

followed by a qualitative study, whereas "QUAL + Quan" would mean a qualitatively driven study that has concurrent qualitative and quantitative components.

Triangulation can be as simple as comparing and contrasting qualitative and quantitative responses in a questionnaire, or between a quantitative RCT and in-depth qualitative interviews or focus groups [15, 20]. *Integration* aims to go beyond 'compare and contrast' to achieve a richer synthesis where qualitative and quantitative methods and data are interdependent and "mutually illuminating" [21].

The *dialectic* stance explicitly recognizes the different 'voices' and worldviews present in the situation under study and welcomes 'divergence and dissonance' so that analytical dialogue can generate new perspectives and insights [22]. Whichever approach is used, the combined analysis can be presented in a narrative, tabular or graphical format [20].

3. Example mixed methods studies in health informatics.

Mixed methods have been used in various health informatics evaluations, addressing topics such as the unintended consequences of computerized physician order-entry (CPOE) [23, 24], use of smartphones for clinical communication [25] and clinician adoption of summary care records [26] and point-of-care systems [27]. In this section we discuss two examples, to illustrate how mixed methods can work in practice.

Wu and colleagues [25] report a mixed method evaluation of using smartphones for team communication in hospital general medicine units. They gathered quantitative data about frequency of smartphone usage (calls and emails) and qualitative data from semi-structured interviews and ethnographic observations. Their analysis presents thematic analysis of the qualitative data and descriptive statistics about the volume and frequency of smartphone usage. The study noted improvements in team efficiency but negative experience in the volume of interruptions and some aspects of professional behaviour (such as inappropriate smartphone usage whilst dealing with a patient). Divergent views were noted about which communicated incidents were genuinely urgent and about inter-professional relationships (with nurses having negative perceptions and doctors reporting positive views). The study integrates some of the statistics with the qualitative analysis; for example, connecting the observations and interview comments about the perceived level of interruptions with the actual usage data. The study draws primarily qualitative conclusions, so can be characterized as a "QUAL + Quan" design.

In [23], Ash and colleagues ("POET" – the Physician Order Entry Team) summarize their four year programme of investigation into the unintended consequences of CPOE. This is a strong example of a flexible, iterative study design that used mixed methods to seek a holistic understanding. Following their earlier work on CPOE success factors, the group developed and piloted qualitative semi-structured interview and observational techniques to explore CPOE unintended consequences at one institution. Then they organized a conference of invited experts to gather additional data and elicit stakeholder advice on the next stage of field work. After the subsequent main phase of qualitative observations and interviews at five sites, POET created a framework of nine types of CPOE unintended consequences. This framework was then used in comparison with results from a short survey instrument to gauge clinician expectations about forthcoming CPOE implementations at three further sites, showing that neither 'average' clinicians nor leaders had a true picture of the likely impact.

POET next developed a telephone survey instrument with both qualitative and quantitative (nominal and Likert scale) content, aimed at all US hospitals using CPOE, followed by a second conference of invited experts to validate the results and plan dissemination of the learning.

The POET research programme was predominantly qualitative, with quantitative data limited to descriptive statistics and correlation analysis in the telephone survey study. The various reports offer a narrative integration of the qualitative and quantitative findings. The overall programme could be described as "QUAL → Quan → Qual". POET explicitly drew upon a mixed methods rapid assessment approach used for public health interventions, and have proposed how this can be used in other clinical information system evaluations [28].

4. Mixed-up thinking? The 'incompatibility thesis' and other stories.

4.1 Epistemological incoherence?

A common argument used against the mixed method paradigm, still raised [5, 29] (and implied in [30, 31]), is that qualitative and quantitative methods and data derive from contrasting philosophical worldviews (a set of beliefs and values giving rise to a particular outlook upon life and reality, typically either interpretivist/constructivist or post-positivist in this context) which are incompatible (or 'incommensurable', as Kuhn characterized successive scientific paradigms [32]). This 'incompatibility thesis' therefore asserts that qualitative and quantitative methods and data cannot meaningfully be combined and to do so would be 'epistemologically incoherent' [33]. This argument is sometimes limited to specific quantitative methods such as RCTs or experimental designs in general. Various descriptors of the allegedly incommensurable ontologies and epistemologies are used. Additional dimensions of incompatibility are sometimes added, such as 'axiology' – beliefs or theories about values.

Numerous authors have discredited this argument [2, 4, 33-35]. The three main grounds of refutation we address are: logical fallacy, pragmatist philosophy and research praxis.

The logical fallacy is exposed by decomposing the incompatibility argument into four steps:

1. Realist and relativist ontologies (and objectivist and constructivist epistemologies, respectively) are fundamentally irreconcilable belief systems.
2. Therefore, knowledge from one belief system cannot meaningfully be integrated with knowledge from the other belief system.
3. Quantitative knowledge is intrinsically bound to a realist ontology and objectivist epistemology. Qualitative knowledge is intrinsically bound to a relativist ontology and constructivist epistemology.
4. Therefore quantitative and qualitative knowledge cannot meaningfully be integrated.

The first two points of the argument are addressed below. The simplest refutation of the fallacy is that the third step of the argument is palpably false. Worldviews are held by people, not by methods and data [36]. The fact that a quantitative (or experimental) method produces a set of numbers does not prescribe how 'real' the referents of those data points are, or what kind of knowledge is claimed by reporting

those numbers. That is down to the interpretation of the results. Equally, the narrative themes of a qualitative study may or may not be 'real', and qualitative knowledge may or may not be reliable and transferable. The debate over 'realist RCTs' (see section 5.1, below) illustrates this point.

Furthermore, pragmatist philosophy suggests that the first two steps of the incompatibility thesis are also false [2]. Pragmatism does not make absolute knowledge claims, but presents only 'warranted assertions'; the values and confidence levels of the 'warrant' are contingent. Pragmatists contend that human knowledge does not have *a priori* foundations: ontology and epistemology are developed empirically and have no privilege over any other data or argument.

Finally, actual research practice demonstrates that qualitative and quantitative methods and data have in fact been successfully integrated in many ways for many years. Clinical practice is a prime example of everyday combination of multiple worldviews (for example, patient, carer, doctor, nurse, medical device or algorithm) and qualitative and quantitative methods and data. To borrow a 'vile positivist' concept, the incompatibility thesis has been empirically falsified.

4.2 Disguised positivism?

It has been charged that the mixed method paradigm is "positivism in drag" [9]. An early form of this criticism was that "Mixed-method designs are direct descendants of classical experimentalism. They presume a methodological hierarchy in which quantitative methods are at the top and qualitative methods are relegated to 'a largely auxiliary role…' …it excludes stakeholders from dialogue and active participation in the research process" [37].

In context, such critique seems not so much about the general mixed method paradigm but more about specific incarnations of mixed method study as defined by certain US research funding agencies. The idea that using mixed methods means excluding stakeholders from dialogue and participation is simply wrong. Nor does mixed methods thinking put experimentalism on a pedestal. However, this observation raises a legitimate question. Is the orthodox 'evidence hierarchy' universally applicable outside the field of medicine? We raise this question again in section 5.

4.3 Spurious holism?

A final philosophical objection is the 'holism misapprehension'. This term is introduced to counterpoint the proposition that "Holism, in any form of inquiry, is neither obtainable nor desirable" [34]. The authors of this quotation were arguing against what we might call 'absolute holism': the unachievable ambition to assess every single aspect of a phenomenon.

Their argument is clearly right in the sense they intended: a map or model is by design only a partial representation and can only be such. However, it is worth reflecting on the more limited (and original) sense of holism that we adduce to justify the mixed methods paradigm. According to the Oxford English Dictionary, the word 'holism' was coined in 1926 as a biological term for 'the tendency in nature to produce wholes from the ordered grouping of unit structures' [38]. This 'wholeness' is what mixed methods evaluation is seeking: a rounded, multi-perspective understanding, not some unattainable definitive completeness. Holism, then, is inherently an idea about organic systems – a direct conceptual resonance with information systems evaluation.

5. Relation of the mixed methods paradigm to theory-driven programme evaluation

The term "programme" is used here to describe a portfolio of interventions that seeks to change individual or group behaviour, or organizational structure and performance, to meet some political, social, commercial or philanthropic aim. Various frameworks have been used to inform the design, development and evaluation of such change programmes.

What programme frameworks have in common is the recognition that changing human and institutional behaviour is highly complex, with multiple interacting contextual factors, so pathways and mechanisms of change need to be unpacked in some detail to understand what is really happening or may happen. Although different terminology is used in each framework, each is trying in some way to produce a 'programme theory': with *these* assumptions, how is it that the desired goals can be achieved in *this* context for *this* programme. This is clearly a relevant approach for health informatics, given that its fundamental *raison d'être* is to change healthcare for the better through improvements in the use of information. In this section, we consider two widely used frameworks: realist evaluation and Theory of Change.

5.1 Realist evaluation

Realist evaluation aims to answer the question 'what works for whom, in what circumstances and in what respects, and how?' [14, 39, 40].[4] Its name derives from its original philosophical roots in Bhaskar's critical realism, a central concept of which is that the objects of investigation are *mechanisms* that can be activated to produce particular *outcome patterns* in certain *contexts*. A mechanism may exist but not be activated, be activated but not observed, or be activated but affected unpredictably by other mechanisms or by the context. Realist evaluation has three principal characteristics: an emphasis on theory and explanation, a multi-method approach and a focus on the context-mechanism-outcome (C-M-O) configuration [14]. The realist hypothesis (of what is happening in the C-M-O pattern) is also called the 'programme theory' (an expression which has other meanings in other frameworks).

The mixed method paradigm and realist evaluation are, broadly speaking, quite consistent. However, there remain echoes of the incompatibility thesis that currently inhibit realist evaluation. Although realist evaluation claims to be 'method neutral', there is disagreement among its advocates whether 'realist RCT' is a meaningful concept [31, 36, 41]. The originators of realist evaluation were highly skeptical of experimental designs for programme evaluation, and contemporary followers remain only 'cautiously supportive of quasi-experimental designs' [31]. They reject the 'realist RCT' and seek to limit application of the term 'realist' to what they endorse as such. The mixed method paradigm suggests a more open choice of methods and does not exclude study designs on philosophical grounds. It is irrelevant that RCTs historically derive from a positivist background with a successionist model of causality. What the RCT results mean is down to interpretation. RCTs control for context, but how they do so is a matter of detailed design; factorial studies or mediation analysis can be used to

[4] See also: T. Otte Trojel et al., Going beyond systematic reviews: Realist and meta-narratives reviews, in: E. Ammenwerth, M. Rigby (eds.), Evidence-Based Health Informatics, Stud Health Technol Inform 222, IOS Press, Amsterdam, 2016.

explore contextual factors rather than 'design them out'. RCT methods may legitimately be used by researchers with positivist, pragmatist or realist worldviews. This more open minded approach has been adopted in the UK Medical Research Council guidance on process evaluation of complex interventions [42].

5.2 Theory of Change

Theory of Change has its roots in international development projects [43]. It is not in fact "a" theory, but an approach or a way of thinking to unpack and articulate "the" Theory of Change for a particular programme. It includes analysis of context (political, organizational, social and environmental), actors (implementers and 'subjects' of the change), assumptions (about the participants or the mechanism or effectiveness of the proposed interventions and indicators) and rationale (evidence or hypothesis that the interventions will work as anticipated). It provides a way of prospectively articulating programme theory in a graphical model with explanatory narrative, based on extensive discussion with stakeholders.

Theory of Change starts from the long-term goals and maps backwards to necessary pre-conditions, causal outcome pathways, interventions, assumptions, rationale and measurable indicators. It is both a process and a product; the product is "a working model against which to test hypotheses and assumptions about what actions will best bring about the intended outcomes" [44]. As such, it offers a framework both for programme design and for evaluating complex interventions [45]. Theory of Change is methodologically neutral and has accommodated both qualitative techniques and studies using randomized controls and other experimental designs [46].

In its present form, Theory of Change has a more prescriptive process than realist evaluation, (though in practice taking various forms and being flexibly applied [43]), but less epistemological baggage. Reportedly, Theory of Change studies in practice often address the 'implementation theory' (how the intervention should be operationalized to meet its objectives) rather than the 'programme theory' (the theoretical causal relationship between the mechanisms of an intervention and the desired behavioral outcomes) [46]. The mixed method paradigm would seem to work quite naturally with the Theory of Change.

6. Practical challenges for mixed method studies

There are several factors that pose practical difficulties in resourcing and executing a mixed method project and may limit the impact of mixed method studies on real world policy and planning. We comment briefly on issues related to funding and resources, the research team, and the relative position of mixed methods studies in systematic reviews.

Perhaps the most obvious constraints are the usual ones – money, people and time. By definition, mixed method studies are trying to do more than mono-method studies and are therefore likely to need more people (with a mix of skills), be more complicated and take longer than a solely qualitative or quantitative evaluation. This raises the issues of affordability, project management, timescale and flexibility of study design. Funders may take some convincing that the benefits of a longer, more expensive and more convoluted project (with some parts likely to be iterative and not fully definable at the proposal stage) are truly justified. This problem might be

addressed by breaking the evaluation into stages and seeking funding for each phase in turn, or finding a scheme to finance preliminary work that may lead to a larger programme (e.g. [47]).

Once a mixed methods project is operational, there may be team working issues [48]. Even if there is no formal incoherence at the methodological level, the ghost of rival epistemologies may haunt interpersonal relationships between specialists from qualitative or quantitative traditions. The tacit knowledge, assumptions and discourse that each individual brings to the team may trigger a culture clash. There are likely to be disagreements not just about the practical logistics of the study but its framing, purpose and priorities. There may, for example, be tension between the 'hard' thinking style of health economists and the 'soft' thinking style of sociologists – or vice versa, or either group may deliberately resist categorization and 'act up' by adopting what they see as the worldview of their 'opponents'. The only solution to this is careful team recruitment that is sensitive to personality types and a management style that cultivates an open minded team dynamic that embraces diversity and consciously tolerates ambiguity.

The consideration of the mixed methods approach as a means to seek holistic knowledge naturally leads to reflection upon the translation of such multi-faceted knowledge into policy formation and programme planning. That in turn suggests reflection on systematic review methods and the hierarchy of evidence. 'Standard' approaches (such as the Cochrane and Campbell Collaborations[5]) have tended to be associated primarily with quantitative methods, with systematic reviews of RCTs at the top of the pyramid (e.g. [49]). Alternative attempts to blend different kinds of evidence have included realist review [39] and meta-narrative synthesis [50][6], with the latter having some echoes of the dialectic approach mentioned in section 2.2 (see also the suggested further reading). Where should mixed method studies fit in the evidence hierarchy? Is not an evaluation that integrates an RCT *and* qualitative data stronger evidence than an RCT alone? Does the evidence pyramid need new layers to grade systematic reviews of mixed method studies? Perhaps health informatics needs its own evidence hierarchy, learning from other disciplines? These are questions to ponder.

7. Conclusions

While the 'paradigm wars' are notionally in the past, there remain some tensions between the instincts and preferences of qualitative and quantitative researchers and the institutional contexts within which they operate. Although the barriers are perhaps less insurmountable than a few decades ago, traditional academic job titles and career paths tend to sustain this contrived methodological and philosophical divide. For example, the labels 'statistician' and 'qualitative researcher' can tend to imply particular backgrounds and contrasting cultural orientations.

The increasing awareness of 'programme theory' in various frameworks is a positive development that supports adoption of the mixed methods paradigm: the

[5] See also: C. Urquhart et al., Systematic reviews and meta-analysis of health IT, in: E. Ammenwerth, M. Rigby (eds.), Evidence-Based Health Informatics, Stud Health Technol Inform 222, IOS Press, Amsterdam, 2016.

[6] See also: T. Otte Trojel et al., Going beyond systematic reviews: Realist and meta-narratives reviews, in: ibid.

mechanisms of change need both to be explained and measured in various ways. Mono-method approaches do not offer the depth and richness that a holistic mixed methods design and evaluation can bring. Government funding agencies, such as the UK Department for International Development, set a powerful example in the expectation that programme applications have a clear Theory of Change (for instance, [51]). As this pattern spreads to other research funders, the case for mixed methods will become correspondingly stronger.

The mixed methods research paradigm is well established and widely adopted, with health informatics perhaps ahead of the general information systems discipline in its use of this paradigm. Practical research questions, not abstract philosophy, must surely take precedence in the selection of methods. Mixed method evaluations are essential for evidence-based health informatics.

Recommended further reading

1. The Campbell Collaboration, *Background*, http://www.campbellcollaboration.org/background/index.php, last access 11 February 2016.
2. Center for Theory of Change, *Publications*, http://www.theoryofchange.org/library/publications, last access 11 February 2016.
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Food for thought

1. How could the mixed method paradigm guide evaluation design in a scenario where there are contradictory stakeholder expectations about the purpose and scope of the study?
2. What types of research questions might suggest a dialectic rather than a synthetic integration of mixed method findings?
3. How might a revised hierarchy of evidence for health informatics be constructed?

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