Qualitative Research in Healthcare

MODERN METHODS, CLEAR TRANSLATION

A WHITE PAPER

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Qualitative Research in Healthcare — Modern Methods, Clear Translation: A White Paper

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List of Abbreviations

BNIM	Biographic Narrative Interpretive Method
CAQDAS	Computer-Assisted Qualitative Data Analysis Software
EBM	Evidence-Based Medicine
FRAM	Functional Resonance Analysis Method
GP	General Practitioner
HCAC	Health Care Accreditation Council
HREC	Human Research Ethics Committee
ICU	Intensive Care Unit
IPDAS	International Patient Decision Aids Standards
IRBs	Institutional Review Boards
LS	Lynch Syndrome
MDT	Multidisciplinary Team
MND	Motor Neurone Disease
NGT	Nominal Group Technique
NHMRC	National Health and Medical Research Committee
ONT	National Transplant Organization
PDCA	Plan-Do-Check-Act
PTSD	Post Traumatic Stress Disorder
Qual	Qualitative
Quant	Quantitative
RCT	Randomised Control Trial
SQUIRE	Standards for Quality Improvement Reporting Excellence
TCRN	Translational Cancer Research Network
TDF	Theoretical Domains Framework
TRN	Translational Research Network
UK	United Kingdom
WAD	Work-As-Done
WAI	Work-As-Imagined

Glossary

Autobiography (also known as *biography* or *personal testimony*): Individual recollections of personal views and experiences, recounted by the individual or by one person on behalf of another person.

Co-design: a process whereby researchers join together or are joined by research stakeholders (including patients and members of the public) to produce a piece of work which is generated by, and representative of, the relevant stakeholders' experiences and needs.

Complex adaptive system: A system that comprises of a number of individual entities that are interconnected such that a change in one entity influences other entities (e.g., primary health care team).

Confirmability: A study's findings are clearly representative of the participants' views, rather than the researchers' preferences.

Credibility: How accurately a study's findings are reported, and whether reporting is congruent with information participants have provided said. Credibility also refers to whether the representation of multiple participant perspectives is reflected appropriately and considered trustworthy (i.e., genuine, reliable and authoritative).

Data sources: Data that are accessed from different places, such as website, the academic literature, the grey literature, hospitals, national health portals, government data repositories.

Dependability: Whether a study's findings could be achieved, and the working methods repeated, if another researcher conducted the same study.

Epistemic: ("relating to knowledge itself"), which differs from *Epistemology*, ("relating to the study or theory of various aspects of knowledge"), an epistemic understanding defines the kind of knowledge that is available to, or needed by, the researcher to place them within a given topic area (their epistemic position).

Ethnographic poetic representation (also known as, but not exhaustively so: *poetic rendition, poetics* and *poetic transcription*): A way of re-presenting qualitative data in poetic form for wide audience interest. This can include the co-creation, by a group of researchers, of meaning from narrative texts in highly reduced rhyming or non-rhyming formats.

Fidelity: Interventions or studies that are delivered as intended (e.g., implementation fidelity).

Focus groups: Groups of research participants interacting together in a group forum to answer questions.

Group interviews: Interviews that are designed to ensure small group-work activities so that the most 'vulnerable' populations are encouraged to feel more confident in speaking out (e.g., children, the disenfranchised, asylum seekers).

Human Research Ethics Committees: Committees that are responsible for reviewing and approving research study proposals before any research is conducted.

Implementation science: The study of strategies to translate effective study outputs into optimised treatment and care initiatives, to influence people's behaviour, policy initiatives or service delivery models. Uptake can be through the application, assessment and spread of new knowledge or through embedding a clinical intervention in real-time practice.

Inter-method approach: Using more than one method across methodological paradigms (e.g., surveys and group interviews)

Intra-method approach: Using more than one method within the same methodological paradigm (e.g., one-on-one interviews and focus groups).

Inter-textual examination: How texts respond to, refer to, transform and are transformed by other data (e.g., other texts, visual data, autobiographies, etc.), and how the range of representations are configured.

Investigator triangulation (also known as *analyst triangulation*): A method of working with data that involves using multiple researchers who independently analyse, and then compare and contrast, data, data analysis techniques and data findings.

Member-checking (also known as *respondent validation*): Involving research participants, at later stages in a study (once the analysis process is underway, or after it is completed), checking research findings and ensuring that findings are in keeping with their own experiences or the ideas they portrayed.

Method triangulation: A form of triangulation that involves the use of a variety of methods for data collection, such as surveys, interviews, focus groups, and observations, where methods are compared and contrasted to one another as an integral element of the study.

Mixed methods research: The collection of both qualitative and quantitative data within a single project or program of work. This is followed by analysis and synthesis of different types of data to ensure an integrative approach (often called method triangulation) throughout the whole of a research study.

Multimethod research: The collection of both qualitative and quantitative data, with each type of data analysed separately and not in an integrated fashion.

Open-ended interviews: Minimal questioning by a researcher and limited researcher intervention in the interview process. Maximum input and direction from the interviewee. These are particularly powerful at eliciting unprompted interviewee responses.

Open-ended proformas: Written qualitative questionnaires, with a brief set of questions (approximately four to six) with each question followed by a gap for respondents to answer questions in their own style. Open-ended proformas are often incorporated into a study design to support other data capture methods.

Peer review: The inclusion of more than one researcher's opinion at various stages of a study, to ensure consistency and seek agreement on, for example, data findings.

Qualitative research: Focuses on describing social construction, cultural change, and individual experiences. Interpretation of qualitative data findings are grounded in personal and group understanding and expressed through text and language.

Quantitative research: Characterised by measurable hypotheses where there is a relationship between cause and effect quantitative research generally aims to produce standardised outcomes through numeric measurement.

Research translation: Identification of applications of study outputs in clinical practice and other situations, and an indication as to how outputs may change patient experience, healthcare practice and/or policy.

Rigour: The quality of the research, and the ability of the researcher and others to evaluate that quality. Rigorous data can often lead to replicability within other studies with the expectation of generating similar results.

Semi-structured interviews: Including questions that conform to an interview schedule with scope for expansion (through interviewer prompts).

Schema analysis: A novel qualitative data analysis method perfected for use in health services research contexts (by the lead author and other members of this team), that examines succinct, narrative, schematic presentations of qualitative data.

Stakeholders: Those with an interest in the design, process, methods and outcomes of a healthcare research project, either with a personal interest (such as a patient or carer), a professional interest (such as a clinician or health researcher), or a financial interest (such as a funding body, policy developer, or healthcare organisation).

Structured interviews: Where the same pre-established set of questions are posed on each occasion. Structured interviews can be undertaken by any researcher using the same set of questions, or by a group of researchers.

Summative analysis: A group technique that is wholly dependent on a collective commitment to, and ongoing involvement with, stories and storytelling. Summative analysis is a qualitative

data analysis technique that was designed (by the lead author) to grapple with particularly complex, difficult, emotive or sensitive texts.

Taxonomic framework: A way of grouping data ready for analysis according to specific component requirements, for example a 'visual taxonomy of objects' may include the type of object, the way objects are grouped, and their relationship to one another.

Theoretical triangulation: A form of data comparison that involves the use of different theoretical perspectives to analyse the same dataset. This can also involve different theoretical frameworks from varying intellectual disciplines or traditions.

Transferability: The possibility that a qualitative study's data findings or theoretical precepts are transferable to other contexts, settings or populations.

Trustworthiness: The assessment of the quality and worth of a study. Trustworthiness helps to determine how closely a study's findings reflect a study's aims and objectives and is derived from the data provided by participants, reactions to study findings, and responses to study reporting and study outputs.

"Seriously ill people are wounded not just in body but in voice. They need to become storytellers in order to recover the voices that illness and its treatment often takes away. The voice speaks the mind and expresses the spirit, but it is also a physical organ of the body. The mystery of illness stories is their expression of the body: in the silences between words, the tissues speak ... Sooner or later, everyone is a wounded storyteller".

Arthur W. Frank, The Wounded Storyteller, 1995

Executive Summary

This White Paper aims to shine a light on how qualitative methods are being used in health services and medical research contexts, and how they might be used more effectively. It aims to fire the reader's imagination by revealing the scope of qualitative methods across a range of studies, and the impact of qualitative methods on research outcomes and healthcare practices. In this monograph you will learn about current methods in use, and how they are making a difference to healthcare practice. These include some lesser-known biographical and photographic methods. You will also learn about the way in which research results are being implemented to improve patient safety and the quality of care.

At the same time, we examine some of the more challenging and controversial aspects of applying qualitative methods in healthcare contexts, in the hope of raising awareness of some of the ethical issues with which qualitative researchers grapple. These include how to ensure findings are trustworthy and reliable, and how to encourage outcomes that are transferable across contexts, ready for upscaling. By so doing, we want to present the argument that qualitative methods can broach not only aspects of more routine clinical care, but also lesser-known healthcare practices.

This monograph is set out according to the following five Parts and a snapshot of its contents is presented as a word cloud at the end of this Executive Summary.

Part I Getting Started;

Part II Modern Methods;

Part III Applications with Named Examples;

Part IV Clear Translation;

Part V The Future.

Part I begins with the presentation of a range of qualitative methods, indicating their variety and scope. Some, such as interviews and focus groups, you will have heard about before, and perhaps used in your own research. Others you may know less about, such as the visualisation of data. We discuss methods and methodologies in detail, to give you a firm

understanding of the basic tools in the hands of the health services researcher, but then move on to the ethical implications of these methods in use. We describe, for example the ethical conduct of the health services researcher, including how to recruit participants, how to get ethical approval for a study, and how to report study findings.

In Part II we describe creative pathways to asking and answering research questions. Included in this is a conversation about a range of modern approaches to data collection, such as the co-joining of biography and photography, approaches to data analysis, such as the use of workgroups and schemas, and to data presentations, such as the inclusion of poetry in academic publications.

In Part III we provide research examples from our own studies. We show you how we worked with these studies and how decisions were made, both in teams and individually, to answer complex, intriguing or difficult questions that draw on patient-centred decision tools, social networks and networking, and models for supporting healthcare systems or services. At this stage we argue for the strength of doing mixed methods research, which can help bring data together effectively. Mixed methods also lend themselves to specific aspects of patient-centred care, such as shared decision-making, clear communication with patients, and medical team-working.

The final two parts of the White Paper, Part IV and Part V, concentrate on the implementation of research outputs and translation of findings to real-life medical and healthcare settings, and we discuss the future of qualitative methods in health services research. In Part IV specifically, we consider system-wide questions for the successful implementation of research outputs. We also examine the implications of using qualitative methods for improving healthcare systems. In Part V specifically, we examine the future of qualitative methods in health services and medical research, exploring a very recent development that is at the cutting edge of qualitative methods-use, that of the 'mobile method'. This we are calling the 'Fourth Research Paradigm', and we describe how mobile methods are capturing more nuanced data, as healthcare practitioners move through wards and across settings with researchers. Using mobile methods enables researchers to observe ways in which individuals adapt their practices to suit the ever-changing world of healthcare delivery. This helps them to understand not only the world of healthcare delivery but also the world of the patient with whom professionals come into contact as they 'travel'.

Within this White Paper you will find contemporary evidence from the research literature that highlights rigorously grounded and theoretically-driven studies. The White Paper also offers details of research studies that have led to extensive improvements in health service delivery in recent years, and more effective, system-wide approaches to care. Some of these have used *'intra-methods'* approaches which refer to the combination of a group of qualitative methods to gain a greater understanding of a topic from a range of angles. Others have used qualitative and quantitative methods in combination, also referred to as *'inter-methods'*, with qualitative methods as only one part of a study's activities. Whether inter- or intra-methods, these can help us to understand, for example, an individual practitioner's role within a healthcare system, a group of practitioners' multidisciplinary team responsibilities; describing both notions of team effectiveness and individual, empathic attention to detail.

We have used this monograph to assess current and past examples of our own and others' research studies. We consider the literature and our own work from both inter- and intra-methods perspectives, including the views of doctors, allied healthcare professionals, service-users, patients' families, and members of the public. We describe how qualitative methods, used rigorously, can reveal success stories and forewarn about problems. In effect, this helps characterise healthcare – how it is rendered, the ways in which it works, places where it falls short, and what people think and do when they are giving, receiving, or researching care. We present valid, credible, insightful information which helps reveal, *inter alia:* healthcare environments in flux; professionals contending with complex technological devices; managers struggling with unwieldy models of care, and patients unsure about the choice of treatment pathway to take. We discuss methods that attend to complex questions. For example: how healthcare systems can manage an ever-growing demand for service improvement in the face of economic variability and uncertainty; how technological proficiency can influence workforce efficiency; and how we can create management systems that are fit for purpose. And while we emphasise the need for increased resilience in healthcare systems, we also identify ways of enabling this. We have collectively learned over many years of study that what works best for one person does not necessarily work best for another, and we live in a world where even the most resilient of systems can leave professionals struggling to keep up with change. This is particularly evident in the face of an aging, multi-morbid patient population, and ubiquitous and unrelenting pressures on systems of care due to many factors including resource constraints and the sheer complexities of the caring enterprise.

We think that there is something in here for everyone – whether you are a healthcare professional or a policy developer. Whether you are from the media or are a manager. Whether you are interested in acute care, general practice, aged care, or care provided in community settings. Whether you see yourself as a researcher or a stakeholder, someone overseeing the delivery of care or someone at the receiving end of care; we believe this monograph will be relevant for you. We have aimed, in the writing, to bring you swiftly up-to-date with the latest in qualitative research in healthcare – to show you a world of discovery and a route to improvement.

We write as an interdisciplinary team of academics and researchers, spanning psychological, clinical, sociological, bio-medical and social science backgrounds. We have worked collaboratively to introduce you to the *bigger picture* of the health services research field without missing out on *minutiae of detail.* We have tried to counterbalance descriptions of adaptive healthcare systems with descriptions of intimate personal interactions, so that we can take you on a journey – all the way from 'bench to bedside'.

We want to challenge you to consider the issues we have raised, and in response stimulate new questions from you in response. But we also want you to know what is currently holding our attention, such as: how we can improve the quality and safety of clinical standards of care; how we can map the journey that different types of patients make as they manoeuvre through the complexities of the healthcare system; how we can make evidence count; and how we can overcome methodological inconsistency to make our studies more rigorous with clearer outcomes, in order to improve the lives of patients and their families.

This monograph covers a wide range of qualitative methods and topic areas which you can read in combination or dip in and out of it, selectively. Many of the sections stand on their own merit while others have been written and cross-referenced to relate to other sections. Whichever way you choose to read this, we would love to hear back from you. What do you think, for example, about the relationship between research development and the implementation of study outputs? How can qualitative research studies help you with your own research or healthcare delivery? What is the next big idea; the next best solution? Let us know about your own work with new treatments and therapies. What is your experience, as a patient, of being what Arthur Frank called in his quote at the start of this executive summary a "wounded storyteller"? What are you doing to improve care-quality? What new policies will you be

formulating to help streamline care? Are you managing to spend enough time with your patients? What 'sticky' research questions do you have? Our intention in writing this has been to offer you the space to reflect on your views not only hear about our own and in reading this, we hope you will be able to find a way to use these versatile methods in your own research proposals, be they implementable or visionary, practical or ethereal, they all count.

Figure 1. A word cloud providing a visual representation of the highest frequency words in this White Paper

Note: Words that are used most frequently appear larger.

Source: Generated using Word Art(1)

The plan of the White Paper

Part I
Getting Started

Part II
Modern Methods

Part III
Applications
with Named
Examples

Part IV
Clear Translation

Part V
The Future
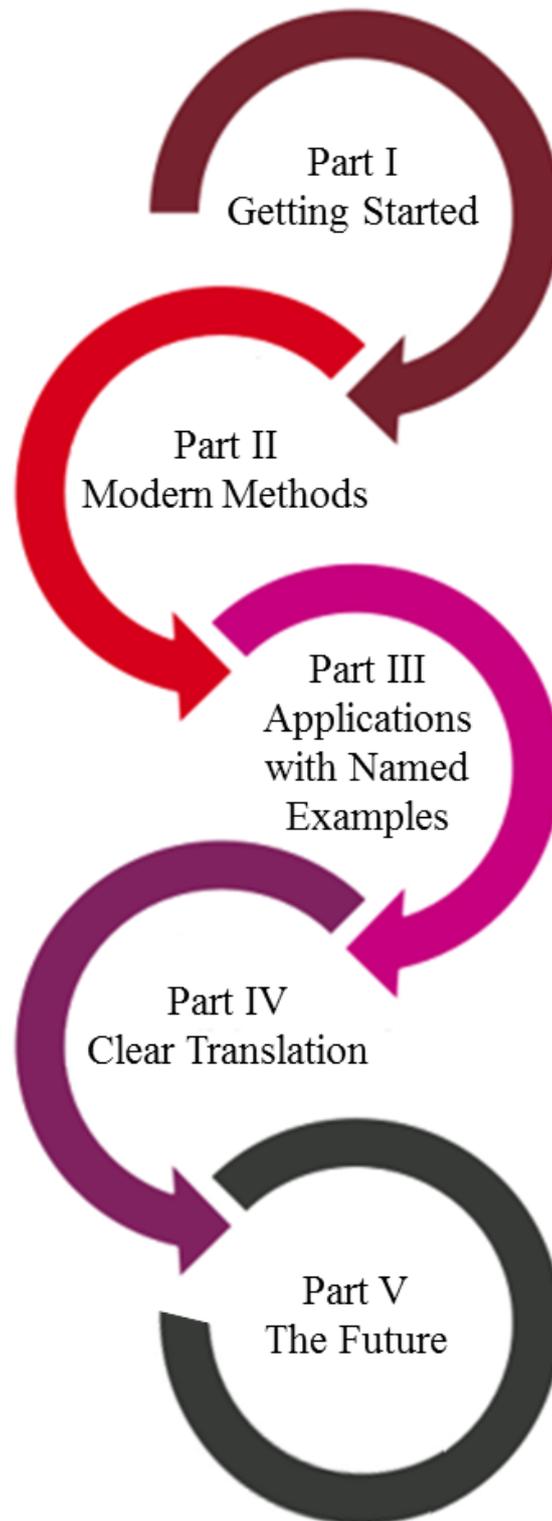
"Health is by no means the 'natural' state of human beings even if it is the preferred one … The World Health Organization's definition of health as unimpaired mental, physical and social well-being is little more than a dream to most of the human race".

Richard Gwyn, Communicating Health and Illness, 2002

PART I – Getting Started: Aspirations for Qualitative Research in Healthcare

We live in a world that is forever changing, a world of moving parts. As our lives unfold not only are we affected by this, but so too are others around us with whom we share environments and lifestyles. As adjustments occur, we look for ways to reassess the world we share. For the qualitative health researcher, this means peering deeply into the world of the healthcare professional and the patient. We derive meanings from our observations by examining how people make sense of the connections they have with others. We construct ways of mapping, coding and deciphering others' actions and behaviours. We scrutinise healthcare systems and the social behaviour of the healthcare workforce. We classify patients' illness trajectories and define their care pathways. Even in a world of specialist language, we strive to create a common language that we can all share. We appeal to ever-wider audiences to recognise and appreciate our academic achievements, and in turn our audiences, hungry for more knowledge, appeal to us to make sense of, and bring order to, the changing world of healthcare delivery.

While qualitative researchers attend to the demands of others, they are forever looking for opportunities to systemise, simplify and slow down the ever-shifting world of 'process and practice', for their own benefit. They go beneath the surface of superficiality to expose how the world manifests itself and operates, by describing behaviours, practices, motivations, attitudes and values, rather than describing statistical means, modes and medians, standard deviations, t-tests and p-values. Qualitative researchers try to understand real-world activities rather than abstract numbers, and they seek to ask questions about the world of the subject rather than to statistically test hypotheses.

Qualitative researchers try to rationalise the obscure, for if things appear opaque they are less likely to be understood. Transparency is important, to dispense with uncertainty, create sustainability and benefit healthcare services. Indeed, qualitative researchers must not only recognise the research areas that need attention, but once recognised, must work hard to answer pressing research questions. They work collaboratively to not only attempt to tame the 'noise' of raw data, but also to create intelligible sound.

Research costs money, and in the current global financial climate, funds are often hard to come by. And once funded, research questions must be quickly resolved. As a consequence, rather than search for the most appropriate way of asking and answering a research question, researchers often use the most familiar approach, presenting solutions in bite-sized, easily-digestible chunks. Researchers also return to past evidence to side-step new theory, rushing headlong into outputs, often at the expense of methodological rigour. Whilst long-term impact remains a healthcare agenda priority, researchers forget to 'top and tail' their current studies with preliminary investigations and post-study evaluations. Preparation is hard to get funded, while 'the right' approach is rarely debated. Studies become end points rather than beginnings and endings. Yet without adequate preparation, and attention to the journey, arriving at a well thought-through outcome is difficult to achieve.

In this White Paper, we attempt to ensure a balanced approach to the qualitative health researcher's task. To do so we return to basics and take you through the whole research process, from beginning to end. To clarify the discipline's strong foundations, we unpack methodological presumptions and presuppositions. To tease out suitable methods, we rationalise what is a successful research outcome. We discuss a range of qualitative methods that particularly lend themselves to strong theoretical underpinnings, and we examine opportunities for their integration into mixed-method study designs. We assess the relationship between qualitative, quantitative and mixed-methods propositions (see Figure 2, Table 1 and Figure 3) and we welcome the subjective with all its nuances. We consider uniquely different methodologies, including textual, numerical, auditory, technological and visual, and we discuss those methodologies that search for variability and those that propose causality (see Figure 3). We present examples of studies that favour standardisation, and others that visualise an ever-changing human condition. We indicate approaches to the controlled experiment, and others that search for generalisable responses to research questions. Qualifying the power of the personal, we examine some of its tensions – such as clinicians' demands for their own autonomy, and patients' pleas for negotiated care. To begin, then, we examine the differences between qualitative, quantitative and mixed-methods approaches to health services research, before offering a guide to some of the more commonly used qualitative methods.

Figure 2. Characteristics of qualitative and quantitative methods

Source: Lavoie(2)

Table 1. Characteristics of Qualitative, Quantitative, and Mixed Methods

	Qualitative methods	Quantitative methods	Mixed methods
Stance	Looks for meaningful relationships between people's behaviours, actions and interactions – subjective reality	Looks for relationships between cause and effect – objective reality	Looks for a balanced understanding of subjective and objective reality – human intentions and causal relationships
Meaning	Meaning is grounded in raw data derived from, or leading to, greater theoretical insights	Meaning is grounded in measurable hypotheses tested to improve theory	Meaning is derived from both raw data and measurable hypotheses that are examined for the validity and limits of the knowledge gained
Approach	Single or inter-method approach (qualitative data)	Single or inter-method approach (quantitative data)	Multiple-methods or intra-method approach (qual and quant data collected together,

			either in parallel or sequentially)
Explanation	Explanation through interpretation based on in-depth descriptive data	Explanation through causal analysis based on invariant laws	Explanation through interpretation, descriptive and causal factors relating to events and behaviours
Interest – individual	An interest in the human condition and multiple truths	An interest in facts, scientific investigation and 'the truth'	An interest in the relationships between human factors and scientific evidence to create a composite truth
Interest – collective	An interest in socially constructed meanings and human interactions	An interest in controlled events, observational statements, verification and prediction	An interest in social meaning and observational statement that neither qual nor quant methods alone can ensure (data triangulation and complementarity)

Sources: Rapport(3)

A user guide to different qualitative methods

A rich variety of qualitative methods are available to the qualitative health researcher. These range from textual to visual methods, methods *in-situ* and methods that can be conducted 'on the hoof', methods that are simple, and methods that are complex. Some researchers use oral testimony and some use historical documents. Depending on how researchers see the world (Figure 3) some privilege group activity and some, an individual's lived experience. Some take an insider, *emic* perspective; others take an outsider, *etic* perspective. Some report on categories of behaviour and some an overarching representation of their subjects' lives.

Qualitative health researchers use the spoken word, written texts and observations (summarised in Table 2) and while we cannot describe all approaches to data collection, we have picked out a few that have particular relevance to our own research or to the research that we cite.

Figure 3. How do you see the world?
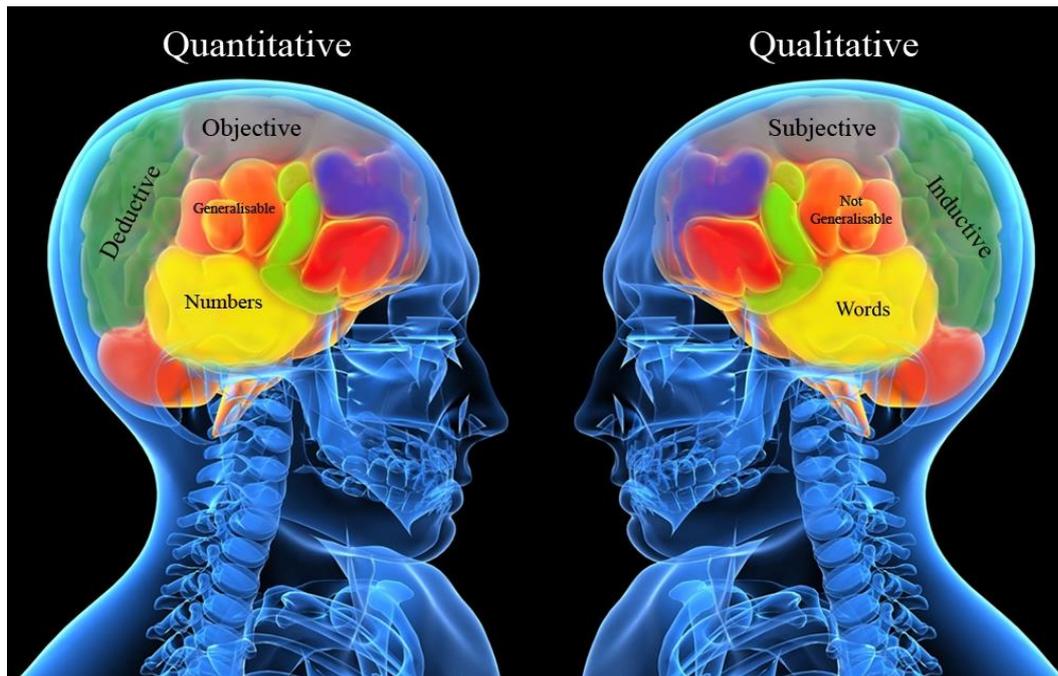
Source: Pombriant(4)

Table 2. Exemplar of qualitative methods in use

Methods	Qualities	Researcher's role in data capture
Structured interviews or semi-structured interviews	Face-to-face or telephone questioning, open-ended (few questions) semi-structured or structured (interview schedule)	Researcher takes responsibility for facilitation of data capture and prepares question format
Open-ended interviews	Face-to-face interviews, built on the basis of researcher-researched trust and respect, often delving into life-stories, or health-trajectories, recalled in great detail	Researcher as bystander and data recorder. Few pre-prepared questions asked
Focus groups	Group dynamics, peer-interaction, observer and facilitator present, semi-structured question schedule	Researcher facilitates and leads the direction of group debate, observer presence
Biography and autobiography	In-depth personal accounts, biographical or autobiographical in nature, intended for story-telling. Written or spoken	No (or little) involvement. Researcher acts solely as data collector or passive recipient

Visual methods	Still and moving images (e.g. still photograph, video) or visual representation (e.g. map, chart, diagram, drawing)	Researcher as collector of data or passive recipient (if data are collected by study participants)
Open-ended proformas	Free-flow answers to a set, limited and specific set of questions. Frequently accompanies other datasets to corroborate and validate findings	No role in data capture, researcher prepares questions and collates data
Realist Tales	Authorial presence, foregrounded as subject-orientated truth, individualistic	No role in data capture. Few pre-prepared questions asked
Observations	Observations *in-situ*. Often in-depth. Different times of day or night, week or weekend	Direct observation, participatory or non-participatory, recorded, notated or recalled
Mobile methods	Data captured 'on the move' with subjects as they interact with others or with space, to examine, for example, 'work as done' or 'memories of space and time'	Direct observation, participatory or non-participatory, recorded, notated or recalled
Written testimonial	Examination of dramatic, difficult, complex or extraordinary events told from single or multiple perspectives. Often relating to past events	No researcher intervention/researcher as witness
Oral history	Spoken word. Verbal recollection, method derived from 'historicity of knowledge'	No researcher intervention/researcher as witness

Source: Authors' own work

The spoken word: Interview-based methods

A range of interview types can be deployed, and these vary in terms of how much the researcher directs questioning, sits opposite an interviewee or conducts an interview via non-face-to-face techniques, and how many participants are involved (see Table 2 and Illustration 1). Interview types include: structured, semi-structured, open-ended, video or telephone, group and focus group interviews. Each has its own unique qualities and characteristics.

Illustration 1. Face-to-face interviews: up close and personal

Source: Youth Ambassador(5)

Structured interviews

Are those where the same pre-established questions are posed on each occasion. Questions are ordered according to a pre-defined format. More than one researcher can be trained to ask questions, and more than one interview can take place at any one time. This allows a team of researchers to reach a wide populous. Interviewers are trained to follow a strict routine, to repeat questions in the same way, and to ensure that cases are similar. Structured interviews can be spoken or written. Written answers are returned to researchers electronically, in person or by post. Qualitative opportunities exist for a limited amount of additional data to be added at the end, or at any time during an interview, for further points of reference to be acquired, but this is rare in structured interview situations. Structured interviews are most commonly analysed according to a standardised analysis template, derived so that people's answers clearly match the interview questions posed, examined in chronological order.

Semi-structured interviews

Combine the conformity of a structured interview and the lack of conformity of an open-ended interview. Semi-structured interviews include questions that comply with an interview schedule and questions that offer scope for expansion. They are facilitated by a researcher who asks the questions but prompts the interviewee to expand on their answers. Semi-structured interviews can be analysed in a variety of ways, including: thematically, contextually, or

through framework or summative analysis (see Part II for details of different analytic approaches).

Open-ended interviews

Are particularly powerful for eliciting unprompted responses. They involve minimal questioning and limited researcher intervention. Questions come at the beginning of a response, to enable recipients to lead the way from thereon in. They are typically conducted face-to-face (see Illustration 1) and designed to elicit free-flowing, personalised responses to self-directed topics. There are no limitations to the style or range of response and due to their unstructured form, they can be analysed in a variety of ways. However, the Biographic Narrative Interpretive Method (BNIM)(6) is often favoured, which investigates data for what they reveal about the: "historical, psycho-social and biographical dynamics of people's lives".(7(p34)) Incorporating three interrelated facets, BNIM uses: biographical history, the way a story is presented, and its social interpretation.

Video or telephone interviews

Are useful for dispersed and hard-to-reach populations. They reduce the problems associated with direct researcher interaction, by ensuring participants feel empowered to speak freely. They are particularly useful when interviewing busy healthcare professionals and patients who are at work during the daytime, or for subjects at a distance. Video-linked or telephone interviews, by their very nature, are commonly semi-structured or structured, so that answers to questions can be easily recorded, and interviews can be brief. Telephone interviews, due to their brevity, are also useful for national and international studies with large cohorts. Video interviews via video conferencing apps such as Zoom© or Skype© have the added advantage over telephone of the visual connection. Analysis can take the form of a content analysis, often supported by a computer software package such as NVivo (NVivo 11, QSR International Pty Ltd)(8, 9) or Ethnograph(10, 11) to handle large amounts of data, search for codes, and reveal frequency of responses and thematic presentations.

Group interviews

Are designed to ensure small group-work activities with vulnerable populations (such as children, the disenfranchised and the elderly). They are based on the principles of

empowerment and peer-group support. They set out to place interviewer and interviewee on an equal footing, with a less formal interview style than other interview types. The layout of the interview space is designed to put interviewees at ease (for example having everyone sitting at a round table). Group interviews combine aspects of both structured and semi-structured interviews. Questions are posed to all interviewees, while the respondents' comfort is paramount. Group interviews are recorded and frequently analysed using similar techniques to focus groups, such as schematic framework analysis, which supports multiple recipient responses (see page 87, for 'Schema analysis').

Focus groups

Depend on groups of attendees (usually sharing something in common though they may not know one another), interacting through group dynamic situations, to answer questions. Optimally, groups of six to eight participants are involved (see Illustration 2). Information is gathered by a lead researcher who facilitates a focus group session, working according to a semi-structured interview schedule, while keeping strictly to a pre-defined time period. It is usually the role of the facilitator to manage, but not lead, the conversation, and to ensure that all attendees are fully involved. Focus group data are commonly recorded, with an observer present, who discreetly takes notes and observes group interaction and non-verbal cues. Recordings are transcribed, and transcripts summarised using for example, schema analysis, which enables a cross-comparison of group data (see page 87, for 'Schema analysis').

Illustration 2. The dynamics of focus groups

Source: OnePlus(12)

Writing as a form of data collection

Autobiography, biography and personal testimony

Provide individual recollections of deep-seated views, recounted by an individual, a group, or a carer on behalf of a patient or significant other. Personal writing can help a researcher to explore a difficult, complex or emotive topic, and can reveal intimate details of testimonials. The researcher can take on the role not only of reader or 'listener' but also of 'witness' or 'scribe'. In this situation, whether data are in the form of a written document (a personal testimony) or an oral record, the researcher's witnessing of the account gives it added meaning (see Figure 4). Autobiography and personal testimony can stand as a finished product (see Reznikoff)(13) or can be re-presented creatively using a range of representational techniques, such as ethnographic poetic rendition (see page 77) or summative re-presentation (see page 82).

Figure 4. Autobiographical and biographical writing
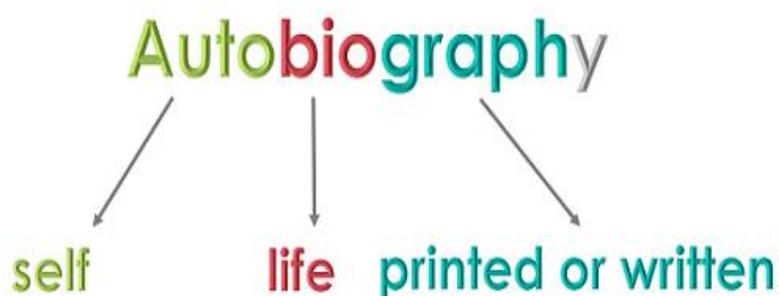
Source: Literary terms(14)

Open-ended proformas

Open-ended proformas usually support other data capture methods. Taking the form of written free-flowing questionnaires, they contain a brief set of questions (typically, approximately four to six), with each question followed by a space for responses (Illustration 3). Open-ended proformas are designed to examine issues from single or mixed datasets. They are useful when a discrepancy has arisen, and they can add crucial details to an already existing dataset, to enrich understanding. They serve the purpose of enabling qualitative researchers to return to a group of study participants for 'member-checking' (see page 38, for 'Member-checking')(15) and they can allow participants to include more detail about their thoughts on

any given topic. Frequently, open-ended proformas are accompanied by a stamped-addressed return envelope, to ease the process of data handling, or are sent electronically (e.g., through email). Once returned, data are analysed thematically or examined for critical pointers to important content and context in other datasets.

Illustration 3. Open-ended proformas in question and answer format

Source: National Business Research Institute(16)

Visualisation as data collection

Include the still and the moving image, drawings and paintings, and visual documents such as maps, diagrams and charts (Illustration 4 and Illustration 5). They orientate the researcher to everyday practices in healthcare settings, clarify understanding, indicate humans approach to socialisation, and provide rich detail of personal gestures, expressions and behaviours. Visual methods can be combined or used separately, and once data are collected, imagery can be analysed using visual techniques derived from anthropological and sociological sources, which have been purposefully adapted to suit a healthcare context. These methods include the use of computerised software packages such as computer-assisted qualitative data analysis software (CAQDAS)(17) or ATLAS,(18) and visual taxonomic frameworks (see for example Rapport et al.).(19-21)

Illustration 4. The power of the visual

Source: Shelley(22)

Illustration 5. Visual methods: help researchers to show and tell what they have discovered about the participants' experiences

Source: Warren and Reid(23)

Observations

Fall into two broad camps: participatory and non-participatory (Figure 5). The latter is most commonly known as 'observation'. Each type corresponds to the degree to which the researcher is actively involved in what is being observed, largely dependent on the relationship between researcher, research question and the observed. Information is collected covertly or overtly depending on whether discreet activity is necessary. Observations can be conducted at different times of the day and night to encourage naturalistic behaviour. Notes are made in a

research diary and conversations can be audio-recorded. The degree to which data collection is visible and the style of data collection depends on: a) the degree to which accurate verbatim quotations are required, and b) how much the researcher wishes to remain covert. Observations can take place across healthcare settings to examine, for example: clinical consultation, ward rounds, operations, and emergency procedures. Journal entries are analysed ethnographically,(24) to understand what was said, how it was said, the context and culture surrounding what took place, and how objects and people are situated in space and time.

Figure 5. Participant and Non-Participant Observation
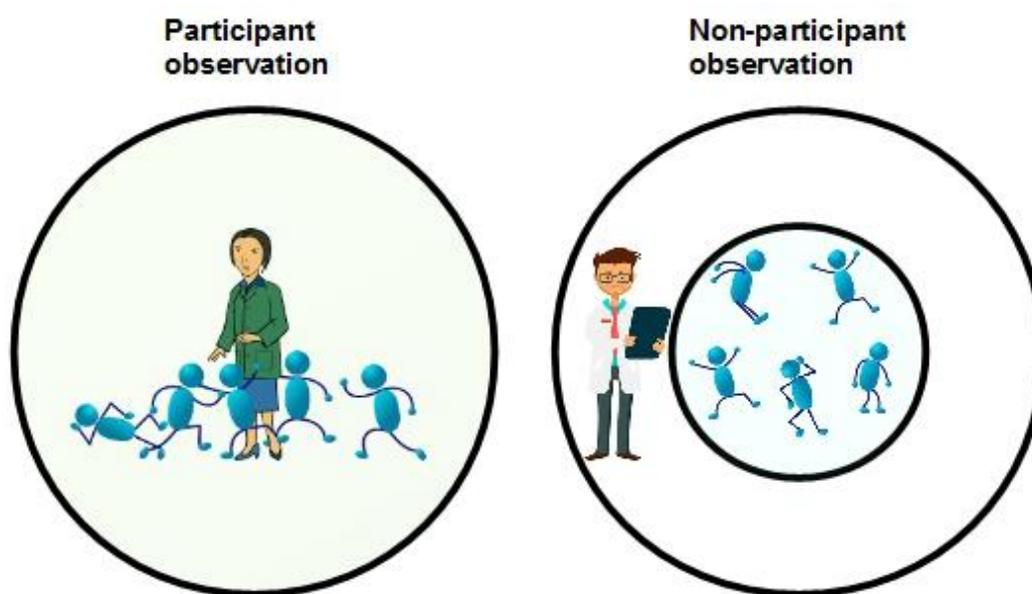
Source: Williams(25)

Strengths of using qualitative methods in health services research

Qualitative methods can be seen to have both strengths and weaknesses. In this section we concentrate on their strengths, namely the ability to derive depth over breadth of understanding, and the opportunities of qualitative sampling. We dispel some of the more commonly-held myths and beliefs about the 'softness' of qualitative data, and the challenges of using small samples.

Depth over breadth of understanding

Qualitative methods delve deeply into behaviours, attitudes, beliefs, feelings, practices, and circumstances of people. Qualitative methods help reveal the minutiae of detail in data and add nuance to understanding, in accordance with the complexities of human behaviour. Qualitative methods do so by examining people's perceptions, interactions, actions and reactions in visual and textual terms. In-depth data mining can disclose examples of people's health status, the settings in which they work and live, and the effect of cultural norms on quality of life, cultural belonging and estrangement. Data mining can also reveal unique individual perceptions of, amongst other things: healthcare delivery, organisational procedure, illness journey and views on health and wellbeing. In-depth data mining supports the clarification of meaning above and beyond an initial surface impression. What is not at first apparent, can be elicited using rich and "thick" description, a term that refers to the anthropological notion of data being linked to culture or community contexts.(26)

However, gathering and mining data can take time (which accounts to some extent for the predominance of small samples in qualitative studies) and depth over breadth is favoured. Data first need to be accessed, and then analysed, to create an analytic framework or template. These frameworks often have to be agreed upon by others (especially if more than one researcher is involved in the analysis process), and revisions and reworking the framework can be a complex process. Researchers need to work together to do this, to create team understanding and to agree on what a turn of phrase or a sentence might mean to the group as a whole. Views are expanded upon with the support of quotations or images, sourced directly from the raw data.

If handled appropriately, analytic frameworks and team-working practices can lead to powerful realisations of what data holds, such as embodied illness experience or habituated practice. In addition, taking the necessary time to work through qualitative data can offer unique insights that quantitative methods simply cannot derive from more surface understandings, and assessment of, for example, cross-population statistical modelling.

Opportunities of qualitative sampling

Qualitative samples continue to come in for a lot of criticism; as Gobo aptly notes: "sampling in qualitative research has had a hard time".(27(p435)) Qualitative researchers are often assailed for producing samples that lack representativeness and are non-probabilistic, while too small a sample is said to lead to results devoid of credibility. Critics of non-random samples, opportunistic samples, purposive samples and snowball samples,(27) argue that they lack statistical power and lead to findings that are meaningless without extrapolation to wider populations. This line of thinking has tended to denounce qualitative data for its lack of generalisability. Without generalisability, it is said, there can be no validity, and without validity, no opportunity to apply findings to other settings.(28) Thus, data is considered unreliable. Much of this criticism rests on misunderstandings or lack of knowledge. We would like to offer a rebuttal to this position through six points.

1. Qualitative researchers have always welcomed variance and the insights that variance affords: a unique opportunity to explore a phenomenon in great detail. Social research does not aim to control conditions where social phenomenological observations take place. Indeed, social researchers refute the possibility of controlling for social conditions. This leads to a deep-seated understanding of a phenomenon in all of its complexity; that can be both qualified and nuanced.

2. Smaller samples reap the benefits of more extensive and in-depth data examination, leading to a greater level of understanding, including not only what data share but also what they do not share, the outliers that are the exception to the rule. No-one is actually an average—this is merely a statistical convenience.

3. Qualitative samples can lead to unexpected disclosures, unplanned situations that are, nevertheless, extremely valuable. They have inbuilt flexibility, to manage, for example, a sudden change in a healthcare professional's behaviour or views, or the tensions born out of attempting to preserve the status quo in service delivery. They can explain these sudden changes or tensions and what results (see for example Shih et al.).(29, 30)

4. Qualitative samples are able to achieve theoretical legitimacy and social significance, rather than generalisability and "statistical logic"(27(p436)) Theoretical legitimacy helps qualitative researchers answer complex questions by ensuring that theory is derived from data using inductive rather than deductive methods.(31) For this to happen, there must be a 'reciprocal relationship' between sampling methods, sample

sizes, data mining and theory development, premised on the need for theoretical rigour rather than causal explanation. Theoretical sampling leads to emergent hypotheses, created through small samples of similar cases, which once created, can be tested for confirmation or refutation.(32)

5. Small samples lend themselves to group-working activity. Here, qualitative analysts are equally responsible for the data, and aim for 'consensus-agreement' on key issues arising. Group-work supports a search for data's commonality and difference, and highlights discrepancies in group thinking. It reveals patterns in the data and indicates both what people say they do, and what they actually do. Group-work also helps to confirm whether findings are valid, reliable and trustworthy representations of raw data. Small samples help ease data handling and ensure a group of analysts can cohere to provide evidence of what is effective and what needs redressing. The level of collaboration needed to achieve this is simply impossible with large datasets, where data uniformity is paramount.

6. Finally, small sample sizes apply a subjective prism to sense-making. Thus, subjectivity adds a 'positive bias' to researchers' understanding.

Qualitative design: Planning and preparation; implementation and monitoring; evaluating; reporting and translation

The rigour, trustworthiness, feasibility and fidelity of a qualitative research project (as will be discussed later in Part 1) is dependent on the study design. Good design allows research questions to be answered in the best way possible, within the limitations of available resources. A good match between the research question, data collection methods and analysis techniques are the foundation of qualitative research in that it is *representative* of the population group being studied and is both *credible* and *authentic*.

Based on our experiences in health services research, we outline a process for designing a qualitative study (Figure 6). This process is conducted in four stages: planning and preparation; implementation and monitoring; evaluating; and reporting, and, where indicated, translation. We provide key questions for those undertaking research to consider as their studies are being designed. Where appropriate, examples are cross-referenced with other methods and other studies that are described in the following sections of this monograph.

Figure 6. A process for designing a qualitative study
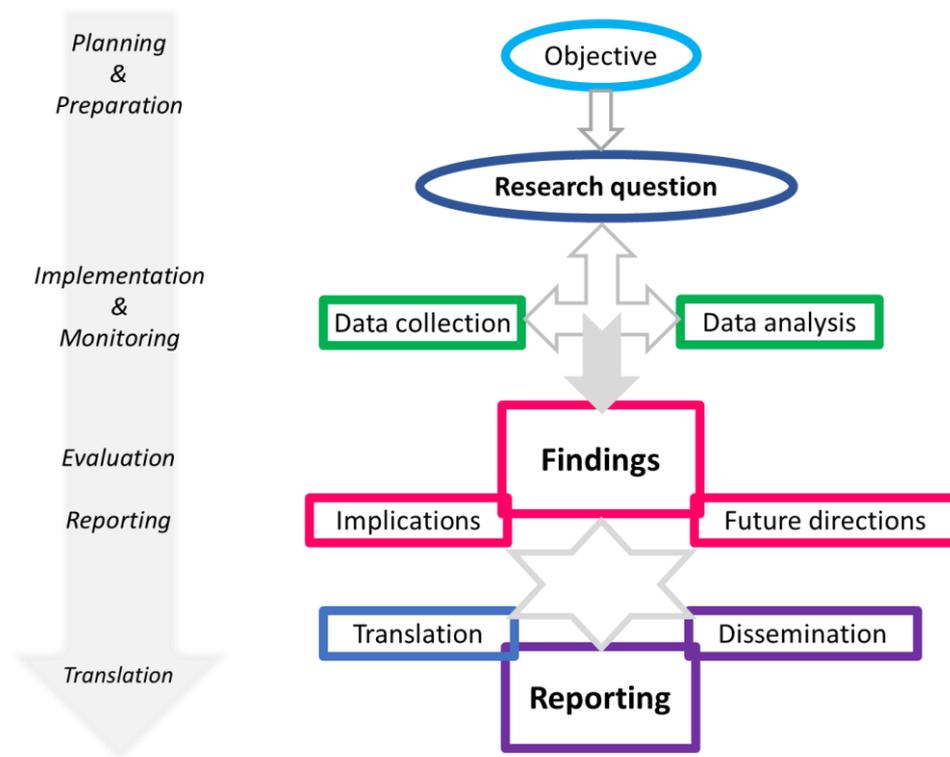
Source: Authors' own work

1. Planning and preparation

The planning and preparation phase of a qualitative study is often the most time-consuming part of the project, and until it is complete, the study cannot progress to the implementation or translation phase. Effective and rigorous research requires good planning, and study designs are strengthened when all known or anticipated aspects of the study are prepared for well in advance. Many elements of a study that occur at the end of a project, such as reporting and publishing results, can to be planned at the start of the study, to ensure enough time and funding is left to execute them appropriately. Furthermore, consumers and key stakeholders should, ideally, be involved from the very beginning of the study, to contribute to the conceptualisation and planning of the design, and ultimately, to promote translation of research findings into practice. The views and experiences of patients (also known as 'consumers') are invaluable to the development of a study, to ensure the study's relevance to the target population, and that the methods used are aligned to the ethos of the consumer group. Additionally, reporting of outcomes should be considered during the planning phases, so that reports can be prepared in advance of deadlines, and publications and presentations can promote awareness of the study.

Qualitative research questions

Qualitative research questions differ significantly from those used in quantitative studies. Qualitative questions are formulated to explore issues in depth or to lead, at the end of a study, to the writing of a hypothesis statement. Qualitative questions ask the 'how' and the 'why' of an issue, and require more than just a 'yes or 'no' answer in response.(33) Even so, the research question should be clearly stated to reflect the study aims and objectives. Research questions are often phrased as primary and secondary concerns, to allow scope for sub-questions to tease out aspects of secondary importance. Examples of how qualitative research questions are posed, is indicated in Table 3.

Table 3. Examples of qualitative research aims, objectives and questions

Research topic	Study aims/objectives	Research questions
The effect of risk classifications on women with breast cancer **Rapport et al.(34)** *(multi-method qualitative study)*	A. To identify how risk is defined by women, at various stages of investigation, diagnosis, treatment, and care for breast cancer, leading up to remission. B. To describe the different journeys women take along the care continuum, and their own expressions of need and experience as they move through the healthcare system toward better health. C. To disclose the views of a wide range of female patients, from those undergoing genetic investigation for risk of breast cancer to those undergoing post-breast cancer treatment.	RQ1.How do women who are undergoing genetic investigation for cancer risk, and those who are undergoing post-cancer treatment define risk? RQ2: What theoretical insights can be added from a social constructivist perspective of the way women journeyed across the continuum of care?
Aged care accreditation **Hogden et al.(35)** *(focus groups study)*	To understand the views of experienced residential aged care staff on developments in Australian residential aged care over the past decade.	RQ1. What factors have influenced the quality of residential aged care? RQ2. What has been the role and influence of the aged care

		accreditation programme on service quality?
Leadership in complex networks **Long et al.(36)** *(mixed methods study)*	To identify how mandated leaders of a translational research network (TRN) use their network position to influence collaborative processes within the TRN.	RQ1. Do the formal, mandated leaders of this TRN hold key positions of centrality or brokerage in the informal social network of collaborative ties? *(quant)* RQ2. If so, do they recognise the leadership opportunities that their network positions afford them? *(qual)* RQ3. What activities associated with these key roles of centrality and brokerage do they believe will maximise the TRN's success and do these activities accord with Gray's leadership model? *(qual)*
Patient journeys amongst melanoma patients **Lamprell, Chin and Braithwaite (37)** *(observational study)*	To shadow the trajectory of patients with melanoma, from first diagnosis to remission or death.	RQ1. What is the nature of the journey of people with advanced melanoma? RQ2. What are these patients' personal narratives? RQ3. How can we contribute to understanding by employing the universal Western storytelling convention of the sequence in which there is a progression of time and place *(qual)*?
Better evidence for earlier assessment and surgical intervention for refractory epilepsy **Rapport et al.(38)**	To examine the factors contributing to the delay of assessment and treatment for resective surgery candidates living with refractory epilepsy, and the effect delay has on patients' lives.	RQ1: What are refractory epilepsy patients' perceptions and experiences of clinical services and practices, including surgical assessment procedures? RQ2: What are the effects of delays in surgical assessment and

(mixed methods study)	surgical intervention on the health and wellbeing of patients?
Shih et al.(39) *(mixed methods study)*	RQ3: Which health system issues, such as resource use, play a part in any delays in surgical intervention?
Mitchell et al.(40) *(quantitative study)*	

Source: Authors' own work

Once the research questions are tightly defined, the study can be designed to address those questions. The next consideration is then *how* should the research questions be answered? In other words, which data collection methods, tools and resources are available to the study team, and how can they be used, to answer the research questions? It may be helpful to think about this in terms of the following queries:

- What kinds of data are needed and what methods allow the researcher or team to derive that data? (see Table 2 for types of qualitative methods in use).
- Should the research team use observational research, an intervention, or both?(41)
- What is the best way to obtain in-depth data with the identified participant group and setting? (see page 2, 'Getting started').
- Does the study need quantitative data to supplement qualitative data? For example, are the researchers after a standardised measure that can assess health status or quality of life, alongside health experience? (see page 46, for 'Mixed methods design').
- Are data collection and analysis tools (such as interview schedules and analytic frameworks) readily available, or is there a need to develop a tool specifically for the study (see examples of analytic techniques: page 82 for 'Summative analysis' and page 87 for 'Schema analysis')? If so, should there be a pilot study of the data collection and analysis tools prior to starting the study so that the tools are fit for purpose?(41)

Resources

Once data collection tools are determined, seasoned researchers take advantage of other resources that are available to conduct the research. These can include things such as funds, data-gathering tools, theoretical frameworks and equipment. Other resources centre on the *people* involved; project staff, experts, colleagues and mentors, or staff providing backfill for clinician researchers. And importantly, especially in multiple agency projects, research partners and stakeholders may act as an invaluable study resource, undertaking roles of key informant, gatekeeper or project facilitator.(42)

Participants, consumers and stakeholders

Qualitative research centres on understanding people and their relationships. A strong qualitative design can enrich this understanding by incorporating the 'people resource' in multiple ways while roles of study participants, consumers and stakeholders can be separated out, or can overlap, to promote an integrated view of the research topic.

The largest group is usually the study participant group. Careful thought is needed to determine *who* the participants should be, what their characteristics are, and how many will be needed. When planning recruitment, it is important that participants represent the population who are central, interested or relational in some way to the issues being investigated. To strengthen their representation, consideration should be given to involving representatives of the participant group in research planning and study design, as consumer representatives.(43) Having consumer representatives review interview schedules, for example, can ensure that key questions are not excluded, and can guide the study team in the most effective ways of recruiting participants.

Stakeholders are those who have an interest in the outcomes of the research, either a personal interest (such as patients and caregivers), a professional interest (such as clinicians, policymakers, media representatives and healthcare researchers), or a financial interest (such as funding bodies and health organisations). Involving stakeholders as research partners, research participants, or both, can benefit a study by boosting the representation of the study population, giving people more ownership over the data being produced, and enabling multiple perspectives to be considered in relation to the issues under investigation.

The number of participants available for research is influenced by a range of factors, including: recruitment strategies, the duration of a project and the size of a research team and setting. Even so, determining a sample size for qualitative research differs markedly from determining a sample size for quantitative studies (see page 35, for 'Rigour' and page 42, for 'Trustworthiness'). Power calculations are less relevant in this context and the number of participants is determined by the number needed (or available) to answer the research question rather than the need to seek representativeness in people's answers to study questions. For qualitative researchers, saturation is more important than large sample sizes.

For some questions, samples can be very small. Examples of where very small samples are adequate include single case studies,(33) phenomenological studies, and single-site studies, such as Rapport et al.(44) and Shih et al.'s work(39) where data from observations and interviews, with small numbers of participants can lead to recommendations for improving service delivery. Lamprell and colleagues' study, shadowing melanoma patients, enrolled nine participants who had been diagnosed with this life-threatening disease; two died, and thus seven were shadowed for six months, until treatment or the study ended.(37, 45)

For other research questions, much larger and more complex datasets may be required. The methods used to generate these datasets, and the logistics and timeframes for conducting these studies, can vary considerably. Greenfield et al.,(46) for example, undertook multiple methods of data collection with 197 participants to comprehensively gather stakeholder opinion on the development and implementation of new national hospital accreditation standards. As national representation was required to address the research aims, data were gathered through documentary analysis of eight government reports, 25 hours of observations and 34 interviews, over several months. In another large study that used a single method (group-based interviews), Greenfield et al.(47) investigated views of 258 participants on the evolution of health service accreditation programs. Again, national representation of stakeholders was required, and this was achieved by members of the research team travelling across Australia to meet with participants to enable them to take part. This variety, of methods, participants and timeframes, is evidence of the flexibility that qualitative methods bring to answering research questions.

Study setting(s)

The choice of setting or settings is frequently predetermined by research partnerships, funding agreements or the pragmatic considerations of a study in keeping with timeframes and milestones; however, that is not always the case, and researchers may be at liberty to make those decisions based on their considerations of the research questions, population distribution and population diversity. Whatever the case, many decisions about the setting need to be made. For example, w*here* will the research take place – at a single site, or at multiple sites? Will data collection be conducted in the participants' workplace or home, or will participants be asked to meet with researchers elsewhere? Will study participants be followed in their natural setting, and observed as they behave and interact *in situ*? The researcher's relationship to the setting will influence how ethical approval is sought, the choice of recruitment strategy, and the resources required. Further questions need consideration, such as *how familiar* the researcher is with the setting? Consider whether familiarity will influence data collection. Moreover, support from those within the setting, i.e. those who are not necessarily participants, but who can facilitate access to participants and provide time and space to enable data collection to take place, is important. Those with responsibility for the setting (often construed as 'gatekeepers'), may include: health service managers and administrators. *When* will the research take place? Will it involve a single visit to a study site or sites, or a period during which a number of visits will take place, demanding a longer time-interval? Will data collection occur within normal working hours, or after hours, such as in a hospital, overnight? *How convenient* is the timing of data collection to the work patterns of the participants? By answering these questions, the details of data collection can be clearly documented for approval from ethics and governance committees and other relevant bodies.

Documentation and approvals

Ethics and governance approvals for qualitative studies are often more complex in comparison to ethics and governance approvals for quantitative studies, as qualitative research involves investigations where research subjects interact personally with a researcher or researchers, answering searching questions directly about their health and wellbeing. All-too-often qualitative research involves intimate questions about people's lives and health status. In addition, in qualitative studies, researchers often need to enter into the study participant's domain. Emotions can be raised, and qualitative studies are examined to ensure that when this is the case, no undue harm befalls the research subjects or researchers. However, research

involving human subjects cannot commence until approval has been obtained from a relevant Human Research Ethics Committee (HREC) and consequently, it is essential that the qualitative research team think through potential challenges and adverse consequences before ethics applications are completed and submitted. The 'Ethical considerations and the trustworthiness of data' section below provides more detailed information (see page 29).

While documentation will vary according to HREC requirements, including the requirements of ethics, governance and funding bodies, qualitative research approvals will require that the study methods are recorded extensively in a formal protocol document. The protocol is the step-by-step guide as to how the study will be conducted, expected working patterns, researcher involvement and expected study outcomes. While it is not normally the case that a qualitative protocol is recorded in a trials registry, protocols can be made to serve a dual purpose – to inform ethics or governance bodies of study methods and timeline, and to advertise research plans to the wider academic community. The protocol can be formatted into a journal publication format, to be a published output from the study (see page 27, for 'Reporting').

As with all research, legal and funding agreements between parties to the research may be necessary. These should be factored into planning and preparatory timelines, alongside checks for researchers working in healthcare settings, including police checks, immunisations, 'research passports' and additional scrutiny of those working with children or vulnerable groups, honorary appointments to healthcare organisations, and security clearances.

2. Implementation and monitoring

The implementation phase of a study is the active phase that takes place as data are collected, reviewed and analysed. Throughout implementation, a monitoring loop is conducted to ensure problems can be resolved in a timely manner, as issues with data collection arise. Monitoring also helps a study to stay on track, by allowing regular adjustments and amendments to data collection, as needed. This can include monitoring the reliability, trustworthiness and generalisability of the collected data (see page 29, for 'Ethical considerations and the trustworthiness of data'), to see if changes are required to the type of data being gathered, or the way data are being collected. For example, a planned focus group

may have to be rescheduled to a series of individual interviews, due to participant time constraints. If participant numbers are lower than expected, recruitment of more participants may need to take place, to enrich the quality of the data, or an extension of the data collection sites may be necessary. Conversely, if data has reached saturation point, where no new information is being added to answer the research question or questions, data collection may cease earlier than anticipated. The implications of any adjustments made during data collection should be thought through, in particular if amendments to ethics approval, funding agreements or project timelines are required.

Data analysis

Some important initial considerations for the qualitative health researcher, where data analysis is concerned, are: is the researcher able to make sense out of the data? Is the analysis method or methods appropriate for the type of data that has been collected; and, will data analysis allow the researcher to comprehensively answer the research question? This is covered in more detail in Part II of this monograph, where we define and describe a range of qualitative analysis methods.

3. Evaluation

While evaluation is not always a requirement of a study design, evaluation of a project involves the review and appraisal of all study components. That is to say, not just the findings and outcomes of the study, but also the methods used, and processes involved in the conduct of the study. The results of the evaluation then feed into the reporting mechanism. It may be helpful to evaluate a study using the following guide (Table 4).

Table 4. Evaluation of study outcomes and processes

Findings and outcomes	Methods and processes
What has been learned from this study? Have the study objectives been met?	What are the strengths and limitations of the study methods used?
How can findings add to the research literature, by: • Confirming what is already known?	How could the methods be improved? • Change of study design • Recruitment methods

• Extending or adding to what is known? • Contradicting what is known?	• Data collection methods and strategies • Timing of study • Location of study • Analysis methods
What are the consequences, implications and applications of your findings? How could your findings change clinical practice or policy?	How will knowledge translation occur?

Source: Authors' own work

4. Reporting

How (and where) should a study best be reported, and what (and how) does a researcher tell others about a study? Who needs to know about the findings and why does it matter to report the findings widely? These are just some of the questions that frequently arise as researchers try to decide on how and where to report their study findings. Research is frequently reported for three distinct (but sometimes overlapping) purposes – and each should be anticipated early in the study design phase:

- The first purpose is to feedback to the funders or organisations supporting a study. This may include research partners and ethics committees. Each constituency's requirements will be different, including how much is reported, and when it is reported. Knowing the requirements and timeframes in the planning and preparation phases of a study will reduce last-minute reporting anxiety.

- The second purpose is to inform the research community – local, national or international. Academic reporting of a study can occur at the beginning and end of the work. As already mentioned in the 'Planning and preparation' section above, this can take the form of a published study protocol, which is a useful way to alert the research community of plans for the work, and to establish researcher interest in the field. The revised Standards for QUality Improvement Reporting Excellence (SQUIRE) provide a comprehensive guide to reporting new knowledge (see http://www.squire-statement.org/ for more information). Examples of our own published protocols for qualitative studies, give ideas about style and content of protocol papers, and include

studies in the field of risk communication,(44) decision tool development(48) and cochlear implantation.(49) Examples of style and content of mixed method study protocols include studies of surgery outcomes(50) and surgical innovation.(51) Furthermore, a study can be reported to interested colleagues through conference presentations and knowledge translation seminars.

- The third purpose of reporting is to feedback findings to study participants and stakeholders, to let them know what they have helped to achieve, and how their contribution has influenced the work and in effect the healthcare field. This can take the form of a project summary, distributed on a project website, or sent directly to participants and stakeholders, patient and public forums, papers for general consumption and wide patient-professional workshops.

Research translation

Following on from disseminating study findings is the conceptualisation and activation of a research translation plan – identifying how study findings can be applied in clinical practice, and how they can change healthcare policy and people's lives. Research translation for healthcare settings is a widely-covered (and debated) field, and the implications for qualitative research are discussed in detail in Part IV of this monograph. For foundational concepts of research translation and implementation, please refer to Rapport et al.'s 2017 publication on Implementation Science and translational effects.(52)

The research cycle: Planning future research

Research is a cyclical activity (see Figure 7). The findings of each study add to our understanding of clinical and healthcare problems, but they also make us aware of more questions that need to be answered and more challenges that need to be addressed in answering them. These may include new problems identified that now require investigation, how a researcher can build upon what was found in the study in the next piece of research; and the next important question for research partners to consider.

Figure 7. The research cycle

Source: Authors' own work

Ethical considerations and the trustworthiness of data

"All human interaction, including the interaction involved in human research, has ethical dimensions. However, 'ethical conduct' is more than simply doing the right thing. It involves acting in the right spirit, out of an abiding respect and concern for one's fellow creatures. This National Statement on 'ethical conduct in human research' is therefore oriented to something more fundamental than ethical 'do's' and 'don'ts' – namely, an ethos that should permeate the way those engaged in human research approach all that they do in their research".(53(p3))

What is ethics in the health research context?

Human health research and its outcomes, whether it involves people or data about people, can have far-reaching implications for the community at large. Although qualitative health research may seem to be classically low risk, depending on the topic, there is a chance that research participants or researchers will come to harm, whether intentional or unintentionally, or that people will feel more anxious or at greater risk as a result of the research work. It is fundamental, therefore, that participants are protected, as much as is possible, from being

harmed or exploited during a research study, by following comprehensive ethical guidelines. This includes maintaining participants' right to confidentiality during the whole research process including the reporting of research study findings.

Ensuring all ethical research considerations are in place before the start of a research study is the responsibility of all the researchers who are planning to work with study participants. Human Research Ethics Committees (HRECs) that can go by other names such as Institutional Review Boards (IRBs) are responsible for reviewing and approving research proposals before any research is conducted. All research that involves humans is required to undergo ethical review by an HREC, and in Australia, must abide by the National Statement on Ethical Conduct in Human Research,(53) included in the National Health and Medical Research Committee (NHMRC) guidelines. The Australian Health Ethics Committee advises the NHMRC, by developing ethical guidelines to underpin the work of both health researchers and HRECs. Researchers must complete an ethics application supplied by and sent to, their relevant, local HREC. All research-active environments will have similar statements, guidelines and ethics application forms to those developed by the Australian HRECs.

Research ethics in practice

Human Research Ethics Committees

HRECs are the gatekeepers for health research projects that involve humans. They are widely supported by the NHMRC, which has commented that:

"*Ethical review by an HREC is required for any research that involves more than low risk*"(53(p23)) and: "*The expression 'low risk research' describes research in which the only foreseeable risk is one of discomfort*".(53(p13))

HRECs exist to uphold the highest standards of research conduct, and as a consequence, represent the best principles of working practice for the benefit of study participants, organisations where research takes place, and researchers. They assess which research is ethically appropriate and acceptable, and what might constitute risk and harm. HRECs review research ethics applications from across all research institutions of learning, considering: the methods proposed; data storage, management and handling plans; data reporting approaches;

and participant recruitment. They ensure there is no participant coercion during the recruitment period, determine the acceptability of the risks and benefits of the research for the participants, researchers and the wider community, and assess whether any potential risk is justified, in relation to the benefits of the research. They examine risk assessment planning, and judge what plans are in place to minimise or manage risk effectively should risk occur. This includes appropriate monitoring of repercussions following the effects of risk, should harm occur to participants or researchers, or affect organisations and sites.

Other key concepts assessed include: maintaining data confidentiality for the benefit of participants and describing how participant anonymity will be enabled. They examine informed consent and if this can be obtained from participants voluntarily and without coercion, and scrutinise plans for dissemination of study results, including publication and presentation of study findings. HRECs will review ethics applications thoroughly, across all these aspects, and advise researchers on any required amendments before research can begin. Often, if research is being conducted at multiple sites, ethical approval will be applied for through one main HREC but will still need to be approved by HRECs in other sites. These may be university HRECs, individual hospital HRECs, or local health district HRECs. Public health organisations are required to assess individual research projects, in terms of whether they have the capacity to engage in the research, and whether they are appropriate projects to be involved in, as an organisation. These site-specific assessments are often reviewed in parallel with ethics applications and are attended to by each organisation's research governance officer.

Ethics and recruitment

HRECs examine research projects for their proposed methods of participant recruitment to ensure they are being conducted in accordance with ethical guidelines. There are many methods of recruitment available, such as contacting relevant organisations to promote a study through their newsletters, or through online social media, and other forms of promotion to the community. Recruitment methods will influence the sample size and type of participants enrolled in a study, and it is important that recruitment methods are not only clearly thought-through, but also designed in such a way as to minimise, as far as possible, participant coercion. For example, it is important that patients do not feel obliged to enrol in a study being conducted by their healthcare professional for fear that if they refuse their care will be affected. Participation in research should be voluntary and fully informed.

Minimising risk of harm or discomfort to participants

Qualitative research has the potential to raise emotive issues for participants. "*Qualitative research that explores sensitive topics in depth may involve emotional and other risks to both participant and researcher. There should be clear protocols for dealing with distress that might be experienced by participants*".(53(p26))

Unlike interventionist clinical research, where invasive procedures may be undertaken which physically impact research participants, qualitative research typically involves no direct physical risk of harm. Even so, qualitative research may introduce psychological distress or harm. For example, if participants are requested to discuss difficult times in their lives or divulge information that they are uncomfortable to talk about, there may be emotional consequences for them. In addition, if participants are asked to recall harrowing experiences they have undergone during their treatments, it can raise anxiety about future treatments or unexpected harm, and can lead to a host of other concerns.(54)

Given this context, researchers are obliged to: 1) ensure they minimise any foreseeable risk of harm to participants, 2) put in place safeguards to ensure ongoing research does not lead to participant harm, and 3) remain vigilant about upholding ethical standards throughout a study. HRECs will assess research risk, and whether the level of potential risk is justifiable, before they approve a research study, and will assess how researchers plan to deal with participant harm and risk should a study have a harmful effect on participants. Researchers are also required to report any such harmful events to the HREC, for them to consider the continuation or termination of the research. Having support services available – for example, health professionals able to assist participants with their distress – is an important aspect of research planning. Likewise, a strategy for reporting adverse events to relevant study leaders and the responsible HREC is an important safeguard for participants. Being well-prepared in this respect lends itself to upholding the integrity of the work and sustaining participants' confidence in the study, while ensuring participant wellbeing is appropriately managed.

Maintaining data confidentiality

Maintaining data confidentiality is another important aspect underpinning qualitative research ethics' considerations. This is especially necessary when working with sensitive information that may reflect a study participant's personal views and experiences. Most

commonly (although not exclusively) in health services research, individual participants agree to engage with research projects on the premise that the information they provide will be anonymous, and that they will not be identified. When working with small populations, it is important to keep confidentiality in mind when discussing participants' views and experiences, as individuals may be more easily identifiable, based on several key characteristics, such as their location, age, gender, occupation and illness type. For example, by identifying the location of data collection, such as a specific hospital clinic, and identifying participants by age and illness type, they may be identifiable to people working at the clinic. Names of places where data are being collected should also be anonymised. In these circumstances, it is sufficient to offer a broad description of the type of institution involved when reporting study results. By maintaining and upholding participant and institutional confidentiality, researchers protect each individual's right to privacy and autonomy.(55)

Obtaining informed consent

According to the National Statement on Ethical Conduct in Human Research,(53(p16)) participants must be fully informed of what a study requires of them, before providing consent to participate:

"Respect for human beings involves giving due scope to people's capacity to make their own decisions. In the research context, this normally requires that participation be the result of a choice made by participants – commonly known as 'the requirement for consent'. This requirement has the following conditions: consent should be a voluntary choice, and should be based on sufficient information and adequate understanding of both the proposed research and the implications of participation in it".

An information pack should be provided with the consent form, so that participants are aware of not only what the study entails, but also what the study is addressing and hopes to achieve. They need to understand any potential risks and benefits of the research, not only those that might affect them directly, but also those that might affect the wider community or disease-specific group that they represent, and they need information about the services that will be available to them in case an adverse event occurs, or they suffer any form of harm as a result of the study. Participants need to understand the purpose of the research, how data will be collected and analysed, which processes will occur during the study, and how their data will be

used, as well as what will be done with the research findings afterwards (i.e., they may be part of a presentation at a conference or written up for an academic journal article). By providing participants with this information, they will be able to make an informed and voluntary decision as to whether to participate. Participants must be able to withdraw from research should they chose to do so, without any consequences to their health or ongoing healthcare, and without affecting their communication with health professionals or others. It is important that participants understand that their involvement is completely voluntary and that they aren't being coerced into participating. If research involves populations who are unable to give informed consent, i.e. children, or vulnerable adults with intellectual disability, consent on their behalf must be obtained from a fully-informed caregiver acting as legal guardian.

It is also important to provide contact details of researchers, so that participants can ask questions about the research, and know who is involved. Any financial declarations or conflicts of interest should be stated in the participant information sheet (this provides all participants with information on the purpose of the study, what participants would involve, the planned use of the data, and ethical considerations) and consent form. In addition, participants should be provided with information about how their data will be used, and whether it will be confidential and anonymised, as well as their right to withdraw from the study. Furthermore, participants' literacy must be taken into consideration when obtaining informed consent, and it is best practice to provide information in clear, plain language, so that people know what they are agreeing to. Verbal consent is an alternative to written consent, where the researcher reads the consent agreement to the participant, and the participant verbally agrees to the details contained. However, ideally this type of consent should be audio-recorded, for record-keeping purposes.

Dissemination of research findings

As discussed in the earlier section on 'Qualitative design: Planning and preparation; implementation and monitoring; evaluating; reporting and translation' (see page 17) a plan for dissemination of research results should be included in the HREC application. For example, the application should state whether the researchers intend to present their work at academic conferences or as publications in peer-reviewed journals, and whether information will be shared with community organisations or other interested parties. Participants should also be provided with information about where their data will be published, and how outputs from the

study might be used, including the use of data for teaching purposes, so they are fully informed before providing consent.

Rigour

To be able to have confidence that qualitative study findings accurately represent the perspectives of the study population, and to ensure that the conclusions from data analysis are meaningful, and potentially have wide applicability, data must be seen to be both rigorous and trustworthy. Rigour in this context refers to the quality of the research, and rigorous methods are ways to evaluate that quality. Trustworthiness, on the other hand, ensures that the study findings are representative of the experiences of participants in relation to the study processes and procedures, and that these experiences are offered by the participants themselves. Rigour and trustworthiness in qualitative research are analogous to validity and reliability in quantitative research.

Rigour has been defined by the Oxford English Dictionary as: "The quality of being extremely thorough, exhaustive, or accurate".(56) When data are collected and handled in a rigorous way, it has been suggested, the approach to their collection, analysis and clarification can be replicated within other studies, using different study samples, or by other researchers, with the expectation of generating similar results.(57) Rigour is supported by a strong and transparent study design that uses a methodological framework in line with study questions, aims and objectives to guide the research process. Ensuring research findings contain detailed descriptions of the context of the research, such as the environmental setting, the participants involved, and the reasons behind using different research methods, enables those receiving or reading about the research to determine the quality of the study, including how transferable study findings are to other populations or settings.(55) Other strategies that assist in achieving rigour, include:

- Clear descriptions of the sample necessary for the study to be meaningful;
- An indication of how and why the sample was chosen;
- Engagement with others, such as multiple researchers, in order to code or discuss data widely;
- The use of verbatim quotations in the representation of data findings;

- Study participant involvement in validating the context or content of the data;
- An assessment of a researcher or group of researchers' assumptions about the data (also known as 'member-checking');(58)
- Peer review of findings;
- Clearly defined study design;
- Data, site, cohort and method triangulation.

Sampling strategies and types of sample

Selection of a sample is an important aspect of a study design. An appropriate sample will ensure that data collection represents the characteristics of the cohort, and the views of participant cohorts who are able to answer specific research questions effectively. Often selected as stratified(59) or purposive,(60) samples in qualitative research can usefully identify a specific mix of participants to suit a study's needs and to ensure a variety of experiences are captured, and participant characteristics are in evidence. For example, purposive sampling can aim to include a mix of men and women of different ages and ethnic backgrounds. Purposive sampling allows for a specific population to be involved, with characteristics of interest to the study team, while also providing variation within and across the sample group population. The size of the sample also influences the amount of data that can be collected or the depth of interrogation of that data that can take place. This is a component that has been strongly linked to judging a study's credibility (see below for more details on credibility).(61) Small samples, as has already been mentioned earlier in this White Paper, can provide in-depth and rich detail but may not be representative of an entire population or study group, while it is unusual for qualitative data to aim for generalisable outcomes. Some research studies aim to achieve data saturation (i.e., where no new themes or categories can be identified in the data analysis),(62) to determine when data analysis should cease. Ensuring that data saturation levels have been achieved is complex, and additional data-checking, which can be labour-intensive, may be needed. The sample size required in qualitative research depends largely on the diversity of the population being studied. If the population is homogenous, then a smaller sample may suffice. In such circumstances, if participants provide similar responses to questions, there may not be the need for a larger number of participants to report on the same thing. However, if the sample is diverse and heterogenous, displaced or extensive, then the size required for data collection may be larger, in order to capture all of the concepts, characteristics, or other variables needed within the field of inquiry.(63)

Using multiple researchers to code data

The use of a predefined data analysis framework can be well-supported by multiple researchers' in data coding. This not only ensures that data are categorised and coded consistently, but that analysts agree on what aspects of the data are important to answer the research questions, and how best they can be presented. This process also ensures that findings are in line with research questions and that analytic methods align with qualitative methodologies underpinning the study. Multiple research analysts, working together, help reduce the effects of an over-dependence on a single-researcher, to define what is inherently important in the data, while groups of researchers strive to work together to achieve a consensus opinion.(64) Using CAQDAS(17) can also add to the rigour of the research work, by making the process of analysis more systematic and replicable.(65) However, disadvantages of using coding software for analysis should be taken into consideration when choosing the most appropriate data analysis method. Not only do these systems fail to do all the analysis work studies need, they often only act as a facilitator for categorisation, and they can restrict what can be achieved through the in-depth work of researchers. However, they do, in many circumstances, make data retrieval, analysis and interpretation by the researcher quicker and easier through their application of standardisation, especially where very large datasets are concerned.(66)

The use of verbatim quotations

Using verbatim quotations during the presentation of research study findings also provides evidence to support the rigorous interpretation of data undertaken by a researcher or group of researchers. It allows the reader or audience to see the subtle differences between perspectives of participants and enriches understanding of the whole. Verbatim quotations should be representative of the sample and not dependent on certain participants' views, while outliers to group agreement are also useful, to demonstrate differing opinions. Quotations are used in the analysis stages of a study, as well as during the reporting stages, to develop data analysis frameworks, categorise responses and devise new data collation approaches. Providing quotations helps to show how well a study's analytic framework encompasses the data held within it – the themes and categories that contribute to the credibility of the research as a whole. Using quotations as representations of categories within thematic structures may improve comparison between different themes, as well as help validate the data analysis framework.(61)

Member-checking ('participant validation')

Member-checking, (also described as 'respondent validation' or 'participant validation'), where a researcher returns to participants with their data and preliminary analytic results, does not always take place in a study, nor is it always useful, as we will discuss in more detail a little further on in this section. But when member-checking is applied, it has been said that it helps ensure a study stays true to the participants' views and experiences. The process is said to increase the validity of the results, and reduce undue researcher influence, or an over-assessment of data.(67) The process, which involves seeking clarification of the researcher's interpretation of data directly from participants, promotes the opportunity for participants to comment on both the work and the preliminary study findings, to confirm whether the researchers' interpretations of data reflect their own beliefs and experiences.(58) The blanket use of member-checking for all situations and occasions is ill-advised, and the technique may not always be appropriate if particularly complex, difficult or sensitive data have been collected. Thus, decisions about whether to involve participants in member-checking, should consider the nature of the data, and whether including participants will evoke positive or negative emotional responses that if upsetting, could, ultimately, lead to harm.

Peer review of research findings

Like inter-rater reliability in quantitative research, peer review involves the inclusion of more than one researcher's views to ensure consistency and seek agreement on data workings and findings. Peer review can help build an analysis framework, engage varying groups of researchers with different competencies and expertise, and meld different disciplinary views. It can lead to research findings with enhanced contextual appropriateness, believability and accountability. In addition, peer review of research findings can ensure that data are not unduly influenced by a single researcher's perspective or wishes, thus strengthening the credibility of the findings for wider audiences.(58)

Triangulation

Triangulation is also considered an important aspect of ensuring rigour is built into a study design. Triangulation can enhance the quality and credibility of the whole research process.(55) Within a qualitative research context, triangulation can refer to the combination of: a) different qualitative methods, b) different investigator expertise, c) different participant samples and

types, d) different conceptual frameworks, e) different theorical paradigms, f) different sources of information, g) different analytic frameworks or processes and h) different interpretive frameworks. By utilising multiple sources of information, a combination of researcher expertise or a range of methods of data collection, for example, a study can be said to be corroborative, leading to richer, more comprehensive findings, increasing the credibility of data outputs,(55) and more plausible representations of a phenomenon under review.(68)

According to Shih(69) there are two main reasons for triangulation: to confirm findings, or add to the completeness of findings; and to increase the depth and understanding of a phenomenon through the combination of methods and theories. The use of multiple types of inquiry may often yield conflicting results, which can lead to new findings or new questions. Such inconsistencies do not weaken existing results, however, but offer opportunities for richer, more comprehensive findings, while posing new opportunities for a deeper understanding of the data and consideration of further research questions.

Although we have mentioned eight possible modes of triangulation in a) - h) above, Denzin(70) and Patton(71) identified four commonly-occurring types: a) method triangulation, b) data source triangulation, c) theory triangulation, and d) investigator triangulation. These are examined below (see Figure 8).

Figure 8. Four types of triangulation
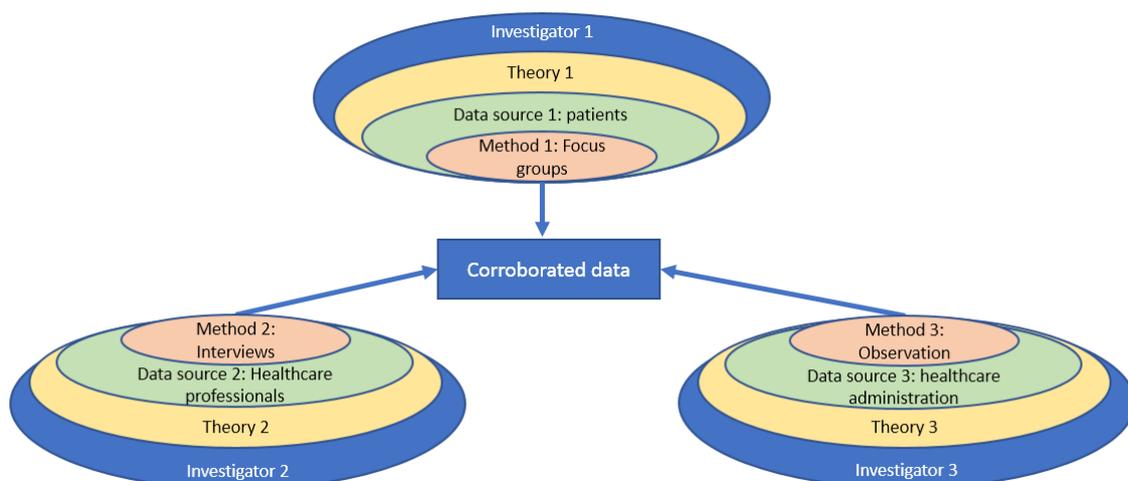
Source: Authors' own work; and the work of Denzin(70) and Patton(71)

- **Method triangulation:** This form of triangulation involves the use of a variety of methods for data collection, such as surveys, interviews, focus groups, and observations. If these result in the same findings, the validity of the study is said to be enhanced. Using multiple methods is also said to minimise the limitations of any one method, used alone.(55)

- **Data sources:** This form of triangulation involves comparing and contrasting findings derived through different sources of data. Triangulating different data sources, such as participants from different socio-economic backgrounds, allows different perspectives to be compared. Triangulating sources from different time points, such as the comparison of data from life history interviews with ethnographic participant observations of the here-and-now, can also provide different explanations for study findings. However, triangulating findings from different data sources may yield conflicting results, in which case, understanding these conflicts, through the reconciliation of findings to their respective sources, may help to provide deeper levels of understanding, and enhance validity. Obtaining consistency within the reporting of findings, where data were triangulated from different data sources or across different time points, is important, as it will contribute to the credibility of the overall study.(71)

- **Theoretical triangulation:** Theoretical triangulation relies on the use of different theoretical perspectives to analyse the same set of data. This can involve different theoretical frameworks from varying intellectual disciplines or traditions.(71, 72) For example, a multi-faceted ethnographical study of emergency physicians and the way they interact with other clinicians to produce effective care for patients as examined by Nugus and colleagues(73-77) can be conceptualised by one or a combination of complexity theory, theories of negotiated order, theories of power, theories of healthcare quality and safety, or communication theory. Alternatively, different theoretical perspectives can be the source whereby data triangulation originates, and in this case, once analysis is complete, data triangulation can help to inform the strength of the original theoretical paradigms, vis-à-vis study outputs.(71)

- **Investigator triangulation:** Investigator or analyst triangulation involves using multiple researchers to independently analyse, compare and contrast findings. This offers a way of minimising reliance on a single view point, and balancing out the subjectivity of a single researcher, to enrich the analytic process. Typically, researcher triangulation occurs when researchers use team-work methods during the collection and

analysis of data.(55) Investigator triangulation can also involve the use of researchers from different disciplines in the same research project, to form interdisciplinary conversations.(55)

Finally, where multiple types of triangulation are used within one research project, for example multiple methods, with multiple participants, using multiple researchers, this is called multiple triangulation.(78) This raises the potential to improve the nature of the study and enrich its design, conduct and results, but can introduce levels of complexity that are hard to manage.

Advantages of triangulation: A brief example

The different types of triangulation: method, data, source, investigator, theory, and the like, can help to enhance the process of verifying data findings and increase the credibility of a study. Incorporating different viewpoints and methodologies, for example, increases confidence that a study's results accurately reflect the experiences of study participants. As qualitative research is highly contextual and case-dependent, it is important to place research findings in the context in which a study took place. Moreover, researchers need to be aware of their own values and experiences, which may potentially impact on how data are collected and interpreted. Strategies to overcome some of these challenges are discussed below.

In a current study looking at the barriers and facilitators to cochlear implantation in adults,(49) triangulation mechanisms were deployed to ensure data were representative of multiple research participants' perspectives. Multiple research participant groups were enrolled to harness a wide spectrum of perspectives. These included: patient groups such as hearing aid users, cochlear implant candidates, and cochlear implant users of various ages, employment levels, and gender-mix, who had experienced different hearing support services from healthcare centres around Australia. It also included several healthcare professional groups, such as hearing aid audiologists, and general practitioners.

The study involved not only an Australian but also a United Kingdom (UK) arm, and data collection and analysis were supported by researchers with varying levels of professional experience and knowledge, working across disciplines. Multiple data collection methods were used, including: focus groups, semi-structured interviews, interviews by email, and qualitative

proforma questionnaires, to examine the barriers and facilitators to cochlear implantation and cochlear implant use.

The initial analyses of the focus groups and interviews considered the main factors that influence patients' decisions to have a cochlear implant assessment and examined health professionals' decisions to make a referral for cochlear implant assessment. Added to this, interviews and focus groups helped inform the design of qualitative proforma questionnaires, which collected more in-depth information about which factors influenced health professionals and patients in sharing decisions regarding cochlear implants.

Applying results from one method to inform the development of another, helped to ensure a comprehensive data capture strategy was put in place from the outset. Multiple researchers were involved in the analysis of the focus group and interview data and this enriched proforma development. Group analysis comprised a range of group-work techniques including schema analysis(79) (see page 87, for more details on this analysis method), and ensured that the analysis stage was not overly influenced by a single researcher's individual perspective or their views of interpretation.

This study is a good example of triangulation in practice, indicating how the collection of data from multiple sources can be assessed by multiple researchers. It is also an example of strong study planning, where triangulation was inherent in the research design and fully considered before any data collection took place, thus behaving as a fundamental foundation to derive research quality.(49)

Trustworthiness

Rigour also relies on the trustworthiness of a research study. Trustworthiness refers to the assessment of the quality and worth of the complete study, while helping to determine how closely study findings reflect the aims of the study, according to the data provided by participants.(15) Trustworthiness, as a concept, is made up of four components: credibility, transferability, dependability, and confirmability.(80) Each of these four components is discussed in turn below.

Credibility

The notion of credibility is taken from Grounded Theory, where a study's findings are based purely on what is to be found, embedded in the data. In Grounded Theory, knowledge and understanding is said to be acquired through a solid grounding of knowledge in the data, with minimal researcher influence on study results.(81) In this context, credibility refers to how accurately a study's findings are reported in study outputs, and whether they can be seen to be congruent with what participants have said in the reporting of responses to study questions and in the process of grounding theory in the data.(80) The credibility of a set of research findings also refers to whether the representation of multiple participant perspectives is reflected appropriately and considered trustworthy, that is to say, whether they are deemed "genuine, reliable and authoritative".(55(p21)) Triangulation and member-checking, as has already been mentioned, can assist in confirming the credibility of a study. Credibility has also been said to ensure results are reproducible, and that different researchers could reach the same conclusions, working independently of one another. By providing detailed information about the research team, such as their credentials, affiliations and experiences, as well as the basis of each individual's knowledge and understanding on a given topic, those reviewing a study can determine how expertise may impact on interpretations and observations.(82)

Transferability

Transferability refers to the possibility that a qualitative study's theoretical position can be used in other contexts, or with other population groups and that findings can be applied to other contexts, cohorts or population groups. The concept is similar to 'external validity', a common concept in quantitative research, where the generalisability of results is desired.(55) However, here we are referring to the applicability of theory or the transferability of a methodological paradigm applied to other populations and contexts, to influence the development of other research studies.(55) By including detailed information about the context of the research, the theoretical paradigm that was used, and how it was applied, the study reviewer (often the academic reader) can consider whether it would be feasible and appropriate to transfer outputs from study results to other situations or settings.(82)

Dependability

Dependability refers to whether a study's findings could be achieved, and the working methods repeated, were another researcher to conduct the same study. To ensure dependability, it is good practice to including 'thick', detailed, descriptions of the study population and context:

"The purpose of a thick description is that it creates verisimilitude, statements that produce for the readers the feeling that they have experienced, or could experience, the events being described in a study. Thus, credibility is established through the lens of readers who read a narrative account and are transported into a setting or situation".(83(p128))

Including details about the chosen methodology, selection and recruitment of participants, data collection methods, and the analysis process, together with 'thick' descriptions, allows for the potential for replication of a study, with, for example, another study group and a different set of researchers.(80)

Confirmability

Confirmability ensures that a study's findings are clearly representative of the participants' views, rather than the researchers' preferences.(80) The process of member-checking supports this, as does the peer-review of analytical frameworks. Confirmability provides an extra level of quality control and enhances the trustworthiness of the study(67) encouraging reviewers to leave emergent findings uncontested.(79)

Feasibility and fidelity

The feasibility of research projects must be considered early on in the design phase of a study, in order to determine whether the research is likely to be successfully completed. Researchers need to consider staffing requirements for data collection, and analysis, and the presentation of results, as well as budget constraints, and required time frames. The feasibility and acceptability of data collection tools must be considered, within the context of incentives and motivation to participate in the research. For example, asking a group of participants to complete a one hundred-page questionnaire survey or attend a two-day focus group meeting is unlikely to be considered feasible by most people. The scope of the project must also be

feasible, with refinement of research questions to a focused topic, and an assessment of whether the proposed workload can be completed within an appropriate timeframe. When considering the feasibility of research, the limitations of researcher expertise must also be taken into account.

Fidelity is related to the credibility of research, ensuring that studies are delivered as intended ('implementation fidelity'). This is important in intervention studies in particular, as it strengthens any conclusions linking the intervention to outcomes and indicates whether a study's findings can be attributed to the intervention, or to other factors. One example of achieving fidelity is to ensure that the intervention once applied, is applied in the same way, or that the data collection phase is conducted in the same way, throughout a study. This can be enhanced by the thorough training of all those managing data collection. For example, interviewing techniques can be taught to a range of researchers, so that interview schedules are applied coherently, and questions are always asked in the same way. Finally, including an element of ongoing evaluation that assesses the way in which a research study is being conducted can ensure fidelity.

In summary, and as this section has attested, qualitative research should be directed by ethical guidelines. Ethical considerations should include recruitment, sampling, methods of data capture and analysis, data management and data reporting. As stated, researchers should be ethically-minded. They should set out to minimise the risk of harm occurring to study participants, attempt to maintain data confidentiality and to ensure that informed consent is obtained from all participants. They should plan for dissemination of study findings early on, with input from others when and if necessary and appropriate. It is the responsibility of the primary researcher or principal investigator to ensure data collection is rigorous, trustworthy and credible, and that data findings and study outputs, including study interventions, are monitored and evaluated to uphold high ethical standards—and thus contribute to society, and the knowledge available to it, in general.

Mixed methods design: What is it, and how do methods complement one another?

"It is the curiosity of the more experienced researchers who wonder what lies beyond their methods horizon that makes mixed methods exciting in their applications".(84(p428))

The case for mixed methods

Medical and health services research has traditionally taken a positivist stance when it comes to choosing appropriate methods for conducting research. Positivism assumes that there is an objective reality that is measurable, and independent of human experience. It underpins much of health services and medical research, which relies on scientific evidence such as experiments, hypothesis-testing and statistics in order to understand scientific and social phenomena. Medical faculties allied to biological science departments, for example, often encourage researchers to use controlled, reductionist, quantitative methods to create knowledge about disease processes, assessments and treatments. More recently, medical 'boundaries' in some academic institutions have slowly become more porous, and interdisciplinary research has become more valued and feasible, resulting in moves toward 'social medicine' or the 'medical humanities'. These fields seek to understand how social and economic conditions affect health, disease and the practice of medicine. This has led to a paradigm shift, still in its infancy in some countries and studies, toward a greater use of, and appreciation for, qualitative research methods, even in clinical trials.(85) Health problems in reality can no longer be understood with reference only to signs, symptoms, and the causes of disease. Health, wellbeing, care and treatment are all social-professional endeavours, embedded in complex politico-cultural contexts.(29, 72)

So, there is a relatively new desire to understand how health and illness affects human behaviour and decision-making, and vice-versa. The use of qualitative methods within health services research allows participants to have a voice in the research study. This can be anything from helping formulate the research question, to enhancing the study design, data collection and data reporting. It also allows researchers to explore aspects of healthcare research more deeply, such as how patients live through, and adapt to, illness or disability, how they make sense of pain and suffering, what is unique and what is common about their journey of

interaction with their systems of care, and how health professionals manage team processes or new technology.

What are mixed methods?

Mixed methods are the collection of qualitative and quantitative data within a single project or program of work, and then the analysis and synthesis of different types of data to produce an integrated response to a research question. It is the integration of the different types of data that is key here. Insights come from how data sit alongside one another, and this is seen to give mixed methods research an added value.(86) Qualitative and quantitative methods are useful in their respective ways, and each have their own strengths and weaknesses, while it has been said that alone, neither can fully explain the nature of reality.(87) The basic assumptions of qualitative and quantitative methods are depicted in Figure 9. Collecting, synthesising and integrating, (i.e., 'mixing') methods aims to achieve both depth and breadth of understanding, align aspects of different methodological paradigms, and empower a research study:

"Mixed methods research is a research design with philosophical assumptions as well as methods of inquiry. As a methodology, it involves philosophical assumptions that guide the direction of the collection and analysis of data and the mixture of qualitative and quantitative data in a single study or series of studies. Its central premise is that the use of quantitative and qualitative approaches in combination provides a better understanding of research problems than either approach alone".(87(p5))

Mixed methods research is therefore distinct from *multimethod* research. In the latter, while both qualitative and quantitative data are collected, they are analysed separately and not in an integrated fashion. As such, they lack the ability to provide any synergistic insight. It should be noted that mixed methods research requires expertise in both types of research design and conduct and may require a team to provide the necessary expertise.

Figure 9. Quantitative and Qualitative Methods

QUANTITATIVE
•A-priori knowledge: knowledge is derived independently from experience.
•Data is hypothesis-driven
•Based on deductive reasoning

QUALITATIVE
•A-posteriori knowledge: knowledge is dependent on experience.
•Data is used to explore meaning and lead to hypothesis development
•Based on inductive reasoning
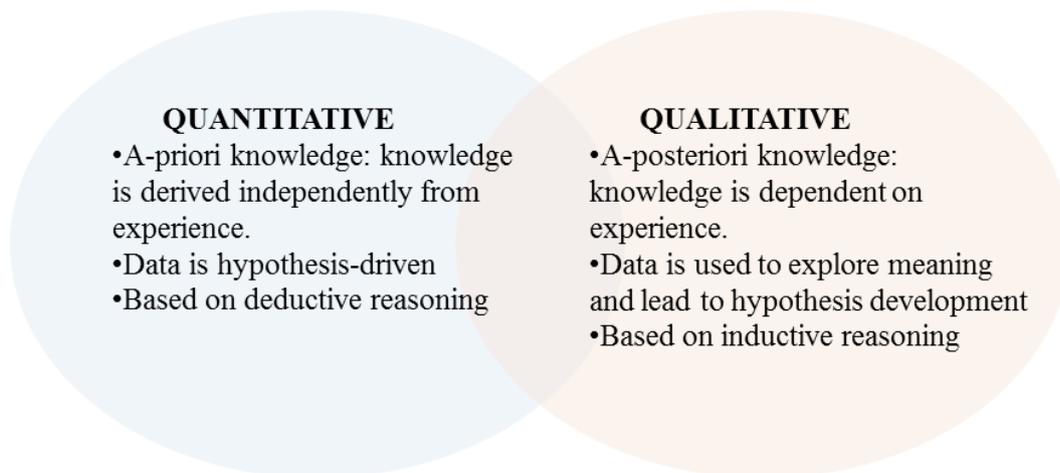
Source: Author's own work

When should mixed methods be employed?

Research questions for whom the use of mixed methods is most advantageous, include: those that are broad, those that are complex and those that are multi-faceted. The mixing of both quantitative and qualitative methods yields a number of benefits, including the ability to answer questions that are both *confirmatory* (e.g., 'does a high frequency of patient 'drop outs' in a treatment program lead to unhelpful perceptions?') and *exploratory* (e.g., 'what are the perceived barriers that are stopping nurses using a new screening tool?'). Moreover, mixing methods draws on the strengths of each methodological paradigm, and counterbalances respective weaknesses.

According to Doorenbos,(88) there are four broad research situations where mixed methods can be the most usefully employed:

- Situations exploring new concepts or those that are not well understood: exploration using qualitative methods before employing quantitative methods.
- Situations where findings can be supplemented using a secondary source of data to increase depth of understanding of a phenomenon.
- Situations where neither a qualitative nor a quantitative approach is substantial enough on its own to understand or address the research question.

- Situations where quantitative results are not easily explainable or interpretable and where qualitative results can be used to explain quantitative findings.

Mixed methods design

Prior to embarking on a mixed methods research project, choosing the appropriate research design is imperative. To do so, it is important to consider (a) what methods to use, (b) the priority given to each method, and (c) whether sequencing methods is desirable (based on when data will be collected, for example). Overall, the decision about which methods to use is largely dependent on the research question. Table 5 introduces four types of mixed methods design and their uses: (1) Triangulation, (2) Embedded design, (3) Explanatory design and (4) Exploratory design. Each of these has a unique approach, which will be discussed in the section below.

Table 5. Types and use of mixed methods design

Types	Variants	Uses	Weighting	Priority
Triangulation	- Convergence - Data transformation - Quantitative data validation - Multi-level	Used to compare and contrast quantitative statistical results with qualitative data to validate or to build on existing qualitative or quantitative findings.	EQUAL	QUANT + QUAL
Embedded design	- Experimental - Correlational	One methodology provides a supporting role in a study based on the other methodology (e.g., a quantitative study embeds a qualitative component such as surveys to supplement and/or explain findings in the quantitative data).	UNEQUAL	QUANT (qual) Or QUAL (quant)

Explanatory design	• Follow-up explanations of data • Participant selection	A two-phase, mixed methods design to help build or expand on initial quantitative findings.	QUANTITATIVE (USUALLY)	QUANT → qual
Exploratory design	• Instrument development • Taxonomy development	This method uses a two-phase design based on the premise that further exploration of results and/or data is needed. This design begins using qualitative data and is useful for developing and testing an instrument.	QUALITATIVE (USUALLY)	QUAL → quant

Note: UPPERCASE notation represents priority given to a method.

Source: Authors' own work

Choosing a mixed methods design

In a mixed methods design, data can be collected sequentially or concurrently (Box 1):

Box 1. Mixed method design

SEQUENTIAL
   a. **Explanatory sequential** (QUANT → QUAL): Qualitative data are used to explain relationships found in quantitative results
   b. **Exploratory sequential** (QUAL → QUANT): Qualitative data are collected first to explore a phenomenon, before quantitative data is collected to build on results of the qualitative phase

CONCURRENT
   c. **Convergent Parallel** (QUAL + QUANT): concurrent collection of both qualitative and quantitative data
   d. **Embedded** (QUAL/QUANT) within (QUANT/QUAL)
      Example: adding qualitative data in a primary quantitative design (e.g., interviews used to supplement results of an experiment or randomised control trial [RCT]) or including surveys within a primarily qualitative research design
   e. **Transformative** (QUANT → QUAL): using mixed methods within a transformative theoretical framework
   f. **Multiphase** (QUAL → QUANT → QUAL/QUANT): combination of both sequential and concurrent data collection and analyses over a period within a major research program

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Source: Creswell and Plano Clark(86)

A process by which to choose a mixed methods research design, by identifying important considerations that must be taken into account at the start of a study, is set out in Figure 10.

Figure 10. Considerations for choosing a mixed methods design

(a) What will the timing of the quantitative and qualitative methods be?

Concurrent timing — Sequential timing

Quantitative first — Qualitative first

(b) What will the weighting of the quantitative and qualitative methods be?

Equal weight — Unequal weight

Quantitative emphasis — Qualitative emphasis

(c) How will the quantitative and qualitative methods be mixed?

Merge the data — Embed the data — Connect the data

Merging results during interpretation — Merging data during analysis — Embed qualitative data in a quantitative design — Embed quantitative data in a qualitative design — Quantitative leads to qualitative — Qualitative builds to quantitative

Source: Creswell and Plano Clark(89)

Integrating data from a mixed methods design

A key feature of mixed methods research is the integration of qualitative and quantitative data, but integration can also be achieved at different points in the research project. It can occur at the data collection stage as part of the study design (e.g., as in embedded designs, where qualitative data are added to a primary quantitative design). Integration can also be achieved at the analysis stage (e.g., where each dataset is used to inform the findings of the others), or different types of data can be analysed separately but can be brought together at the end of a project (e.g., in the discussion section of a paper), comparing and contrasting results.(90)

Creswell(90) uses a useful metaphor to explain the two main ways that integration, the 'mixing' in mixed methods, is achieved. Mixing of qualitative and quantitative data may produce findings no longer recognisable as one or other data type, as when flour is mixed into a cake batter and loses its identity as flour. Other mixing of qualitative and quantitative data is more akin to raisins being mixed into cake batter; the raisins are still recognisable as raisins, yet they are integrated into the whole.

There are three broad approaches to integrated data analysis (see Figure 11), dependent partly on the logistics of the study design; i.e., whether the data collection is concurrent and independent, or sequential and dependent. An obvious pre-requisite for all approaches to mixing is that there is rigour in the analysis of both qualitative and quantitative data regardless of how they will be subsequently integrated.(68) Integration of the qualitative and quantitative data analysis should be predefined in the study design. This is important to ensure the first dataset aligns with the other dataset or sets. The design of data collection tools should consider the point at which data will be integrated, to ensure data will be complementary.

In the first approach of integrated analysis; 'merging', the qualitative and quantitative data are analysed separately then lined up side by side for comparison and contrast. The findings may be merged into categories of themes previously defined, with some overlap or unique themes can be revealed for each dataset.(68) The second approach to integrated analysis; 'connecting', is used in sequential mixed methods research where data from one of the methods (e.g., qualitative) is used to explain or build the next phase of data collection (e.g., the quantitative). The first dataset may highlight participants of interest and be used to define the sample for the second dataset. The first dataset may also be used to design elements of the second dataset, such as the results of a qualitative focus group, may inform the development of a quantitative data collection tool, such as a quantitative survey, or may help to determine which variables are of interest in a quantitative dataset.(91, 92)

The final approach to integrated analysis; 'embedding', is useful when the primary study question is supported by a secondary question. In this scenario, the secondary question may involve a secondary method, and typically this method will become part of, or be 'nested' within, the primary method's framework. For example, while the primary (quantitative) method of a study may identify the outcomes of an intervention, the secondary (qualitative) method may support the findings by exploring the interactions between staff and patients involved in

the intervention, to elucidate how their communication and interactions impact the delivery of the intervention. Curry and colleagues(68) argue that it is important that this is justified by the multistage methods of the study, and the interdependence of the study stages.

Figure 11. Three approaches to mixed methods data integration
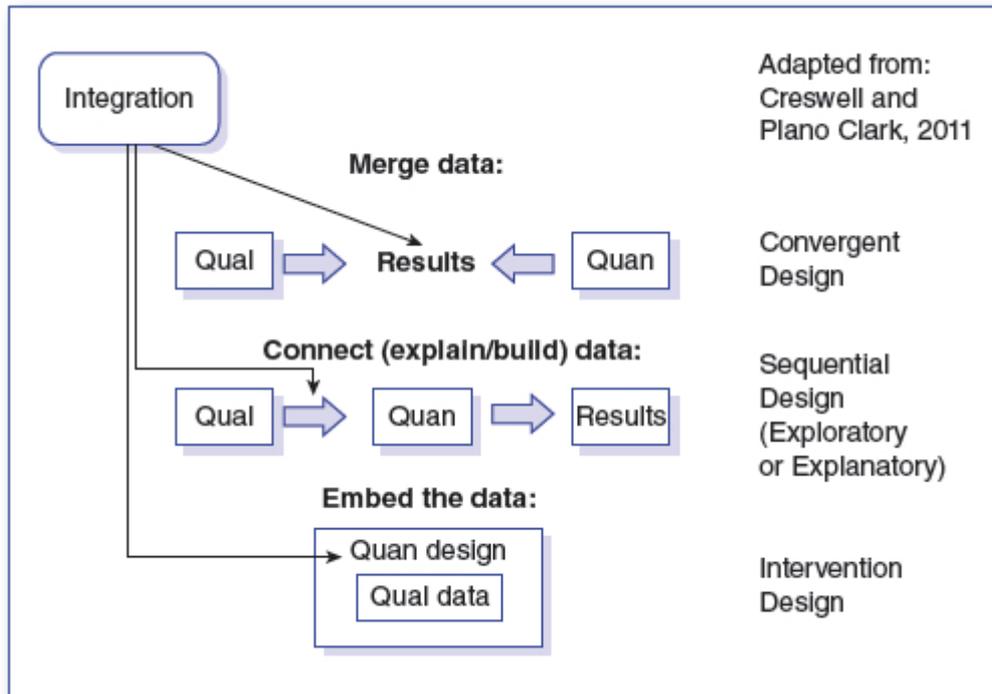
Source: Creswell(90)

The challenges of mixed methods research

Several factors can impede the successful integration of mixed methods' results in a study and these are outlined below in detail. It is worth noting that there is often insufficient time left to manage this aspect of a study and consequently, results are not written up in an integrated fashion. This can be exacerbated by researcher uncertainty regarding how and when to integrate findings which can lead to a neglect of qualitative findings in reporting, where other findings, such as quantitative findings, take the spotlight.

1. **The problem of integration**

Data source integration: One of the main challenges associated with mixed methods integration is the problem of ensuring data sources form a part of the cohesive whole. Despite

starting out with good intentions, many mixed methods researchers do no always include their sources as part of the work of reporting their findings.

Readership: Mixed methods researchers are faced with an additional challenge, of considering how to write up their findings, once their study is complete, to suit different audiences. In addition, peer-review journals often have methodological preferences toward the reporting of one method over another, rather than welcoming the reporting of a number of disparate methods, which may limit the ability to publish data in certain journals.

Methodological preferences: Despite the use of mixed methods and methodologies, some mixed methods researchers still favour a particular method, leading them to neglect a full analysis and comprehensive integration of methods, handled equally. This may stem from researcher familiarity with a way of working, or with a specific method, or a researcher's capability to confidently apply an integrated approach to working.

Researcher capability: To overcome a lack of skill-mix, mixed methods researchers may form teams with different capabilities and specialisations. Ideally, this results in a division of labour and a harnessing of different qualitative and quantitative researcher strengths, for a clear integration plan. However, bringing together a team of researchers poses the challenge of how to systematically integrate data when different people may favour a particular approach to data management, with different expertise and differing perspectives.

Nature of results: After data collection, researchers may feel that one dataset is more compelling or interesting than another. This may lead to one dataset being prioritised over another in the write-up.

Timeline: A major challenge with mixed methods research is the data collection timeline being out of kilter with different research components. For example, collecting interview data often takes longer than collecting standardised survey data responses. Moreover, there may be pressure to start publishing research findings when data analysis has yet to be completed. Another challenge can relate to the lifespan of a study. Collecting both qualitative and quantitative data and then conceiving a clear plan of integration is time consuming, and a study must have the appropriate funding, staff and resources available to allow for thorough working practices.

2. Examples of mixed methods research and data integration

Mixed methods research can seem straightforward on paper but can take research down unexpected pathways. In this section we present three examples of mixed methods studies, indicating in each example how we have used mixed methods to address a number of diverse research questions. In the first example, we describe how comparison of qualitative data from clinicians' perspectives was markedly different from a quantitative audit where data were being collected at the same time; this led to a change in the research study's focus and direction. The second example shows how integrating qualitative and quantitative datasets in a study can give results that far exceed the value of using either dataset alone. The third and final example highlights how mixed methods, in the form of process mapping, can be used to understand everyday work.

Lynch Syndrome: Addressing barriers to referral and management of patients

The first example of mixed methods and data integration is from a study that aimed to examine and address barriers to referral and management of patients at high risk of a hereditary cancer syndrome.(93) A two stage, exploratory, sequential, mixed methods design was used to examine reasons why a new screening test for a hereditary cancer called Lynch Syndrome (LS) was not being incorporated fully into routine practice. LS is a hereditary cancer syndrome which predisposes carriers to a higher incidence of a range of cancers (e.g., colorectal, endometrial, bowel, stomach and ovarian cancer). People with bowel cancer, admitted for surgery, are now routinely screened for LS. The test can determine if there is a high likelihood of LS or a low likelihood of the syndrome. Best practice in the case of a patient identified as having a high likelihood of LS is referral by a cancer treatment team to a genetic service. This service will further assess the likelihood of LS and carry out a diagnostic test for the syndrome. A positive diagnosis can be managed by tighter surveillance of future occurrences of cancer and prophylactic surgery, as appropriate (e.g., the removal of ovaries to prevent ovarian cancer). Family members may also be contacted and offered screening by a genetic department.

Prior to this research project, audits of the new screening test had shown a low referral rate of patients found to be likely carriers of LS to the genetic department across a number of Australian hospitals. The aim of this study was to work with one multidisciplinary cancer team within one of the hospitals to identify reasons why referrals were not consistently being made

to the genetic department in response to the test results. Implementation teams were selected at each hospital to work with researchers to identify the barriers to referral and to co-design interventions to address these issues. Implementation teams were made up of members from all the professional groups involved in treatment, screening and management of bowel cancer patients within these hospitals: surgeons, oncologists, pathologists, and genetic counsellors.

Data were collected in two stages (shown in Figure 12). In the first stage, qualitative data were collected. The newly formed implementation teams met to map out the patient journey and referral process, and to discuss the complexity of the referral context. Data collection occurred as detailed meeting notes and process map diagrams were created. Team members outlined the factors they considered responsible for any patient missing a referral.

Quantitative data were also collected during the first stage of the study, through a retrospective audit of the previous 12 months of completed screening tests that were matched with referral data from the relevant genetic department. The two sources of data, qualitative and quantitative, were integrated to produce a graphic (shown in Figure 13), by adding in the audit data details to embellish the process map that had been already developed. Stage one clearly revealed that the perceptions of the multidisciplinary team (MDT) were incorrect: the qualitative data showed that the team thought only one or two patients in the last year had been missed, while the quantitative audit data showed that 20 patients had been missed. Likewise, the qualitative data showed that clinicians were confident that their common practice of deferring making a referral to the genetic department until the second or third follow-up consultation still resulted in a referral; while the quantitative data showed that referrals were made close to the receipt of the screening test result, or not at all. Ongoing prospective audits confirmed this over a longer time period. A second implementation team meeting provided members an opportunity to study the integrated data results and respond to them.

Figure 12. Mixed methods study design showing how qualitative and quantitative data was integrated in the two phases
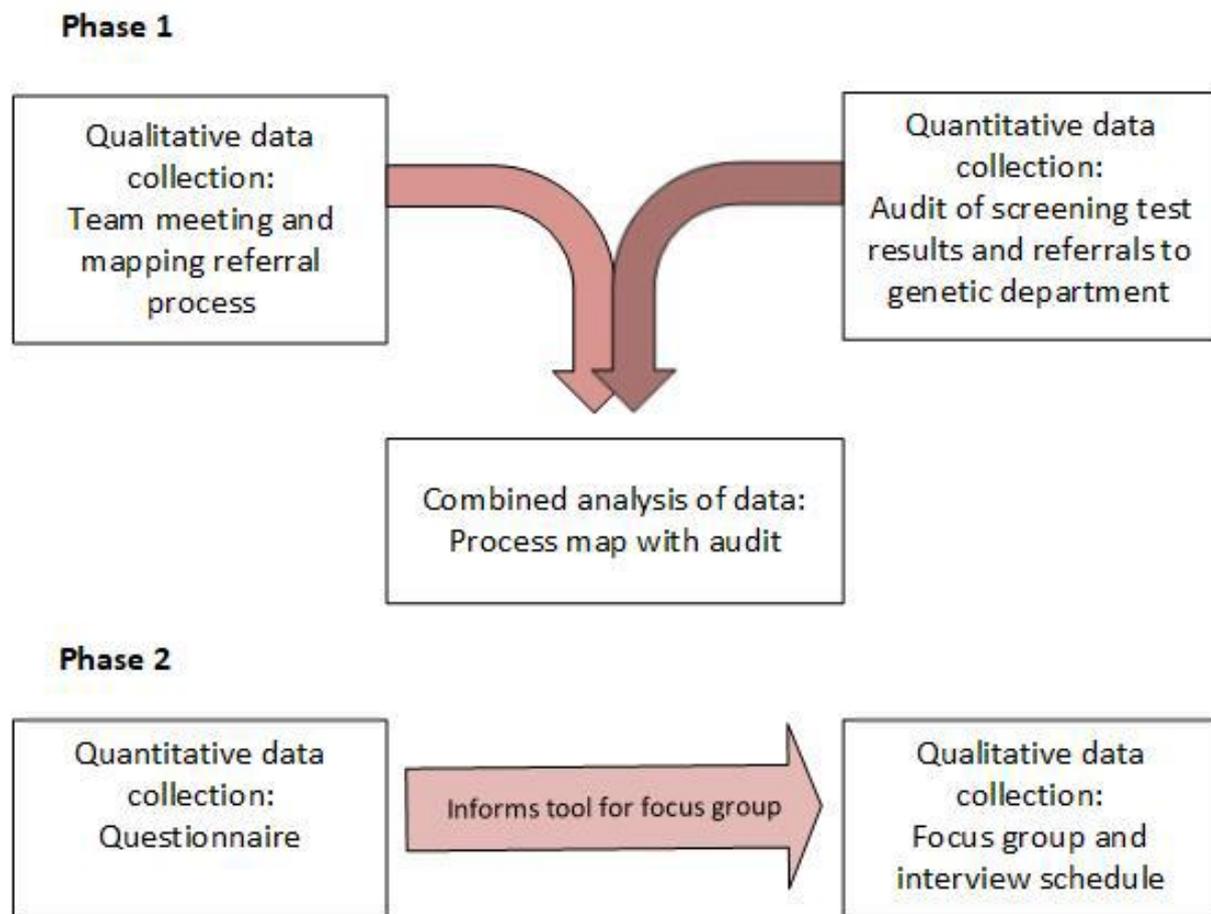
Note: Arrows indicate the integration of data.
Source: Authors' own work

The second stage of the study used a questionnaire (quantitative data) called the *Influences on Patient Safety Behaviours Questionnaire*(94) to identify the barriers to referral using the Theoretical Domains Framework (TDF).(95) The TDF uses psychosocial theory to identify barriers to changing behaviour. It uses a Likert scale format and mean scores across construct items, which can be ranked to determine the most significant barriers. The questionnaire was administered to the entire oncology department staff of each hospital involved in this study (response rate 52% [37/71]). The top-ranked barrier domains were environmental context and resources, skills, beliefs about capabilities, and cognitive and decision-making processes.

The questionnaire was followed by four focus groups (n=22) and seven interviews (qualitative data) with a range of clinical, genetic and pathology staff (including people not

previously involved in the implementation teams). The purpose of this phase was to test the validity of the quantitative questionnaire findings and to work with the researchers to co-design interventions to address the barriers found. Quantitative data were integrated prior to this activity by scripting the focus group and interview schedules based on the questionnaire findings. The focus group interview schedules were designed to flesh out details of how each construct from the questionnaire was understood. For example, in the 'environmental context and resources' domain, focus group participants discussed how the referral process was still largely paper-based with many issues around availability of referral forms and lack of communication back from the clinic. In the 'beliefs about capabilities' domain, participants spoke about the confusing wording on screening test reports and how variable and sometimes ambiguous the wording could be.

By integrating the qualitative and quantitative data in the first stage of the project researchers were able to present clinicians with a readily understandable graphic that not only quantified the extent of the problem but also provided rich data on the context. The quantitative data from the audit alone could not explain the practice of deferring a referral, nor identify the many factors that the clinicians had to consider before making that decision. For example, the screening test results were often returned at a time when the patients were still dealing with distressing post-operative pain and struggling to come to terms with incontinence or a changed body image. Far from a simple trigger, when a screening test came back positive and led directly to a suggested referral, deferring that referral was often seen as appropriate and compassionate. A better time to discuss the implications of the screening test results and ramifications for the patients and their families, was also seen to be something for a later follow-up, when a patient had recovered. The quantitative data showed that deferring the referral was not a sound option, as results were being inadvertently overlooked.

The qualitative data were also able to discount a range of issues that researchers had hypothesised might be barriers to referral, such as lack of familiarity with the guidelines, or a conviction that the screening test was not useful. The commitment of clinicians to manage future cancer risk was clear from the meetings, as was their understanding of the consequences of not identifying someone at high risk. Clinicians were able to recite the referral criteria without prompting. Quantitative data from the questionnaire identified some new barriers, which a breakdown of participant demographics further uncovered. Junior doctors who participated in the questionnaire (but who were not represented in the implementation teams)

scored highly for the construct 'beliefs about capabilities'. This was then teased out in the focus groups, revealing that some trainees did not receive any training on hereditary cancer, interpretation of test results, or how to refer.

The sequential exploratory design of this study allowed qualitative and quantitative data to be progressively collected and integrated appropriately, with time to build a picture of the complexities involved in referral. Teams went on to co-design interventions. Researchers were able to pull together both theoretically-derived and intuitively sound recommendations, by analysing the mixed methods in an integrated way.

Figure 13. Mixed methods graphic showing process map of screening test, and referral for patients with colorectal cancer
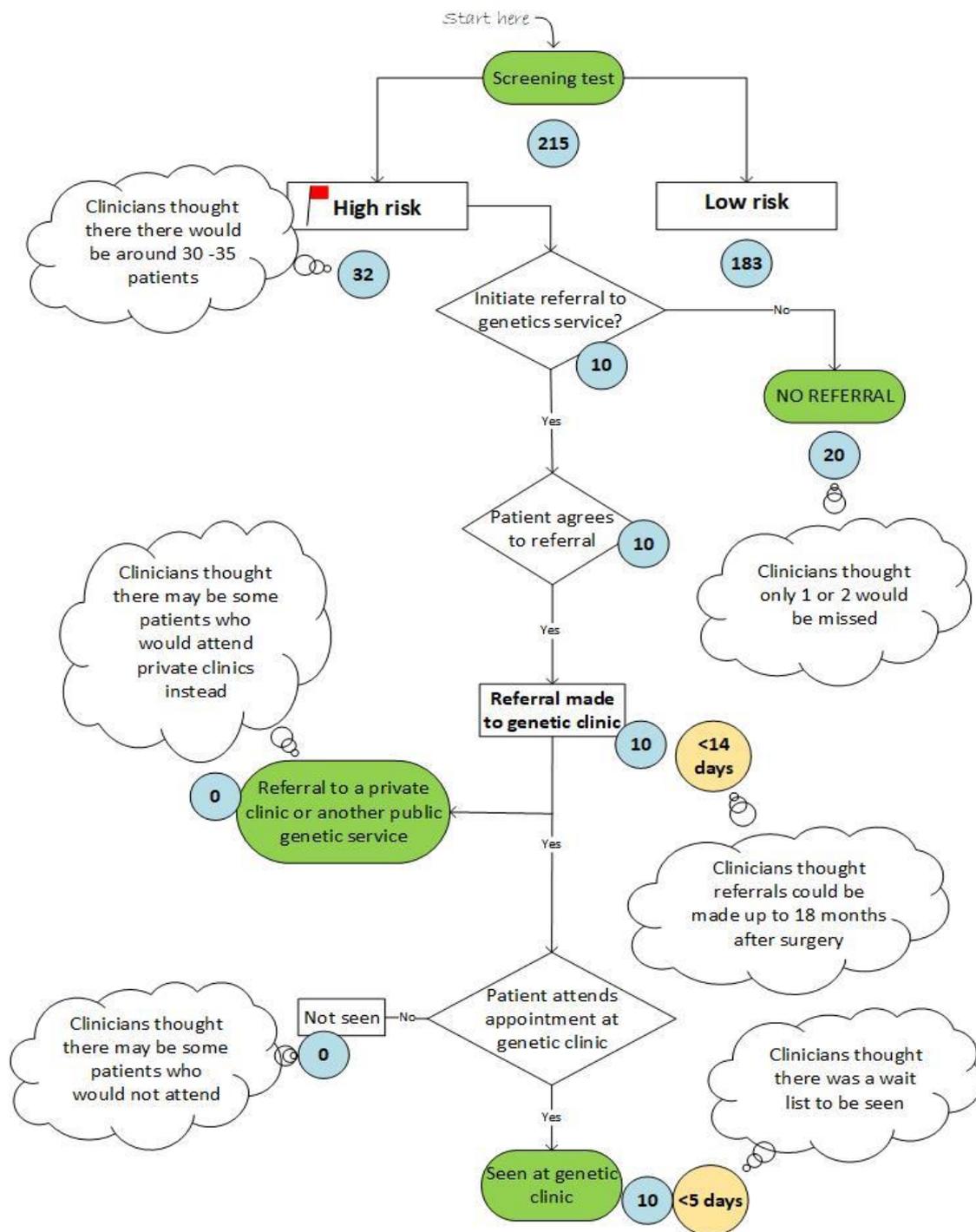
Note: Quantitatively derived audit data (numbers of patients in blue circles, time periods in yellow circles) and qualitatively derived perceptions of the clinicians involved. Results pooled from two hospital sites.

Source: Authors' own work

Integration of social network and interview data to examine leadership in complex networks

The second example of integration work, is based on a study that examined leadership in complex networks and the importance of network position and strategic action in a translational cancer research network.(36) This second example of mixed methods use applied a concurrent explanatory design to social network data (quantitative), and interview data (qualitative) with data compared and combined to explain the patterns seen in the data. Social network research is a quantitative methodology that collects relationship data from its participants and then maps relational ties. Graph theory is then used to compute various parameters of interest in the resulting network of ties. Ties can be any relationship that people within the social network of interest hold and must be carefully chosen by the researchers. For example, social network methods could be used to map friendship ties between children in a classroom, and the most popular child could be calculated quantitatively for that data—the child in the middle of a complex web of relationships. Any cliques or clusters that exist, and any child who spans the cliques by having friends from more than one group can also be computed. A participant's position in a network of ties defines his or her opportunities (e.g., children who are friends are likely to share things), and the constraints on their actions (e.g., a child may miss out on an invitation to a party if they are not friends with the birthday child). Network data can tell researchers where in the network of ties each participant is positioned. However, it cannot tell researchers how they got into that position or how each participant may actually use that position.

The context for this study was a new translational cancer research network (TCRN) which had been set up to provide social, financial and administrative support to translate new research into practice. There were 68 members at its inception in 2011, made up of university-based biomedical and health services researchers, and hospital-based clinicians. A governing body of 14 members was established. Translational research networks are a recent strategy to drive translational research. The aim of this study was to identify what opportunities and constraints existed within the TCRN for the mandated leaders and how they understood they would enact their leadership in this context.

All 68 members of the TCRN (including the 14 members of the governing body) were invited to complete a whole network survey in early 2012 when the network had been operating

for six months. Part of the survey asked participants about their existing collaborative relationships with other members of the network; i.e., with whom they had a working relationship before the network was formed. Around the same time, members of the governing body were invited to take part in a semi-structured interview that explored perceptions of their leadership role within the network. Figure 14 shows the mixed methods design used.

Quantitative data collected from the social network survey resulted in the diagram of existing working ties shown in Figure 15. Governing body members were shown to have high centrality, meaning that they had the largest number of working relationships among the network members, and several had high brokerage potential, meaning that they had ties to two or more members who themselves had no direct relationship to one another. This brokerage potential makes it possible for people to manage a number of roles such as coordination, gatekeeping, being a go-between, or providing some services to other members (e.g., translation or interpretation of information relevant to the network or to individuals in the network).

Figure 14. Study design showing the integration of data
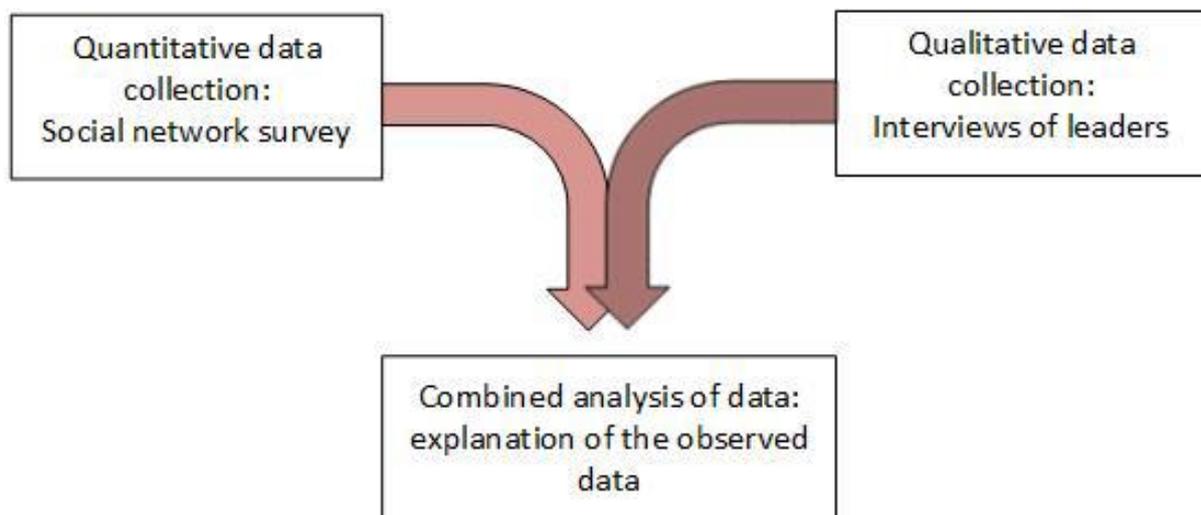
Note: Qualitative data explaining and adding richness to the quantitatively collected social network data.

Source: Authors' own work

Qualitative data, collected in the interviews (see Figure 14), provided rich descriptions of how these network positions influenced leadership roles and spelled out how they were

operationalised. Governing body members who had the highest number of existing working ties spoke of using this knowledge of other network members to coordinate translational research efforts, to provide expert advice and decision-making, ensure clear communication, and to act as local opinion leaders. Governing body members were all in brokerage positions. The interviewees spoke of enacting brokerage roles by being a go-between to link up would-be researchers with appropriate partners, helping members gain access to resources (one participants described this as "gate-jumping" compared to "gate-keeping"), and acting as an advocate or representative for the various subgroups involved. Some interviewees also included conflict resolution as part of their leadership brokerage role.

The mixed methods design of this study was particularly effective at revealing leadership roles in the TCRN. The design was carefully considered with the integration of data in mind. The governing body members were hypothesised to hold demonstrable key player positions in the social network data, thus providing a clear structural basis for their leadership activities. Quantitative network data could show the leadership *potential* in terms of social influence and connections, but the qualitative interview data allowed an explanation of *how that potential* could be operationalised and enacted.

Figure 15. Social network diagram of ties between TCRN members before the network started
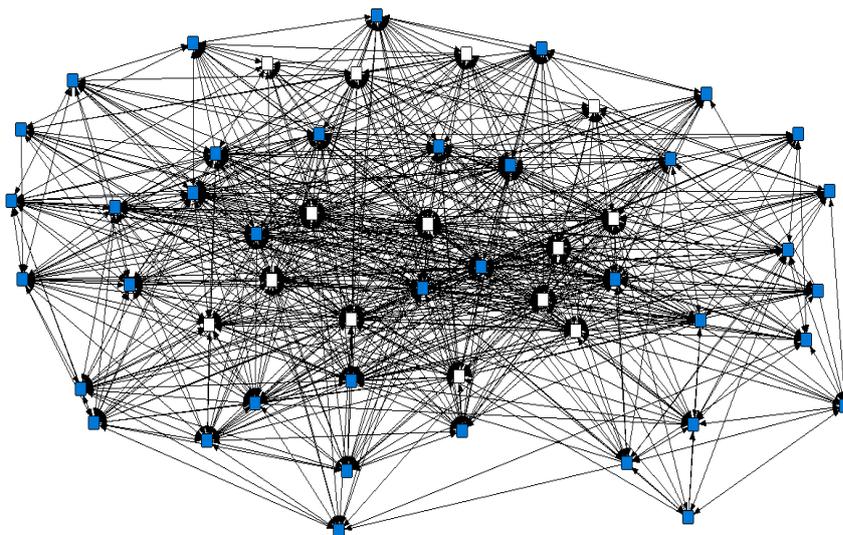
Note: Each square represents a TCRN member and the lines indicate working relationships. White squares are governing body members.

Source: Authors' own work

Using models to understand complex processes: Functional Resonance Analysis Method (FRAM)

The third example of a mixed methods study shows how qualitative methods, combined with process modelling, can be used to understand Work-As-Done (WAD) in complex systems. Process mapping is a useful method for understanding how work is enacted in the workplace and can be used for improving work process design and investigating unwanted events. Process mapping tools that are traditionally used for this purpose can be very effective in mapping linear, technical systems, but sometimes break down when processes are more complex (or when process variability or adjustments form a normal and necessary part of everyday work). The Functional Resonance Analysis Method (FRAM)(96) has been specifically developed to map processes in complex socio-technical systems. FRAM is a method that produces a model to describe a task, in terms of the linked set of activities that make up that task.

The data for developing a FRAM model is collected through a variety of approaches that can include any combination of ethnographic observation, interviews, focus group data, and documented processes. Each activity (or 'function') is then described in terms of six aspects (see Figure 16):

1. **Input** (I) is what the function acts on or changes (an input is also used to start the function).
2. **Output** (O) is what emerges from the function (this can be an outcome or a state change).
3. **Precondition** (P) is a condition that must be satisfied before the function can be commenced.
4. **Resources** (R) are materials or people needed to carry out the function, or material consumed during the function.
5. **Control** (C) is how the function is monitored or controlled.
6. **Time** (T) refers to any time constraints that might affect completing the function.

Figure 16. A FRAM activity (or function)
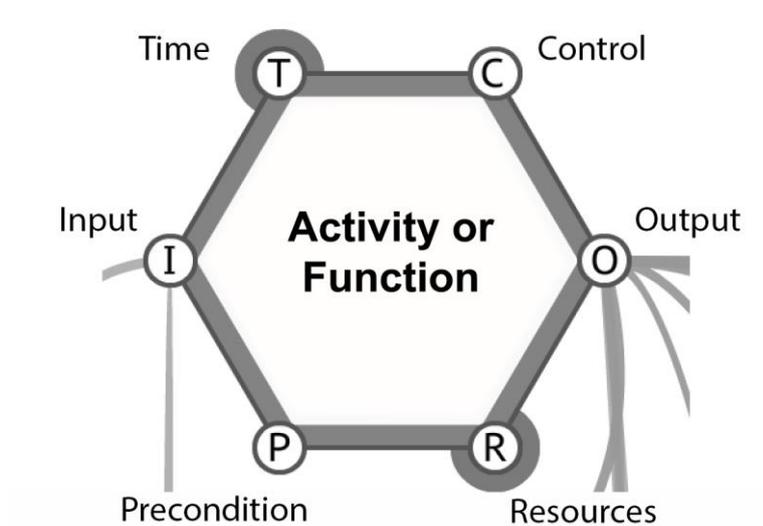
Source: Hollnagel(96)

A FRAM is created by mapping activities to show how the task is completed, including where and how the activities depend on each other. For example, a FRAM of the task 'how to make a cup noodle' is shown in Figure 17. In the FRAM, making a cup noodle is comprised of eight tasks: 1) buying the cup noodle, 2) boiling the water, 3) folding back the lid, 4) adding boiling water to the cup, 5) closing the lid, 6) letting the cup stand for three minutes, 7) opening the lid and stirring the noodles, and 8) eating the cup noodle. We can see, by looking at the activity 'eating the cup noodle', that the final activity necessary to complete the task is dependent on time (wait three minutes), resources (buying a cup noodle in the first place), and a chain of activities involving boiling water and adding that to the cup. While this model is very simple, creating FRAMs of more complex tasks can show how complex work is accomplished, and how, for example, activities that are completed late or not done at all can adversely impact on successful completion of the task.

Figure 17. How to make a cup noodle
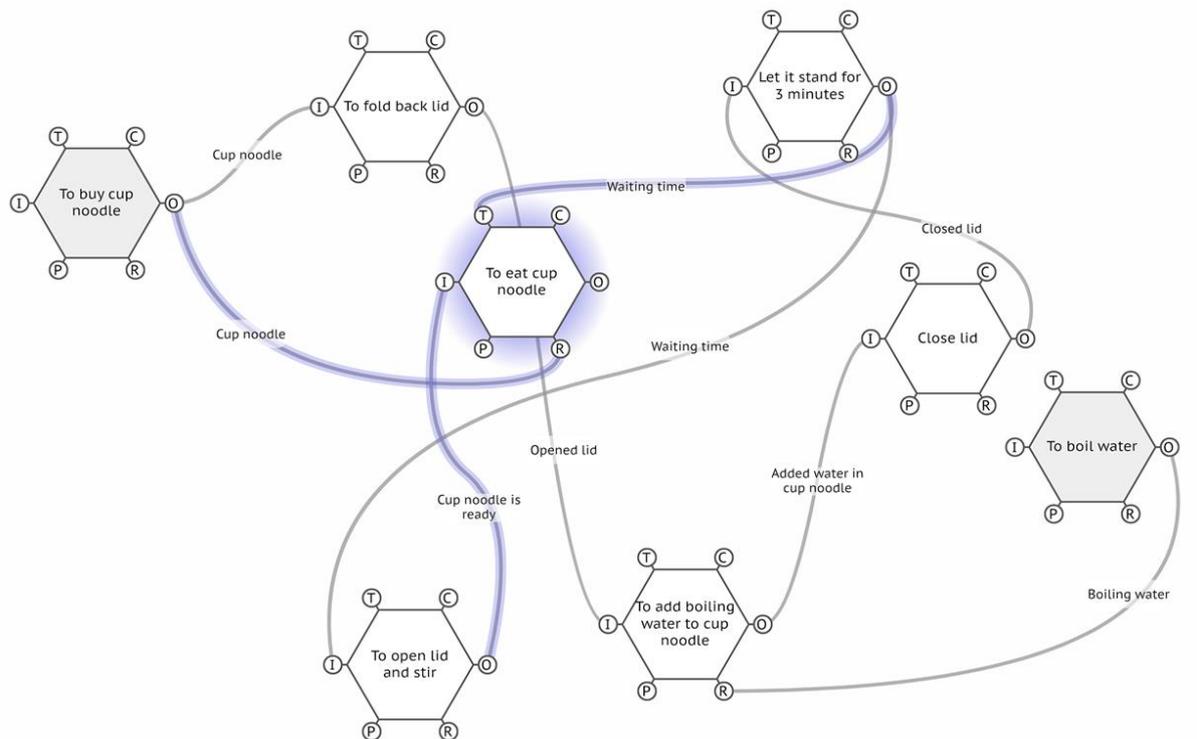
Source: Authors' own work

FRAM is used both retrospectively and prospectively to improve systems in many fields (including the aviation, transport, and petrochemical industries) to ensure quality and safety, and is particularly well suited to understanding the variability that is necessary to accomplish everyday work in healthcare.(97)

In this section we have presented the way that qualitative research can be used to understand how work is done by clinicians at the frontline of patient care, and how workplace culture may contribute to organisational performance. We can use that understanding to improve both workplace processes and workplace culture.

Future directions: Where to from here?

Mixed methods research allows for a deeper understanding of research questions than is often possible using a single methodological approach or method, alone. The integration of qualitative and quantitative data can build a rich and nuanced picture of what is going on *in-situ*, and the possible motivations and mechanisms behind people's activities, interactions and

actions. A recent editorial in the *Journal of Mixed Methods Research*(84) noted that recognition of the value of mixed methods research by funding agencies has opened up some new opportunities for these research designs. This will go some way to broadening publishing opportunities, as journals begin to acknowledge the value of mixed methods approaches and integrated data.

By recognising the benefits of, and needs for, researchers to form specialised teams for mixed methods approaches, with team members bringing strong qualitative and quantitative skills to bear, we predict that mixed methods research will really come into its own. Specialised software is also emerging to support mixed methods research designs; for example, designs that can help researchers to analyse a combination of numerical and narrative data together. This is welcome news, as the availability of "big data", despite its inherent problems in terms of the management of extensive datasets, opens new and exciting avenues for qualitative researchers.

"Seeing comes before words. The child looks and recognizes before it can speak. But there is also another sense in which seeing comes before words. It is seeing which establishes our place in the surrounding world; we explain that world with words, but words can never undo the fact that we are surrounded by it. The relation between what we see and what we know is never settled".

John Berger, Ways of Seeing, 1977

PART II – Modern Methods and Creative Pathways

New ways of seeing data: Data capture through imagery and words

Bio-photographic elicitation technique: What is it, what is its value, and how does it work?

In the last 10 years, still photography and biography have emerged as important social scientific research methods. These two, in combination as 'bio-photographic elicitation techniques', are part of a wide range of new techniques specifically designed to encourage researchers to describe and interpret how we view the world.(98) New approaches to apprehending social action and interpreting it provide researchers with opportunities to move away from formulaic notions of conducting research,(99) while encouraging people to take an interest in research that extends beyond belief in the 'status of numbers'.(100) By broadening the scope of qualitative inquiry, methodologies like biography, auto-biography, video imaging and still photography have become more than ploys to elicit data in creative ways. They have become alternative epistemic positions. Our knowledge of the world and how to be in the world, and our stances from which to view the world, are all enlarging, and enriching as a consequence.(101, 102)

In health services and medical research contexts, researchers are also moving into intra-methods approaches whereby more than one method within the same methodological paradigm is being harnessed, i.e., qualitative and quantitative methods used in conjunction with each other. And, as we have seen, mixed methods approaches are also being increasingly popular—so that more than one method is deployed across methodological paradigms, i.e., qualitative and quantitative methods in combination. These are described in detail in the 'Mixed methods design' section above. Many health services researchers mix methods, as this is now regarded as more mainstream.(41, 86) But intra-methods can also support triangulation of data, enabling researchers to group findings from different qualitative datasets together, and by comparing and contrasting the results, providing a greater depth of understanding.(103) While some qualitative researchers have criticised this as leading to method undercutting and the blurring of boundaries,(104) Todres and Holloway(105(p100)) have remarked how this can be avoided

if the data collection and analysis procedures are clearly explained, and by highlighting the research team's "intentions and philosophical underpinnings".

Intra-methods triangulation of data, where, for example, two qualitative datasets are combined, can also be applied to photographic and biographic data used in conjunction.(106) Text and imagery is a powerful combination, enabling research teams to see and read about what people do, why they do it, and to what end. In combination, this allows researchers to not only compare one set of data with another,(107) but also to introduce the possibility that one dataset extends the other in new and dynamic ways. While there is a current over-familiarity with textual data in health services research (and in other domains of research activity, too), introducing visual data often triggers a powerful response in study participants to enthusiastically join research studies and ensure high-quality data.

Triangulating biographic and photographic data findings encourages researchers to reconceptualise the work they are undertaking and consider what exactly they are hoping to achieve through the analysis of not only words, but also imagery. Thus, rather than falling back on 'reading' the possibilities that words render, an over-dependence on understanding through words alone, is radically reduced. Consequently, researchers are encouraged to find other ways to approach data and its presentation, and search for valid and reliable methods that make sense in the context of their research studies. To examine the power of bio-photographic elicitation techniques further, let us delve into the realms of photography and biography.

Photography

Within health services research and medical research, unlike in the social sciences and anthropology more broadly,(108) the photograph has played only a minor role in data capture to date. In addition, its focus has been primarily on data generation to underpin the development of a research question, or a set of questions, rather than as a way of generating data that are an end in themselves. However, photographs can give birth to stories that are essentially valuable and valid.(109, 110) Photographs that are shown to research participants in the context of bio-photographic elicitation interviews (where photographs and biographies are shared with participants in an interview context) help clarify issues arising in the photographic detail. They also enable a researcher to watch a participant's response to their data and record its emotive effect. They can, for example, stimulate views on what or who really matters in a person's life,

the impact of their lifestyle or relationship on their quality of life, and their hopes for a disease-free future. In addition, they can offer study participants a platform from which to provide their own commentary on the power of visual images, thus supporting researchers to not only 'read' their meaning but also define the value of the technique. Take, as an example, the work of Radley and Taylor,(111) where patients photographed aspects of a general medical hospital ward that related to their experience of illness and recovery. Data were discussed at a later stage through bio-photographic elicitation interviews to clarify patients' reflections on their healthcare needs and the stage they were at in their illness recovery journey. Photographs revealed, in this case, how the process of remembering is one of transference between different representations, and Radley and Taylor concluded that by responding to the photographs, patients were indicating ways in which the physical setting was integrally linked to recovery through a 'coexistence' of body and ward.

Images have been employed many times by anthropologists to serve as records of reality; "documentary evidence of the people, places, things, actions and events they depict";(110(p4)) and, less commonly, as aesthetic products or evocative images (see for example Barthes).(112) In 'A Fortunate Man', Berger and Mohr(113) used photographs to evoke different rural environments where general practitioners' (GPs) reside, illustrating how different settings provide the context within which people's lives and lifestyles take place. Their work led to a consideration of the deceptive nature of landscapes and the way that they can provide 'a curtain' behind which the theatre of life is played out: "For those who, with the inhabitants, are behind the curtain, landmarks are no longer only geographic but also biographical and personal".(113(p13))

Rapport has used photographs in her own research(21, 114, 115) putting data collection into the hands of the research participants (see Illustration 6), and enabling GPs, nurses, and pharmacists, all working in community and primary care settings, to examine the impact of workspace on practice. She has encouraged practitioners to take their own photographs of their working environments and through the visual images they have collected, to tell a story of their workspace. Her work moves beyond a conventional reliance on single-source data for interpreting workspace presentations to the use of multiple sources, rich in imagery and narrative content. The work recognises that textual expression alone can only offer partial insights into human experience and that by employing photographs taken by practitioners and biographies written by practitioners, as vehicles to knowledge, richer examples of work

environments can be disclosed. Rapport's work delves deeply into different styles of practice, and the impact of healthcare environments on patient care, as well as the emotions and memories that this engenders for practitioners. Analysis of data from these studies enabled teams of researchers to work together to consider whether visual data findings were echoed in biographical data findings from the same groups of practitioners, and around similar themes.(20, 21)

Illustration 6. Photography and the visual image

Source: The Irish Times(116)

Biography

Like photography, biography also offers a departure from traditional data collection methods. Biography gives insights into different languages-in-use on a global scale (see Illustration 7), indicating how different people and cultures 'word the world'.(117) Biography may also lead to personal revelations and offer research participants a forum to tell their lived experiences to others, through the recreation of the lived world, without the direct influence of the researcher. Traditionally, biographies have been used to help formulate hypotheses in research, based on the notion that biography in and of itself lacks reliability.(118, 119) However, according to Hatch and Wisniewski(120(p128-129)) biography provides us with a range of alternative notions of reliability, including: "adequacy, aesthetic finality, accessibility, authenticity, credibility, explanatory power, persuasiveness, coherence, plausibility, trustworthiness, epistemological validity and verisimilitude".

Illustration 7. Biography: a global concept
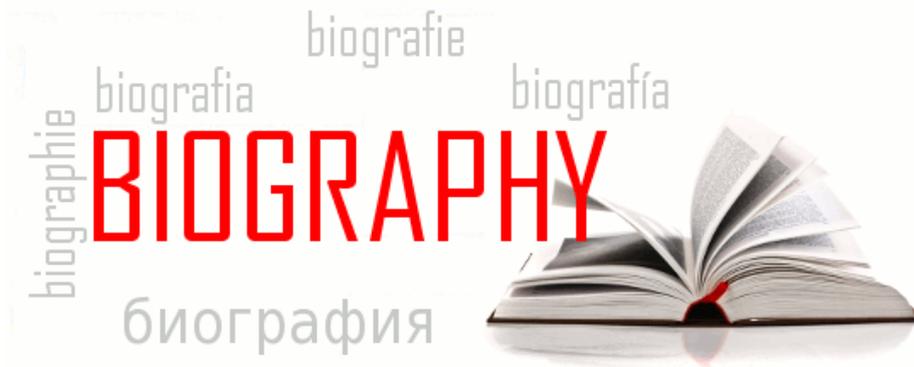
Source: Bettin(121)

Biography, within a health research context, can clarify how individuals give meaning to health and illness and can instil social realism into data collection.(122) It can also help research participants to situate events within a meaningful and socially significant frame of reference. Extending beyond the human, researchers may also undertake biographies of objects, in order to reveal the 'social lives of things', from their myriad uses and 'careers' to their manifold powers and affects.(112, 123-126) Object-orientated biography is an especially powerful technique for disclosing how the form, function, and significance of objects is fashioned in context and mutable over space and time.(127-132) For example, a brick in the hand of a builder has neither the same capacity for action nor the same meaning and social significance as when it is taken up by a conceptual artist or a rioter. Object-orientated biographies allow the researcher to trace the impact that objects have in our social worlds,(133) and the social interests that they serve.(134) The fact that inanimate objects are usually considered in relation to what they allow humans to accomplish, or to reveal how humans place themselves in the world in relation to the objects in question (human agency), has only a limited recognition in the world of the healthcare researcher. The potential of object-orientated biography as a potential stand-alone research topic in health services research is, therefore an exciting prospect, but one that is currently less than self-evident.

In its range of forms; including oral testimony, written text, autobiography and the examination of personal artefacts, such as diaries, letters and memoirs, subject-centred and object-orientated biographies can be analysed both as a stand-alone product or grouped with other data, such as photographs, as an 'inter-textual' activity.(118) Inter-textual examination explores how texts refer to, respond to, transform and are transformed by other data (texts,

visual data or otherwise), and how the range of representations of the social world from these linked or referential data are configured. "We understand the social world through the lens of prior representation, because whenever something is invoked which happened somewhere else, or in some other time, or to someone else, then representation is being utilized" (Stanley and Morgan).(135(p3)) Consequently, inter-textual examination makes links between datasets based on the manner in which one set of data triggers, invokes and eventually clarifies understanding of the range of possible representations of others' social worlds. In our consideration of how object-orientated biographies and photographs impact one on the other, in terms of their power as research methods, it is the inter-textual nature of these datasets that is most usually investigated.

Analysis of bio-photographic data

There are a wide variety of different approaches to undertaking an inter-textual analysis of bio-photographic data (with or without the inclusion of bio-photographic elicitation interviews). Bio-photographic datasets are usually and most usefully analysed by multidisciplinary research teams, drawn from across a wide variety of disciplines to bring several viewpoints to bear, including, but not being limited to: human geography, psychology, health science, education, and health services research. Individual researchers can work alone, at first, to view datasets (looking at still images of photographs, or videos, and reading in-depth biographies), before coming together to compare and contrast their initial responses to the data. Group analysis sessions usually take place on more than one occasion and can be lengthy. These help the group to bond, to recognise each other's disciplinary strengths and points of view and to encourage a thoughtful response to all the datasets. Sessions enable researchers to move away from over-generalising the data, to concentrate on the particularities of their and other researchers' observations. They also facilitate group discussion of the complex, multi-perspectival relations within datasets and the juxtaposition of parts and wholes of images and texts. Each dataset is treated both as a discrete unit and in relation to the other dataset or sets, so that inter-textual interpretation and intra-method triangulation can take place. This is usually accomplished in terms of: the process of data collection, the ability of data to address study aims and objectives, revelations regarding study content and context, and the rich display of imagery and written work relating to the way in which reality is rendered.

Rapport's work using bio-photographic elicitation techniques led to the development of a visual taxonomic framework (a framework with clear component parts that relate to one another) that helped sort and clarify visual data findings (see, for example, Rapport's work with GPs, nurses and community pharmacists).(20, 21, 103, 115) The taxonomic framework takes into account: visual and textual context and content, object presentations, clustering and frequency, and visual affect. In addition, the taxonomic framework can help to reveal: connections between photographs and biographical writings, and resolutions to research questions that may be concerned with, for example:

- Descriptions of working practices, daily routines, everyday events and extraordinary events.
- Expressions of self-identity and self-worth.
- Connections between people and places and people and things.
- Impact of environment, treatment, and illness on people's lives.
- 'Practitioner situatedness' (how people feel in different settings or in relation to different healthcare systems) and spatial awareness.
- The 'positioning' of people in relation to one another, and in relationship to objects and spaces (see also the work of Crang(136) and Garlick(137)).

Finally, researchers can use a taxonomic framework to explore special or social organisation, social function, and people's actions, while group analysis sessions that include biography and imagery together can help reveal emergent patterns in content, context, stylistic approach, format and presentation.(138)

There are many approaches for analysing biographies described in the literature (e.g., Denzin(139) and Creswell(140)). One such approach is the interpretive biographic stance(138, 141) where interpretation of both form and content of biographical detail is encouraged, first individually and then in a group, leading to a biographic analytic framework. The final framework with biographic data can be derived thematically, stylistically, narratively, or in the form of a succinct story.(122) As with visual data analysis, group analysis sessions can help researchers concentrate on: what has been written, how it was written, and how exactly it relates to research questions, or study aims and objectives. In the case of Rapport's work, that examined the relationship between health professionals working in community and primary

care settings. The study examined care practices and interrelationships and conducted interpretive biographic analysis of primary and community care practitioners' views of their professional personas. This revealed a strong relationship between self-identity, workspace and practice, seniority and action, and personality and affect (emotive investment in the professional workspace).(20, 21, 103)

Most commonly, during group analysis sessions biographic and photographic datasets are treated in their entirety to ensure a thorough 'reveal' of visual and textual evidence to support the developing taxonomic and interpretive frameworks. However, when it comes to study reporting, due to the limitations of space, the inclusion of complete biographic and photographic datasets is unrealistic, and choices must be made about what to include, and how. Data presentations are normally representative of the wider datasets, showing patterns or incongruities in those datasets, dominant themes in each dataset, or revelations from the work of data triangulation. Presentations need to uphold each dataset's consistency and integrity, such that even when datasets converge, one cannot be discounted as merely serving to illustrate another. Here, as elsewhere, visual and textual data from two distinct series, and the relationship between them, is always differential, and never identical.(100, 142) This is why it is necessary to present both the words and the pictures together, in order to express a particular power or affect. For even where the content of each appears to be the same, neither the text nor the image is redundant. They stand in a relation of 'supplementarity' (supplementing one another, and adding substance and meaning to each other) while at the same time they express a 'difference producing repetition'.(143) The visual and textual are always juxtaposed so that the reader or audience can consider how ideas are rendered differently with different media. They highlight different styles of data presentation and indicate how these different styles lend themselves to an enriched understanding of the special contexts in which a researcher is working.

Ethnographic poetic representation: What is it, what is its value, and how does it work?

What is it?

Ethnographic poetic representation, also known as 'poetic rendition', 'poetics' and 'poetic transcription', is a method for the co-creation of meaning in narrative texts derived from the

implicit relationship of a storyteller, a listener and an audience, participating together in an act of shared knowing for a particular purpose.(144) As a qualitative methodological technique, ethnographic poetic representation is far outside the norm. It has yet to come of age in health services and medical research fields, despite being held in high esteem across a range of social science disciplines.(145-147)

How does it work?

If any, one, qualitative method could be described as non-conformist, then ethnographic poetic representation would be it. Based on literary experimentation, this method is dramatically different, to, say, thematic or content analysis, cracking open academic restrictions. It works by rendering, through expertly crafted re-presentations, others' statements about the authenticity of life and biography. It is dependent on the management of language that is strongly mediated by dialogue. It melds academic and creative writing skills, and it looks for the idiosyncratic expressions that result from a researcher's engagement with others. It takes an original dialogue and breaks it down into its composite parts before quickly rebuilding it again. It appeals to wide audiences to take responsibility for meaning-making, be they academic, lay, health service or other, apportioning meaning to others' words. It reclaims ordinary language and through reconstruction, presents it as poetry. It abides by the doctrine that with words "meaning is poetry".(148(p23)) It aims to make the familiar fresh and strange, by redesigning stories in poetic form. It "revivifies language and narrative"(149(p32)) and holds dear the notion that there is an energy in speech. It upholds the working method as much as the end product, reflecting on the symbiosis between the energy of speaking and the energy of listening, reproduced as poetic inscription. It is a 'poetics in practice', demanding intense engagement from the researcher, searching to shape and place original narratives as new stories according to strict boundaries but with non-prescriptive working methods. It aims to ensure that the end product is ethically sound. To understand another's story often involves returning time and again to the storyteller, revisiting the story, and gaining the storyteller's approval. Where necessary this may mean modifying the work, until it is accepted by the storyteller.

Ethnographic poetic representations are derived from research scenarios that are within raw data. Once recognised, these are drawn out, line by line, sentence by sentence, phrase by phrase, paragraph by paragraph, as distillations of a complete body of work. "Identifying and drawing them out, whilst recognising what is superfluous, is a complex process born out of a

sense of coming to know the material and careful distillation".(150(p87)) The process retains nuance and rich description, as well as the ambiguity of speech, but leads to a more "urgent" piece of prose, full of dense, rich language. Boundaries of the method mean that words cannot be changed or rearranged, though some may be lost. All that is laid down on paper is as it was in the original text, irrespective of grammatical irregularity, spelling error or unusual phrasing (see Figure 18).

Figure 18. Staying true to original texts irrespective of typographic errors

This text has some problems

This text has other problems, although similar in nature

Source: Hoffman(151)

The method demands that the researcher worries and works the material extensively,(150, 152) until sense-making, born out of a notion of where this all leads, gives the text a fuller weight, texture and flow. The process has its own internal dynamics,(153) and while precise stages cannot be readily defined (this is not a step-by-step, one-size-fits-all technique), broad stages can be followed:

Stage 1: *Thinking within the material* – as the researcher and storyteller co-create meaning through their dialogic relationship, they become interdependent through a questioning and answering format, repositioning the story and determining its direction. As they get to understand one another more, and appreciate the work more fully, they draw a story out, using language to word their relationship.

Stage 2: *The development of research scenarios* – a thoughtful and reflective consideration on the part of the researcher allows the dialogue that has ensued to become clearer, and through further discussion with the storyteller, around events, conversations and self-realisations, research scenarios appear in the text as lynchpins for the story's coherence.

Research scenarios are removed from the story in the order in which they were presented, word for word.

Stage 3: *Data distillation* – The distillation of research scenarios, in keeping with other ethnographic approaches to data management, is self-regulated (see Box 2 below for detail). In this instance, words remain unaltered and their order remains constant. Data distillation aims to capture the essence of a story in prose format, compacted to encapsulate key moments and key expressions that give the story its resonance, and when the final pieces are presented to an audience, meaning-making begins.

Box 2. Data distillation and self-regulation in ethnographic poetic representation

- Words are handled in the order in which they appear in the text.

- Sentences retain their original order.

- Sentences retain their original tense.

- Sentences retain grammatical inconsistency and typographic errors.

- Distillation can only take place with research scenarios.

- Research scenarios are derived from the stories, resulting from the researcher's ability to think with the material to hand.

- Data must be presented in the order of the original story, irrespective of topic or factual chronology.

- Ethnographic poetic representations must be allowed to have their own temporal storylines according to events as told.

Source: Rapport and Sparkes(154)

Judging a piece of ethnographic poetic representation

The value and strength of a piece of ethnographic poetic representation can be judged according to the following criteria outlined in Box 3.

Box 3. Judging ethnographic poetic pieces

- Does the piece engender an empathic response from the reader or live audience?

- Does the piece appear believable?

- Does the text appear to be 'truthful' expositions of what happened during data collection?

- Does the piece take the reader on a journey through the storyteller's experience, including their thoughts, emotions, connections, opinions, and interactions?

- Does the piece reveal the merit and demerit of re-presentation?

- Does the piece encapsulate a story fully or does it appear to have elements missing?

- Does the piece encourage the reader or live audience to 'bear witness' to the story as told, transporting them to the scene of the event, interaction or experience?

- Does the re-presentation appear 'truthful' or over-indulgent?

Source: Authors' own work

In appreciate the application of this method, the reader may wish to read more about its use in practice. If you wish to do so, you can find detailed examples in the following references to Rapport's work.(150, 154)

Making sense of complex data

Summative analysis: What is it, and how does it work?

How was summative analysis developed?

Summative analysis is a qualitative data analysis technique that was designed by the lead author to grapple with particularly complex, difficult, emotive or sensitive texts using qualitative applications. Once designed, between 2009 and 2010 the method underwent a period of tests as it was applied in research contexts in the UK, the United States, and Norway. Groups of researchers, health professionals and other interested parties tested its relevance to their own and others' work, through group workshops (two per group, twenty in total), following which, the method was refined and then published.(155)

Summative analysis was the result of a seven-year study that examined female Holocaust survivor's health trajectories and biographical life stories.(148-150, 153, 154) The study assessed: a) the impact of 'events-as-told' (also known as the 'lived life')(156, 157) on mental and physical resilience, b) change-over-time, c) personal initiatives for the management of trauma, and, d) the impact of the 'lived life' on others' health trajectories and biographical life stories. Testimonials were collected from survivors and family members in the form of lengthy, personalised accounts, disclosed through multiple, open ended, face-to-face interviews that led to an extensive number of qualitative interview transcripts.

The method was originally designed to manage these data(155) but grew to encompass other complex, qualitative data in a range of textual formats, collected from people who found themselves disenfranchised from society or experiencing some kind of mental health problem or trauma. The method indicated what was distinctive and impactful about their experience and encouraged others to analyse stories that were difficult to tell and difficult to hear. It was applied to a wide variety of stories from different storytellers, mainly people who felt they were living on the edge of society. It was also considered useful for work with people who described themselves as being part of a minority group or a dispersed population, subjected to a harrowing experience or a life crisis.

What is it?

Summative analysis is a group technique that is wholly dependent on a collective commitment and ongoing involvement with stories (see Illustration 6 for interconnections through group-working). Analysts must be interested in a topic to come to it with a shared passion to reveal what is meaningful about it. The group work facilitator (often a researcher) decides which data to use, and irrespective of his or her own knowledge of the topic or insights into the data, commits the group to reveal its 'critical moments' (also known as 'eureka moments' or 'precious vignettes'). These are the moments that give the data its meaning; that the storyteller has presented through the telling of his or her tale, and that offer the story its unique resonance. However, critical moments may not be immediately apparent, and while they give the text substance, they have to be not only disclosed but also agreed upon by all analysts, before they can be inscribed and interpreted.

Summative analysis is in-depth and protracted, but at the same time very powerful and equalising. It encourages groups of likeminded people to come together enthusiastically, as peer collaborators and on an equal footing. It endorses the notion that everyone's view and set of experiences is valid, and part of the ongoing co-creative process. It also supports the view that everyone's opinion adds something to a new, shared narrative, that will be derived from the work, to embellish the 'lived life', by enabling stories to become more than the sum of their parts.(13, 148, 149)

Illustration 8. Group work diagram
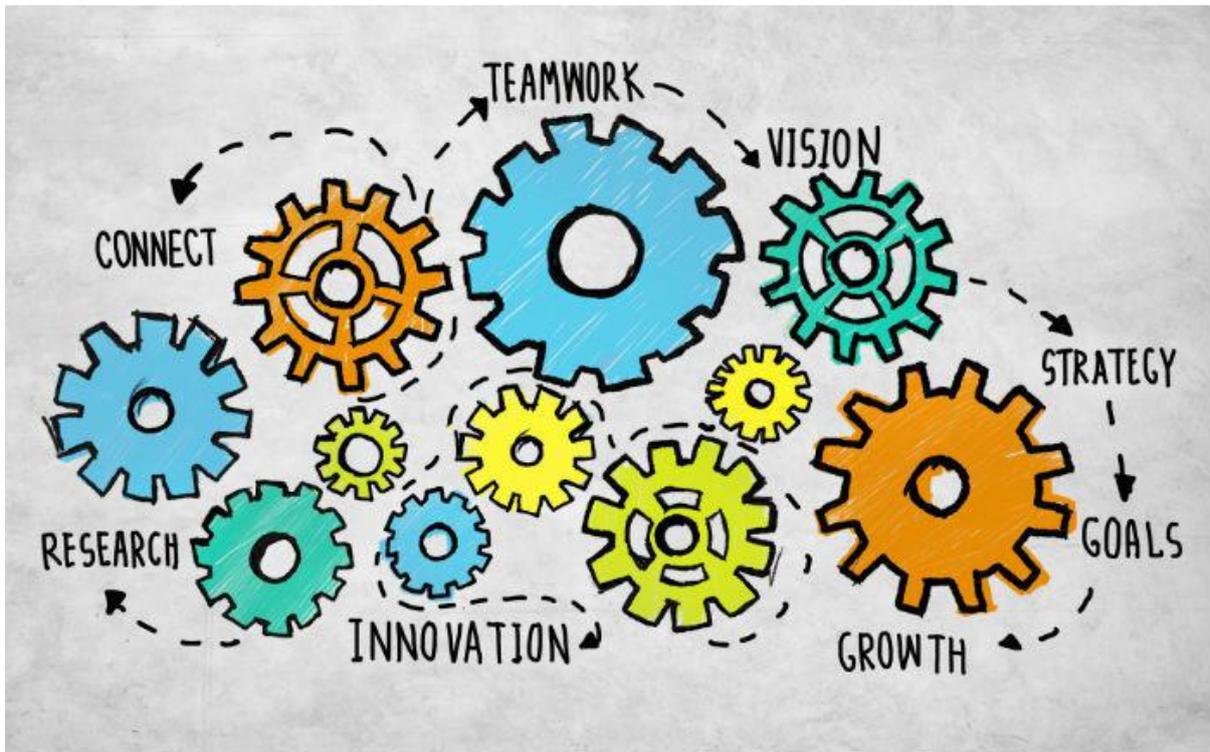
Source: Center for Management & Organization Effectiveness(158)

Qualitative texts in health services research contexts often take the form of interview transcripts or focus group transcripts,(159) and are predominantly handled by a single researcher who works alone. This is not the case with summative analysis. Here, transcripts or textual data in other forms are managed by a group, who study them, following some initial individual work. As the work is time consuming, texts are often chosen to represent the complete dataset, but choices about which data to consider depend on the demands of the study and the facilitator's wishes. Irrespective of the quantity of texts being used, summative analysis aims to examine: a) the research topic, b) the story's content and context, c) the storyteller's style and intent, d) the working relationships that unfold as people negotiate and renegotiate group understanding, e) the ideas of the group, and f) how the group coalesce around group understanding.

Co-researchers (as they are known in this activity) can be chosen for any number of reasons, including: *Purposively*: to cover a mixture of research backgrounds and expertise. *Representationally*: to support different academic bodies or levels of knowledge. *Disciplinarily*: to marry, for example, different healthcare sectors, early- mid- and senior-career

researchers, public and professional bodies, and patient representative groups. Whether the constituencies represent academic, healthcare professional, mixed-group, or public bodies, the working methods should remain the same: everyone should have a voice and an equal part to play, and everyone should be responsible for the ethical reporting of study outputs, defined collaboratively.

How does it work?

As Miles and Huberman(160) have noted, all analysis is reductive, and to this extent summative analysis is no different. It searches for critical moments, without which, the complete body of work would lose its inherent meaning. Summative analysis presents these critical moments comprehensively, ensuring none of importance are missed, and all are fully defined. Critical moments give entry points to a text. They are revealed rather than taken for granted. They result from an intensive reading and re-reading of texts in whole and in part. They contextualise texts within any given situation or setting, and they encourage researchers to consider: the relationship between speaker (storyteller), listener (often the researcher), and audience (at this stage, the analytic team), and the story's content.

Summative analysis uses critical moments to craft a refined version of the storyteller's tale. Critical moments are markers according to which the group can weave a path through the narrative and direct the overall summative style and presentational effect. Critical moments take time to realise. Building on an initial phase of individual work, critical moments are agreed upon by the whole working group. They are ordered and reordered, conceptualised, described and eventually interpreted. Work develops through fluid prose presentations, and the group aims to lay down the known facts that the raw data discloses before turning these into a group response to the data – giving data a group voice. Group work needs to be uncontested and endorsed by all members, as descriptions become interpretations, and interpretations become critical analytical references to what is happening and why, within a contextual framework. This is achieved through consensus-building activity, ongoing group meetings that aim to ensure that not only are research analysts grappling with texts that on their own they might shy away from (seeing them as too difficult or distressing), but that the group members can come to know and appreciate each other's perspective over time.

Stages of summative analysis

Summative analysis comprises four Stages:

Stage 1: Individual paragraphs are produced as summative responses to the raw data. They aim to encourage individual analysts to: a) crystallise the content of the story, b) consider the storyteller-listener relationship, and c) reveal the critical moments running through the story. They are there to impart information descriptively, rather than encourage an interpretation of the data or provide an analytic or theoretical critique.

Stage 2: Group work re-stories individual data according to group discussions through ongoing workshops. Based on consensus-building activities, group work involves all members equally, discussing and examining individuals' paragraphs, and then classifying all the critical moments that the group agree upon, and presenting them chronologically, hierarchically, or in some other meaningful order that the group decide. Group work relies on the raw data, and positions critical moments according to the relationships and contexts that give them relevance. Critical moments offer markers or way-lines that direct group work and keep the work bounded.

Stage 3: The development of a single group paragraph for each piece of text reviewed summarises the groups' synthesis of the co-researchers' work. This is created by all analysts and must both retain the individuals' work and thought processes and be collaboratively produced—and thus is a new piece of work. The strength of the group paragraph lies in the depth of thought that has gone into its production, derived from both personal awareness and a collective voice.

Stage 4: This is the stage where the group is at liberty to interpret the group paragraph. This is also the stage where critical moments are 'exploded' or 'unpacked', so that all critical moments that make up the final summative paragraph are embellished. This is achieved through an interpretative group stance. During Stage 4 the facilitator ensures that the work includes nuance as necessary, and that the paragraph takes account of the contextualising features of the topic under review (be it, for example, set within a political, financial, organisational, system-orientated, or societal framework).

The strengths and challenges of summative analysis

Summative analysis takes time and energy. It is not a method to be undertaken lightly and the facilitator must be prepared to be an arbiter or group-work chair so that the process runs smoothly. However, if support is needed, the facilitator must be able to provide it, without overwhelming the group or diminishing the work. The strengths of the method are manifold. Summative analysis enables researchers to learn from one another, share disciplinary strengths and skills, combine ideas and working methods, share common goals and determine shared understanding and reasoning. It encourages team members to immerse themselves in rich, detailed and varied data for an extended period of time, and it makes difficult, complex, or convoluted stories understandable and manageable. It ensures that issues are dealt with sensitively and compassionately while staying close to the storyteller's voice, and by so doing, upholds the speaker's intentions. It levels as it empowers and sets a steady pace, by preventing individuals from running away with the work. The iterative nature of the activity helps to reveal the true meanings belying the text, built layer upon layer, until a final, carefully revised, explanatory summative paragraph can be prepared for wider audience consumption.

Schema analysis: What is it, what is its value, and how does it work?

How was schema analysis developed?

Schema analysis is a novel qualitative data analysis method perfected for use in health services research contexts by members of this team. While previously derived from the work of Rapport and others in the field of oncology decision-aid development,(19, 161) most recently, schema analysis has been ascribed by the team to help clarify the role of MDTs in breast cancer risk communication.(34) As with summative analysis, schema analysis is a group-working method, but it stems from the Nominal Group Technique (NGT), which examines problems, looks for solutions and shares decisions for those solutions with group members.(115) Similarly, schema analysis examines data, looks for ways of effecting a re-presentation of that data schematically, and examines, with input from researchers, the best way to do that. Instead of working with exemplars that are agreed by all group members, that ascribe to the data levels of clarity (as with NGT), schema analysis depends on the creation of schematic frameworks to indicate a shared understanding of a whole body of text, while ensuring findings can be clearly linked to a study's research aims and objectives.

It is a method that is dependent on team member awareness, and unlike the Realist Constructivist method,(162) or descriptive phenomenology(163) which favour the omnipotence of individual researcher opinion as unique and special, it shies away from authorial presence in favour of shared creativity. The debate continues as to the value of individual awareness and single-researcher working methods over group-work methods and team awareness (see Illustration 9). Furthermore, schema analysis, unlike thematic analysis, which breaks texts down into chunks of data ready for sorting and coding,(164) joins text up into flowing, complete narratives that through their wholism, bring meaning to others' lives.

Illustration 9. Arguments against individual working in favour of group-working methods
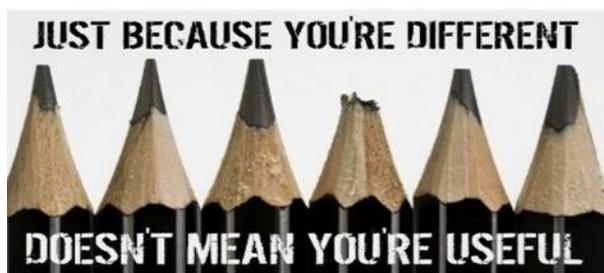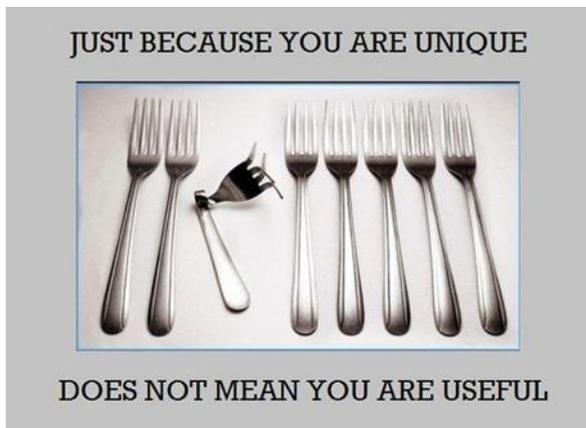
Source: (Top) The Windsor(165) (Bottom) Ramachandran(166)

Schema analysis rejects over-determinism. It is predicated on narratives that are malleable, which can be altered and varied, and which indicate both the researchers' decisions but also the story's direction. A piece of work that is derived from a schema presents a beginning, a middle, and an end. It does so through the production of one or more schematic frameworks, one per piece of data examined. They must be flowing rather than discombobulated, and meaning-laden, rather than disembodied. The purpose of a schematic framework is to recreate a text in

a new form, that is briefer than the original but nevertheless foregrounds the qualitative attributes of rich 'thick' description.(26)

The method aims to offer a clear representation of the original piece of narrative text in an essentialised format. Unlike summative analysis, which concentrates on critical moments, schema analysis avoids breaking up the text in any way. There are no hierarchies within the text. Rather it demands a re-presentation of the whole text, be it in a much-reduced format, with each re-presentation dependent on a richly fluid, new narrative which, while briefer, does not lose any of the original text's mannerisms, style, or effect. Schema frameworks appeal to the mimic, collaboratively recreating the original according to their own presentational style which once created, can then be examined for their interpretive overtones. Schema analysis is particularly effective with lengthy transcripts, from, for example, focus group data, and schemas can include verbatim quotations from study participants, to reflect a single speaker's voice or group of speakers' voices. Schema analysis workshops, with groups of researchers working together according to an ethos of shared decision-making, ensure group dialogue around which aspects of the original text to retain, and which to discard. Group workshops are dependent on an openness and awareness of the views of all group members, with individuals prepared to bow to the consensus-view, adapting to fit in more appropriately with the group.

How does it work? The stages of schema analysis

Schema analysis is principled on three critical stages:

Stage 1. Individual schemas: Individuals agree to attend three group workshops following the development of their own schematic frameworks. These are created 'blind', before any group interaction takes place, based purely on their reading of the raw material. Raw materials that are appropriate take many forms: focus group transcripts, biographic or autobiographic narratives, and open-ended interviews. Individual frameworks are personalised but aim to crystallise data into a much-reduced form of a half to a full page of text. Individual schemas should retain the feel of the original and be descriptive rather than interpretive. No additional material should be added that was not contained within the original text. Individual schemas can be written in a prose format that reflects the form in which the original was delivered. Schemas are not dependent on an individual researcher being familiar with the topic, context, or methods that led to the data being collected. Rather, they take into account the style and

intent of the original presentation, the research participant's approach to the topic, use of words and phrasing, and the critical 'truths' that together blend into a whole, to give a piece its uniqueness and originality.

Stage 2. Group schemas or 'meta-schemas': For each set of individual schemas, depending on the number of texts being worked on at any one time, there will be a set of group schemas or meta-schemas created during ongoing group workshops. Group schemas are co-created from a combination of all the individual schemas, with overlapping materials discarded, and shared ideas re-presented in an agreed format to create one flowing, directional narrative. These are holistic presentations that take time to design. They follow discussions about the integration of each person's individual schema. They are derived from how individual sections have been worded and are built, in effect, through meaning-in-the-making. The group must decide what is relevant, and what adds character or is a distraction. They must also decide whether the originator's voice is being heard or is being lost along the way. In creating group schemas, researchers consult and take equal responsibility for the finished product, letting go of some of the work they individually created, and standing behind others' ideas and presentational styles, for a truly composite end result.

Stage 3. Interpretation of meta-schemas: This is the stage for interpreting the meta-schemas. Up until this stage, interpretation is avoided with the whole group working purely descriptively, however as researchers come to know the texts better they begin to consider their meaning. During Stage 3, the group are at liberty to aim for a higher-level of understanding which will embellish the brief presentations with layers of interpretation. This adds to the richness of the presentations, with interpretations lying alongside rather than embedded within, the meta-schemas. Meanings are derived through shared understanding, illustrating what pages of text have to offer wider audiences. At this stage, the context can also be brought into the mix, to clarify how the meta-schemas sit within a wider political, social or organisational context. The context can also present descriptions of the environments or settings surrounding the meta-schemas. Following interpretation and embellishment, reporting can include all three stages, or can simply present the meta-schemas and their interpretations. The manner of reporting will be up to the group but is dependent on the needs of the group to produce, for example, an internal report, a funder's report, an academic publication or a piece for general consumption.

The strengths and challenges of schema analysis

Schema analysis enriches the learning process, bringing groups of researchers together to learn from each other, while encouraging mixed disciplinary, multi-level researchers to work together. It also ensures that data are rigorously handled and adds to the validity of the outputs, indicating meta-schemas as reasonable, dependable and credible. It links back to a study's aims and objectives, and through its working methods, convincingly achieves meaningful findings.

However, the process is extensive. Meta-analyses are not achieved quickly, and trustworthiness must be upheld throughout the working method, by the group returning to the raw material to ensure members are being true to the data and to the participants involved. Until group consensus is achieved, at each of the three stages, the group cannot move on to the next stage, and this to-ing and fro-ing may mean that results take longer to generate than with single researcher analysis methods.

Results, however, when achieved, are very clear, and groups of researchers can be confident in the results being highly polished and ready for publication and presentation. Meta-schemas are also transferable to other contexts and indicative of how data can be applied to other situations and settings.

"Critical illness offers the experience of being taken to the threshold of life, from which you can see where your life could end. From that vantage point you are both forced and allowed to think in new ways about the value of your life. Alive but detached from everyday living, you can finally stop to consider why you live as you have and what future you would like, if any future is possible. Illness takes away parts of your life, but in doing so it gives you the opportunity to choose the life you will lead, as opposed to living out the one you have simply accumulated over the years".

Arthur W. Frank, At the Will of the Body, 2002

PART III – Applications with Worked Examples

This section presents three examples of the application of qualitative methods in practice across a variety of health areas. The first examines decision-making in a deteriorating condition; the second, the culture of hospital services and healthcare systems; and the third explores decision-making and communication in breast cancer treatment.

1. Caring for patients with a deteriorating condition: A study of patient-centred decision-making and co-designed decision tools

Chronic and deteriorating conditions present a range of challenges to patients and families, as they attempt to manage their health and wellbeing in continually changing circumstances. In this context, qualitative methods are used to capture the lived experience of people with deteriorating conditions. Qualitative methods elicit in-depth responses from participants to understand their viewpoints on the problem under examination. In the example of deteriorating conditions, participant views give us insights into the barriers and facilitators to appropriate healthcare, and the roles that patients, family members and health professionals undertake. Ultimately, the goal of this kind of research is to improve the care patients receive, and the way that care is delivered. This is particularly pertinent to conditions where treatments have little impact on the disease course, and symptom management and quality of life measures are more relevant. If patients are unable to be cured, or have their disease effectively slowed, they must make choices that align with their values and principles, such as whether to use equipment that artificially extends life. Qualitative research can assist patients and health professionals to understand patients' values, rather than simply relying on predetermined quality of life measures, and direct care in a more patient-centred way, tailored to individual preferences. Uncovering patient preferences and values requires methods that allow participants time and space to express their thoughts, such as unstructured or semi-structured interviews. To demonstrate the application of qualitative methods, we present an example from the field of patient decision-making, set in a deteriorating and terminal neurological condition—motor neurone disease (MND).

MND is a terminal neurological disorder without a cure. Death occurs, on average, two to five years after diagnosis. The course of MND is characterised by continual slow deterioration

as nerve cells in the brain responsible for movement progressively die. The presentation of the disease, and speed at which it progresses, varies considerably between individuals. Physical and cognitive changes may be present. Physical symptoms can include loss of mobility, hand and arm function, speech, voice, swallowing and respiratory function. Many people will also experience mild changes to behaviour, memory and thinking skills, while a minority will present with a form of dementia, with or without accompanying physical symptoms. While a small number have an inherited form of the disease, for most, the cause is unknown. As yet, there are no effective treatments to stop or slow the disease. Management is through multidisciplinary care of symptoms with the aim of providing services and equipment in rapid response to patients' changing symptoms. Family carers play a vital role in patient care as the patient becomes more physically dependent, providing logistical and hands-on-care, as well as emotional support. A range of health professionals work closely with the patient and family to ensure effective care, from diagnosis to end-of-life care.

People living with MND require timely services and skilled care to respond to their changing priorities and needs as the disease progresses and their health deteriorates, and as they continually negotiate care services and symptom relief options to make their life more comfortable. Nevertheless, the shock of receiving a diagnosis of MND frequently affects patients' capacity to engage with MND health professionals and participate in their care, even within specialised multidisciplinary services.(167) This can challenge patients' decision-making, which needs to be well-timed to be most effective when it comes to optimal symptom management.(168) Decision tools that support patients and families to make well-timed, and well-informed, care decisions, are one means of achieving this aim. By capturing the lived experience of people with MND and their family members, decision tools can assist health professionals and researchers to learn first-hand what is important to people with MND, what effects their decision-making, and how they can be best-supported. Moreover, by eliciting the perspectives of health professionals in this, researchers can identify ways to improve patient services, and tailor care to the needs of each individual amongst this complex patient group.

To illustrate the use of qualitative methods in improving care, we present a sequence of two studies which act as case studies of decision-making in MND. The first is a case study about the development of a decision-making model to guide MND care; and the second is a case study about the development of decision tools to support people living with MND that

aims to support patients when they are faced with making difficult choices over care and quality of life.(48)

Study 1 – Understanding patients' decision-making in MND care: Towards a decision-making model

This study, conducted as a doctoral thesis (2010-2013), uncovered multiple aspects of the decision-making processes of people living with MND for their symptom management and quality of life.(169) Decisions faced by patients can include the use of: medication; equipment for assisted respiration; devices to augment or replace speech; artificial feeding and hydration; end-of-life care; and whether to undergo genetic testing. The study employed semi-structured interviews with 13 MND patients, analysed thematically, to uncover the perspectives of people living with MND on making their decisions for care and quality of life.(170) In addition to patient perspectives, eight family carers were interviewed(171) and 32 MND health professionals' advice was sought, as key stakeholders,(167) in order to identify their views and roles in the patient's decision-making process. Patients and family carers identified a cyclical process of decision-making, where patients moved back and forth between gathering information about the option being considered and deciding whether to go ahead with their choice of end-of-life care, or to take a quality of life approach. Patients relied on support from family carers and health professionals to help them to make complex decisions, ranging from whether to use a powered wheelchair, to deciding whether to have surgical interventions, such as gastrostomy insertion for artificial nutrition and hydration. Carers spoke of their need for high quality, evidence-based information, as patients frequently depended on them to synthesise the information on their behalf. Patients and carers depended on health professionals to inform them of the options available to them, and to facilitate the process of implementing their choices, such as procuring equipment and services. Health professionals identified a range of challenges to providing proactive and well-timed advice and services that included connections with external service-providers and reported on the difficulties of engaging with patients who were unable to accept their diagnosis. Enablers of good care included being able to present consistent, evidence-based information, and working together as a united team.

The study data gave a group of researchers a valuable triad of perspectives from which to form the basis of a model of decision-making (as yet untested), which could be used to guide

decision-making discussions between patients, carers and health professionals in MND multidisciplinary care (Figure 19).(168) During the study, it became evident that for the model to be effectively implemented, some form of decision support for patients and health professionals was needed. Decision tools (or decision aids) have been used in cancer and chronic diseases to assist patients to make informed choices between options available for treatment, that align with their personal preferences and values.(172) Participants in our study agreed that tools that gave patients evidence-based and best practice information, and assisted patients through making decisions were of value. Thus, the second study was to develop decision tools to support MND patients in clinical care.

Figure 19. Model of patient decision-making to guide MND multidisciplinary care
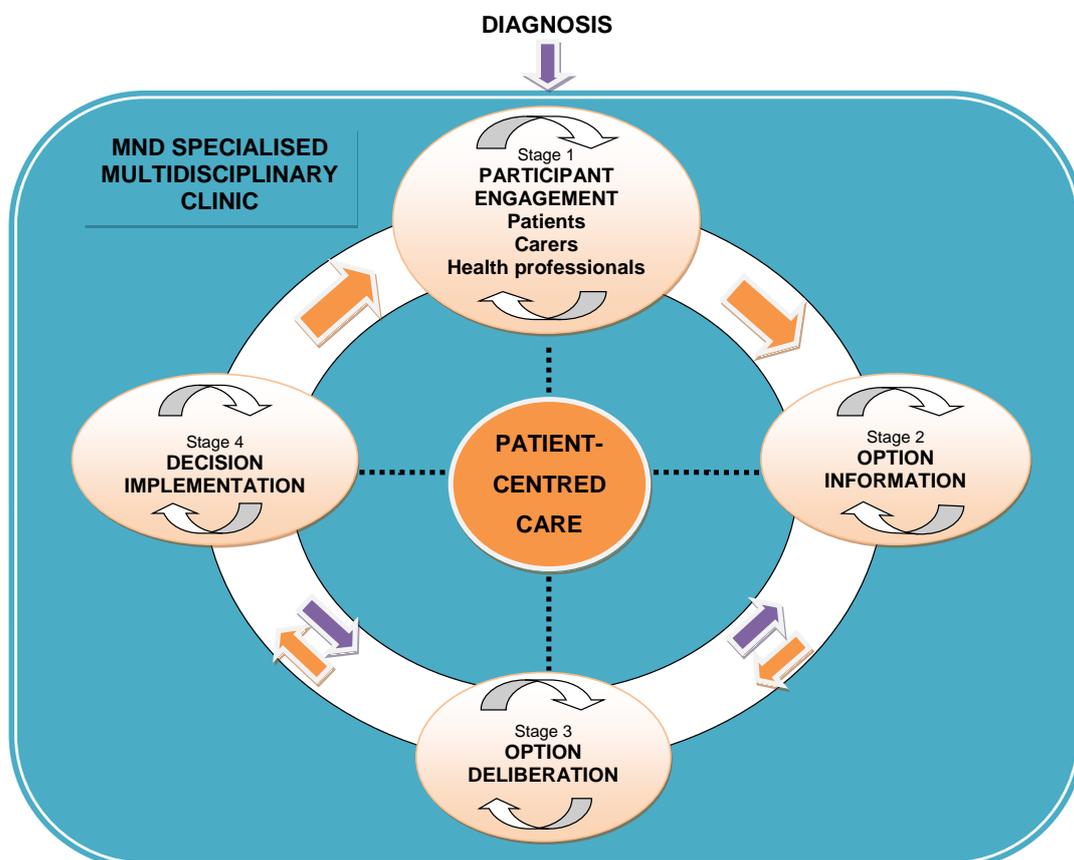
Source: Hogden(168)

Study 2 – Development of decision tools to support people living with MND to make care decisions

Decision support tools are used to facilitate discussion between health professionals, patients and families, to inform patients about the treatment options available to them. They also help patients to recognise and clarify their personal preferences, values and attitudes, and understand the associated risks and benefits of treatment, therapy or care options, including the likely health and quality of life consequences for them in the short- and long-term. Patients are then better equipped to make informed choices to optimally organise their care and uphold a reasonable quality of life.(173)

Decision support tools can come in various forms. They can be provided as paper-, web- or app-based modes of delivery. They have been shown via a Cochrane review to increase patient engagement in healthcare decision-making, facilitate good communication between patients and health professionals, reduce unnecessary treatment and avoid emergency admissions.(174) There are few evidence-based decision support tools for people living with neurodegenerative diseases and their families, and the particular challenges that these conditions present for preference-sensitive decision-making.(175) Moreover, until this research there were no tools available for people living with MND. This second study was designed to identify which kind of support tools would be useful to patients with MND, their carers and health professionals, and then develop and evaluate tools to support patient care for end-of-life quality improvement.

Decision support tools can improve the lives of people living with MND by offering a framework to enhance patient-centred services and quality of care, by facilitating discussion between health professionals, patients and families. Patients are then able to make decisions based on a clearer understanding of the risks and benefits of the available options for treatment and care, and the possible consequences of delaying active treatment, or choosing to do nothing.(176) With limited life-extending options available, treatment and care choices based on patients' personal preferences and values become increasingly salient as to how care is negotiated.(19)

This second study asked two research questions:

1. Which decision-making tools are needed to support MND patients?
2. What is the optimal content, format and delivery of tools for MND multidisciplinary care?

To answer both questions, we used a co-design process(177, 178) to identify topics for tools, determine their optimal format, and begin their development.(179) Co-design (also known as co-production) is a process whereby researchers join with other stakeholders to produce a piece of work which is generated by, and representative of, the stakeholders' experience and needs.(180) By involving participants who are also people for whom the tools are designed (the stakeholder in this scenario along with health professionals supporting patients' care), researchers can ensure that the resulting tools are as much as possible developed 'by the people, for the people'.

Other advantages of co-design are the enhancement of a patient-centred foundation for the tools(181) making them, as a result, more clinically useful and client-relevant. Furthermore, decision support tools that researchers develop with patients, carers and health professionals can optimise patient participation in care planning, enhance patient quality of life through well-timed decisions, and provide a greater sense of patient ownership over planned treatments. The contribution of health professionals to tool development promotes their feasibility within clinical settings, with a focus on placing the patient and their carers at the core of decision-making. Being able to co-design solutions—whether as strategies for symptom management, methods of service delivery, or issues of healthcare policy development—is an effective and rewarding way of supporting health professionals to improve the lives of people living with MND, with the potential for longer-term, sustainable, positive impacts on quality of life.(19, 161)

The disadvantage of co-design is that consultation costs. It can be a slow and lengthy process to ensure that all participants have time to contribute their viewpoints and stay engaged with the project, and so is difficult to contain within a short, or rigid, time frame. Counterbalancing this, the quality of the final product is safeguarded by allowing extensive time for iterative consultation.

This study relied upon three- stages (Table 6), conducted through an iterative and comprehensive consultation process with potential tool users (MND patients, their family carers and health professionals from MND clinics) and other stakeholders with a professional interest in MND tools and their design, including MND support association representatives, and representation from the advocacy and education peak body, MND Australia. Researchers with expertise in MND healthcare, decision tool development and human factors engineering also participated. Together, these 14 stakeholders acted as an expert panel, to contribute their experience and expertise to tool development, and validate the tools for usability and feasibility in clinical care. As panel members were located across Australia and internationally, the consultation process between the study team and panel members was conducted by email.

To answer the first research question, the expert panel members were asked to identify topics they considered would benefit from a decision tool. Participants were educated in the characteristics of a decision tool, and how they differed from information websites or fact sheets. Consultation occurred in rounds, as follows: the lead researcher sent a document to each of the expert panel members, who then returned it with comments to the study team. Once all comments were received, the primary study researcher (AH) updated the document and sent it out again for further comment. A preliminary list, drawn from the MND symptom management literature, was emailed to panel members. The expert panel contributed suggestions to the list, identifying 56 options for symptom management and quality of life that were frequently encountered by people living with MND. These options fell into a range of categories that included: medication, procedures, support services, equipment and end-of-life concerns. From these categories, six high priority topics were selected as suitable for development into a decision support tool. This was achieved through a ranking process, whereby each of the 56 topics was rated on a 7-point scale, according to participants' agreement with the statement: "MND patients will benefit from decision support tools to inform them and clarify their preferences". There was strong agreement on six topics, and these were prioritised for tool development: use of gastrostomy for nutrition and hydration; use of assisted ventilation; decision-making for genetic testing; choice of end-of-life care location; equipment to augment or replace speech; and advance care planning. Most of the remaining topics were considered more appropriate for development into fact sheets, where none currently exist (such as those already available on MND support association websites).

Once question one was answered, the second research question could be addressed. A review of the decision support tools and implementation research literature, including discussions with decision-tool developers, indicated that web-based (as opposed to paper-based or mobile app-based) tools were the optimal mode of delivery. It was determined that the tools should be developed as websites, to ensure they were readily accessible by patients, families and health professionals, and easy to handle, both at the point of care (clinic or home-based), and outside of clinical consultations. This would also make accessibility easier from mobile devices, such as a tablet, laptop or phone, to allow clinicians to discuss decision-making wherever convenient to the patient. Ideally, these tools would be able to be used in a range of MND clinical settings, with individual practitioners or within an MDT. Guidelines for use reflecting this range of settings was planned to be built into the tool websites and the tools are currently in the process of being developed to a prototype stage.

The mode of delivery of decision support tools is also likely to influence their clinical usefulness and sustainability. Tools developed as websites offer advantages over paper- or app-based tools, in that they are easily accessed at the point of care and outside consultations, and more readily updated and maintained. Moreover, as websites they are able to link to other evidence-informed MND sites. The MND Australia and MNDcare webpages, for example, offer a rich source of-best practice information for patients, families and health professionals.

As a co-design process was used to develop the tool, plans were put in place to not only evaluate the tool itself, but also assess the process used to develop the tool (Table 7). Qualitative methods were considered the most appropriate means to achieve this, allowing stakeholders to feed back to the study team about their involvement. Expert panel members will be asked, for example, once the prototype has been tested, to comment via email on the development process using a free-text proforma, to gather their views on the benefits and challenges of the process, and how it might be improved. Aspects for evaluation were perceived to have maximum impact if they focused on inclusion and consultation, modes of communication, frequency of contact, and representation (see Table 6 and Table 7).

Table 6. Stage 1 Prototype development process for professional feedback and evaluation

Process	Objective	Method	Outcome
Planning and preparation	Identify best practice for: • MND care • decision tool development processes	Literature scan of: • MND symptom management • Quality of life issues • Decision tool development processes • User-centred design	1. Determine evidence base and user perspectives from literature 2. Gain ethics approval for study
Implementation	Form expert panel	Recruitment of expert panel members from stakeholder group	3. Determine tool users' priorities for MND tool topics
Implementation and monitoring loop	Development of tool drafts	Consultation via email: • Expert panel discussion • Voting process • Feedback loop with panel members as development progresses	4. Nomination of five highest priority tools 5. Tool draft for consultation
Evaluation	Review of draft tools	Consultation via email: • Review by expert panel on tool content and format • Assessment against international decision tool criteria (IPDAS checklist)	6. Tool prototype
Evaluation	Validation of tool prototypes	Consultation via email: • Expert panel and study team consensus	7. Signoff by panel members
Reporting	Knowledge translation and dissemination	• Written reports • Publication • Presentations	8. Funding body report 9. Peer-reviewed journal publication (study protocol) 10. Presentation to MND community

Source: Authors' own work

Table 7. Stage 2 Validation of development process (planned)

Process	Objective	Method	Outcome
Evaluation	Refinement and validation of tool development process	• Feedback from panel members on development process • Documentation of development process • Validation of process by expert panel and study team	• Formal mapping and documentation of the development process used in the study • A draft of this document will be circulated to the expert panel • The expert panel will be asked to give feedback on ways the process could have been improved • The process will then be refined according to participant feedback • Documentation of process for knowledge translation
Reporting	Knowledge dissemination	• Reporting to HREC • Reporting to funding body • Feedback to participants • Publication of study findings	• Written reports • Email newsletter to participants • Peer-reviewed journal publication for clinical and academic communities • Seminar presentations to MND community

Source: Authors' own work

Once the working prototypes are developed, Stage 3 is planned to begin. Firstly, the primary study researcher (AH) will pilot the tools in a clinical setting to further refine them for clinical use, based on feedback from patients, carers and health professionals. Following this, a widescale project will commence to implement and evaluate the tools across a range of clinical settings. It is anticipated that 12-18 months will be required to achieve this in a range of MND clinics across Australia. The evaluation will use qualitative methods, such as focus

groups and interviews, to garner the triad of patients', family carers' and health professionals' responses to the decision support tools, and to determine how the tools contributed to improving care for, and quality of life of, people living with MND.

Our two studies add to the growing body of qualitative work in MND, most recently reviewed by Sakellariou et al.(182) A range of studies have explored patient, carer and health professional experiences on living and working with MND, encountering and delivering health services, from diagnosis to end-of-life. Methods of data collection have included: individual interviews (semi-structured,(183, 184) narrative,(185, 186) and open-ended(187)); group interviews(188) and focus groups.(167) Analysis methods have ranged from concept mapping(187) to thematic analysis(170, 184) and grounded theory.(189, 190)

This second study is the first to apply co-design techniques—more frequently used in decision tool development work(191)—to MND service delivery. By so doing, we offer a practical solution to a pressing clinical problem. We anticipate that this comprehensive approach of iterative consultation, built on a foundation of in-depth research, will result in tools that improve the lives of people with MND. As revealed in this monograph, there is scope to broaden the range of methods used, deepening our understanding of what it is to live with MND, and enabling patients and families to contribute to improving the care and services they receive.

2. Working at the coalface: The culture of hospital services and healthcare systems

Understanding organisational behaviour has been key to efforts to improve the safety and effectiveness of patient care. Behaviour related to patient safety can be characterised in terms of two related concepts: safety climate and safety culture. Safety climate refers to the perceived value placed on safety in an organisation and is usually determined through quantitative methods. Examples include accreditation audits,(192) and assessment of attitudes and teamwork via surveys such as the Safety Attitude Questionnaire(193) and other metrics. Safety culture consists of the shared beliefs, values and traditions in relation to safety in the workplace, typified by the phrase 'how we do things around here'. Unlike climate, culture is not something that can be easily quantified. While there are broad instruments, such as the Competing Values

Framework,(194) available to characterise the culture of organisations, it is unlikely that any single tool can provide a valid and reliable assessment of an organisation's culture.(195) To understand norms or shared values, we need to talk to people in the workplace and observe their behaviours—in short, we need qualitative methods.

An example of work examining cultural norms and values within an organisation's culture is a study recently conducted by Clay-Williams et al.(196) in a large regional Australian hospital. The aim of the research was to observe and evaluate the implementation of an Intensive Care Unit (ICU) intervention (see Box 4) to improve patient flow through the ICU. Frequent cancellations of elective surgery at short notice, due to lack of ICU beds, resulted, in this hospital, in poor relations between staff in the ICU and staff in the Surgery Department, and conflict between clinicians within the ICU. Provision of ICU beds is expensive due to the complexity of treatment. While there can be large variation in requirement for ICU beds resulting from unexpected arrivals at EDs or deterioration of the health of patients within hospitals, in this case, the resources required to maintain continuous capacity for peak load were unduly prohibitive. Consequently, a better way was needed to effectively manage variation in demand within a setting where there were clear resource constraints. To address this problem, senior clinicians and managers in the hospital collaboratively developed an escalation plan in order to optimise flow of patients through the ICU, and to balance planning of major elective surgery with unpredictable emergency admissions.

The study used a multi-method approach to examine cultural norms and values within the context of this case, involving staff interviews, process mapping and the collection of audit data. Process mapping of the activities and professional relationships associated with managing ICU beds was conducting using FRAM.(97) The FRAM method was previously described in Part I. Collection and analysis of audit data for this project used quantitative methods, though these will not be described here as it is outside the context of this monograph.

The ICU intervention consisted of the implementation of an ICU Escalation Plan, introduction of a multidisciplinary morning meeting to determine ICU status in accordance with the plan, and an optional education session for health professionals on resilience and systems thinking. The ICU Escalation Plan (see Figure 20) is a workplace guideline with three readiness states: GREEN, AMBER and RED.

Box 4. The ICU Intervention (196)

- GREEN readiness indicates the ICU can accept a greater patient load, such that further elective surgery cases can be considered.

- AMBER readiness indicates the system is approaching capacity in the next 24 hours such that elective surgery may be cancelled.

- RED readiness indicates the ICU is at capacity and that surgery requiring ICU support will be cancelled and emergency admissions may not be accommodated.

Figure 20. The ICU Escalation Plan

Green	Amber	Red
ICU can accept 2 unplanned admissions / 24hrs PLUS Elective surgery patients	ICU expecting to be at >13 patients / 24hrs	ICU at physical capacity (14 beds) - Elective surgery cancelled - Delayed / denied ICU admission
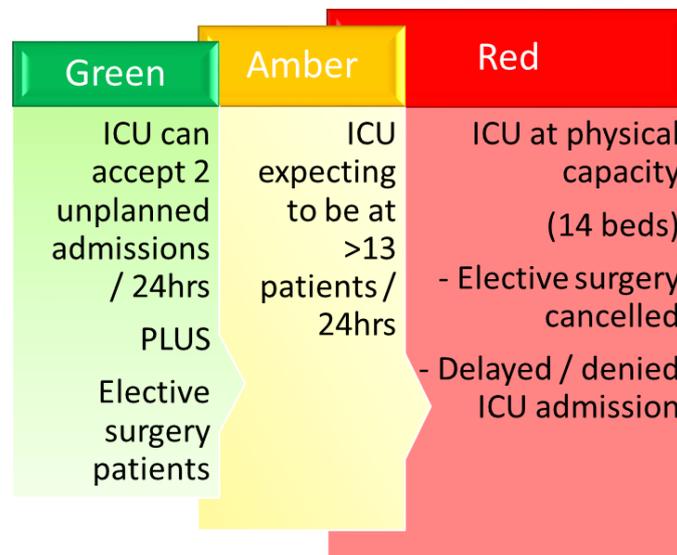
Source: Adapted from Townsville Hospital and Health Service Workplace Instruction: TTH ICU BED CRISIS ESCALATION PLAN: November 2013

Methods

Pre-implementation, semi-structured interviews were conducted with 12 ICU doctors, nurses and hospital managers, to collect information on staff perceptions of ICU workplace cohesiveness in light of the pressures of too few available beds. Post-implementation interviews were conducted with 19 ICU doctors, nurses and hospital managers, several months after the escalation plan was introduced, to collect staff perceptions of the plan, implementation

processes, and ICU performance. The aim of these latter interviews was to establish whether effects, such as improved communication and collaborative working, seen earlier on in implementation, persisted, changed, or were degraded or lost, and to discover any new impressions after natural evolution over time, and the bedding down of the intervention.

Data were analysed in an integrated fashion. Inductive interpretive analysis of transcribed interviews was undertaken to identify key themes relating to the introduction of the escalation plan. Applying this systematic method ensured analysts did not impose categories unnecessarily on any data developed *a priori,* but rather allowed participants' views to come to the fore to help structure the analysis. Although the same set of questions was asked of each participant, the semi-structured nature of the interviews enabled the interviewer to bring variation into question ordering, allowing conversations to flow more naturally, and encouraging participants to reveal their own understanding of an issue without excessive prompting. Thematically coding the data(197) allowed data to be organised efficiently, and codes helped the research team to explore connections between data elements. Once coded, segments of data were linked to one another to allow themes to emerge, and to determine relationships between different datasets. This technique is frequently applied to the study of real world complex systems such as those found in examinations of healthcare cultures.(33)

Participants in this study identified a number of perceived benefits of the intervention,(196) including improved teamwork and better communication. These benefits manifested as smoother information flow, closer MDT working and enhanced professional relationships, and facilitated a common understanding of the ICU bed state and its implications for other departments. Implementation of the escalation plan meant that it was clear how decisions were made and who was responsible for implementing those decisions. This clarity led to greater initiative in solving problems, with clinicians willing to 'own' their part in ICU bed planning. This resulted in less conflict within the ICU and better rapport with other hospital departments, leading to improved job satisfaction for ICU clinicians. Participants also felt that the intervention resulted in new ways of thinking, including moving from a 'silos' to a 'systems' viewpoint. Clinicians started to think in terms of the 'system', and how patient flow was about the whole of the hospital, not just the ICU, Surgery Department or ED.

3. Understanding decision-making and communication in breast cancer treatment

Clinical implementation issues in breast cancer treatment

Breast cancer is the most common cancer amongst Australian women, with approximately 16,000 new diagnoses in 2016.(198) In recent years, improvements in treatment and detection strategies have increased the 5 year survival rates to 89%(198) highlighting the important role played by high-quality patient care in reducing breast cancer mortality.

Treatment decision-making in the breast cancer context can be complex.(199, 200) Clinical treatment and adjuvant therapies may include one or more surgical interventions, and several courses of chemotherapy, radiation therapy, and hormone treatments. These can vary in sequence and length, depending on the response of the tumour. With each medical option, as patients progress to a new stage of treatment, there may be greater uncertainty, as outcomes of each stage are difficult to predict, and the benefits of treatment may come with potential risks, complications, and side-effects.(201, 202)

For both patients and clinicians, there are key issues in the implementation of breast cancer treatment that require better understanding. The way that patients think about their current and ongoing risk status, for example, can be influenced by their own and their clinician's intentions for treatment and care, where they are in the treatment pathway, their concerns for their future health, and their expectations for ongoing care and support.(34, 203-206) For clinicians, increasing collaboration within MDTs can enhance the quality of care, but can also make communication with patients and care transitions more complex, as patients are managed by ever-growing numbers of different clinicians with different opinions, approaches, and practices.

If we want to bring about positive outcomes from breast cancer treatment and risk management, better understanding of the diversity in practice between clinicians is needed. Even more importantly, insights into how patients, clinicians, and other important stakeholders (such as close family members and patient carers) communicate with one another could underpin more patient-centric strategies of risk communication.

Study design

A team of us conducted a qualitative study to examine patients' and clinicians' perspectives on oncology treatment decision-making, and the effect of communication and inter-personal relationships on patients' experiences of risk management.(34, 206) The study took place between August 2016 and January 2017, at a breast cancer program in a metropolitan private hospital in New South Wales, Australia.

The study, based on a previous UK study's results,(34) utilised an intra-qualitative methods approach, applying more than one qualitative method in combination with data managed corroboratively using triangulation (see page 38 for more detail). The first ten patients undergoing treatment at the study site who consented to take part in the study between October and December 2016, were sampled. Inclusion criteria stipulated that patients needed to be competent in English language, had to be 18 years of age or over, and deemed, by clinicians, to be physically and mentally capable of participating. Eight clinicians within the metropolitan private hospital who played a role in caring for one or more of the patients involved, were also recruited. Purposive sampling was applied to clinician recruitment, to ensure maximum variation of consultation style, treatment approach, and length of service. Fourteen clinical consultations were observed, and 17 individual, in-depth interviews with patients and clinicians were conducted, once observations had taken place. Observations of the clinical consultation examined communication between clinicians and patients, including the timing of discussions, the language used during consultations, and the intentions expressed. In addition, observations noted whether risk status, and risk management were discussed during the consultation, whether conversations included other clinicians responsible for the patient's care and what plans were made for transitions between healthcare services. We also observed whether other family members or carers were involved in decision-making around patient treatments. A study researcher took detailed notes during observations and conversations were audio-recorded. Semi-structured interviews, which lasted between 30 and 45 minutes, followed observational work. These were also audio-recorded and notated, before being transcribed verbatim.

Group schema analysis of data

A schema analysis of the transcribed, raw data was conducted. We applied a schematic framework to help with the analysis of textual data, ensuring all the essential elements of a dataset are captured in one, free flowing, narrative text, and enabling researchers to work together to craft succinct descriptions of all data content.(79, 207) The analysis team of four worked individually to write personalised schemas before creating meta-schemas from their work together. Once individual analysts had written their own schemas and had come together to discuss their work, the meta-schemas could emerge. At each stage of analysis, the group concentrated on the meaning derived from full transcripts from the perspective of the research participants (clinicians or patients) and discussed how the rich, crystallised vignettes of each piece of text ensured essential meaning of the original pieces was retained and re-presented, in the form of coherent, free-flowing narratives. Meta-schemas, one for each transcript, grew out of the group-work activities.

Group-work allows multiple perspectives to be shared(208) and in this study the four researchers worked collaboratively, led by a senior academic experienced in schema analysis. Members of the analysis team also examined the study researcher's observational fieldnotes, which were used to underpin a richer, group understanding. Observation notes and interview transcripts were considered side-by-side at each analysis meeting, and together they enhanced the accuracy of each dataset, while different perspectives and notations around similar situations and events, once clarified, adding to the validity of the data analysis process.

Results of the study

Here, we report from both the perspective of the patients (Finding 1) and the health professionals (Finding 2).

Finding 1: Patients' self-management of breast cancer risk: Gaining control in clinical and non-clinical settings.(209)

A key aspect of patients' understanding of breast cancer risk resulted from a sense of uncertainty about the outcomes of their illness and treatments. Taking active management of

their cancer, by undergoing medical treatment, while seeking out regimes of self-care outside of the clinic, were considered valuable ways of gaining a greater sense of control over one's illness, in times of extreme uncertainty.

In the clinic, taking control of tumour growth was recognised by patients as a surgical intervention, with or without chemotherapy or radiation treatment. Patients relied heavily on their relationships with clinical healthcare professionals for guidance on clinical illness management. By maintaining trust and confidence in the treating team, they were able to feel more certain of the clinical context.

However, outside the clinic, patients gained a sense of control by feeling that they were actively managing their own health. Self-initiated care regimes included: seeking additional information from internet sources about risk, risk management and treatment; getting advice from friends and family; making lifestyle changes through improved diet and exercise; reconsidering household hygiene; obtaining psychological support from psychologists and others; and seeking alternative therapies. Reassurance, derived from actively pursuing regimes of self-care, enhanced patients' quality of life and gave them more confidence in the outcomes of clinical treatment.

Through practices of self-care and self-management, patients achieved a heightened sense of control over the uncertainty of their illness and their long-term quality of life. This was an important addition to the reassurance and support offered by others, such as clinicians and close family members. These ways of seeking more certainty over risk status were clearly complementary. In turn, healthcare services guided patients towards sources of information that might help them and suggested non-clinical ways of seeking support that complemented clinical care.

Understanding risk in breast cancer is less about offering patients a concrete definition, than explaining the contextual circumstances in which patients find themselves, while recognising their shifting sense of uncertainty and certainty about the treatment journeys they are expected to pursue. A variety of clinical and non-clinical means of establishing greater certainty and confidence are vital management strategies that could help patients gain a greater sense of ownership over their bodies at this time. Building better links between clinical and non-clinical means of establishing certainty could also encourage patients to feel more in

control and supported in both realms. For example, guidance from clinicians about the most appropriate diet and exercise can help patients to take better care of themselves. Patient support groups, endorsed by treating clinicians, could then link patients to clinical and non-clinical realms of support.

Recognising that patients need greater certainty around their risk status, and clarity around risk management strategies would also help them participate more effectively in sharing in the decisions about their healthcare with clinicians, towards a co-created set of outcomes.

Finding 2: A multidisciplinary team's thoughts on supportive relationships with breast cancer patients.(210)

Our team analysed four in-depth interviews with health professionals using case study analysis technique.(211) Case study analysis aims to examine a case, or a specific example of a phenomenon, in-depth, within its real-life context, to allow a deeper understanding of the phenomenon. The revelatory case study approach was used in this instance, as a single-case that allowed researchers to access descriptive details of MDT working patterns. The case study was considered holistically, using a single unit of analysis to build a rich picture of individual practice within the unique context within which MDTs function. In this study, the case was four individual members of a breast cancer MDT. This case study aimed to demonstrate how the clinicians worked together to deliver patient care. The case contextualised MDT working practices in breast cancer and demonstrated how patient care was delivered through teams of clinicians working together.

The four members of the MDT were: a clinical psychologist; a radiation therapist; a medical oncologist; and a breast cancer surgeon. They described their approach to patient care as entailing: "effective communication" and: "consistent information exchange", that is, the sharing of information with patients about their concerns or emerging treatment issues as treatment progressed. The four clinicians suggested that effective communication and consistent information-exchange provides patients with reassurance, whilst enhancing understanding of patient needs and the values of the clinical team members. Adapting to MDT teamwork, and if necessary, changing communication strategies to support a more person-centric approach, was valued. Each individual clinician related to his or her colleagues in the professional team and the patients being treated according to their own roles,

responsibilities and disciplinary values (Figure 21). For example, the medical oncologist and the surgeon tended to provide patients with clinical advice and guidance. However, patients often drew on the support of allied health professionals, such as the clinical psychologist and radiation therapist, to support them in making decisions, as well as in coping with the intensity of cancer treatment. The clinical psychologist played a mediation role between the patient, the surgeon and the medical oncologist, to ensure patients' values were reflected in treatment decision-making. On the other hand, the radiation therapist would spend a lot of time in personal contact with patients, to support their physical and psychological health during treatments. Most crucially, the aim of the MDT was perceived as ensuring patients remained at the centre of collaborative working practice, despite not all team members communicating directly with one another.

The results of this finding from the breast cancer study showed that whilst MDTs function to ensure coherent treatment planning and clearly defined clinical pathways, both team-based and individual practices are needed. Furthermore, whilst individual clinicians' responsibilities vary by role, with each clinician operating according to work-based relationships, they all bear influence on patient care. Case study methodology in this study was an effective means to examine how practitioners interact with one another within a specific context, and how decisions are made, with emphasis on the unique qualities of the case or 'case conditions'.(211)

Figure 21. Making patients the centre of attention through multidisciplinary team work
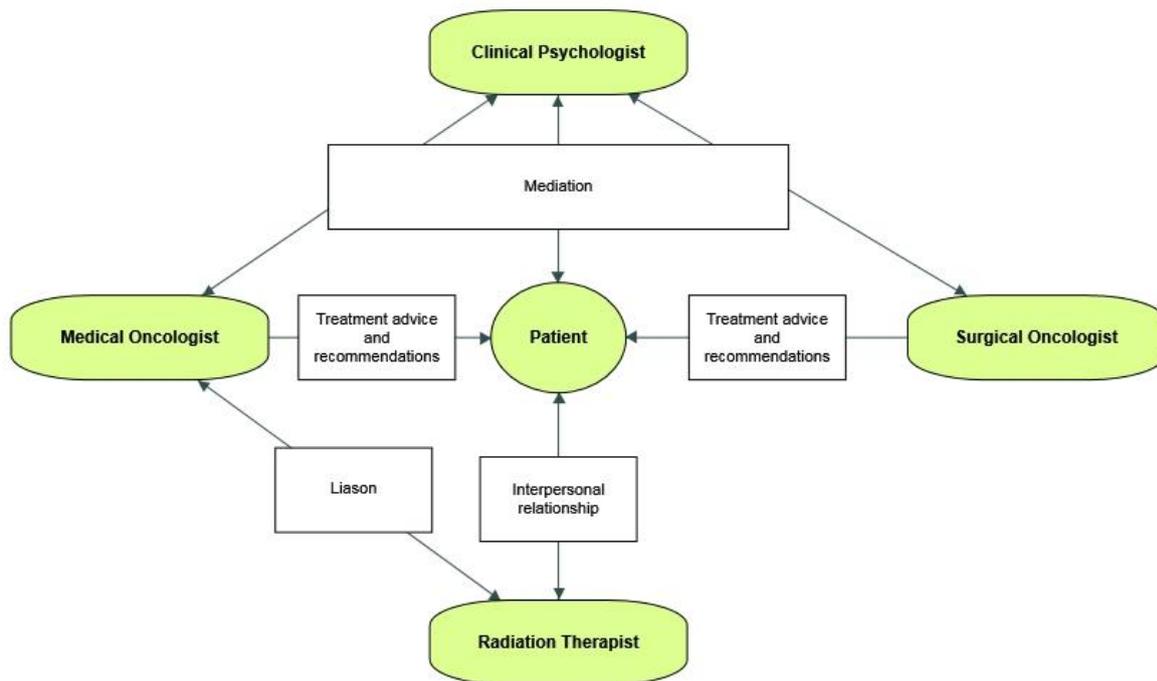
Source: Author's own work(210)

Conclusion

The findings of the breast cancer study provided a deep understanding of breast cancer treatment decision-making. It showcased the deeply contextualised way that individual patients and clinicians made sense of their respective roles in breast cancer treatment and care.

Our study showed that treatment decision-making does not always follow a procedural system, but rather, is based on a social exchange over time, strongly influenced by the specific inter-personal relationships that form between clinicians and patients, and between clinicians as a team. The need for patients to gain a sense of control in a time of uncertainty mobilises their proactivity in engaging with the social and physical resources around them, including their relationships with loved ones and their clinicians. Our study suggests that while the notion of patient-centred care is welcomed by clinicians and patients, it is not necessarily achieved consistently or systematically. Rather, it is a principle to work towards when support systems and relationships are strong.

"...under the masks of culture and custom, suffering people want roughly the same things from their healers, in whichever society they happen to live: relief from discomfort, relief from anxiety, a relationship of compassion and care, some explanation of what has gone wrong, and why, and a sense of order or meaning, imposed on the apparent chaos of their personal suffering – to help them make sense of it and cope".

Cecil Helman, Suburban Shaman, 2004

PART IV – Clear Translation

Implementation science: Practices and pathways

Implementation science has at its core a mission to get evidence into routine clinical practice. This sounds easier than it actually is. The evidence-based medicine (EBM) movement began in the 1990s(212, 213) and we can conveniently date the idea of implementation science from the beginning of the journal, Implementation Science, in 2006. So, in a way, implementation science is a continuation of EBM thinking.

Since those key dates it has becoming increasingly apparent that it is not a trivial matter to get clinicians practising in an evidence-based way. There are many reasons for this including that this is a 'wicked' problem; then there is the sheer complexity of understanding all the evidence, aggregating it and then making it available in a useable form, and then working out how to help clinicians on the front lines to practice in accordance with the most recent evidence, and having them keep continuously up to date. This often defeats even the most fervent advocates of EBM. To shine a light on only one part of the challenge: the evidence is accumulating at unprecedented rates. For example, there are 75 randomised trials and 11 systematic reviews published every day.(214) And we also know from ours and others' work that only around 60% of the care provided is in-line with level one evidence or consensus-based guidelines(215-218) across a plethora of common conditions in both adults and children. So having clinicians 'be evidence-based' is a challenging, complex problem.

As a complement to all the trials and systematic reviews making up the EBM endeavours, increasingly, qualitative work is being conducted to develop a grounded understanding of what a science of implementation means.(152) Work has been and is being undertaken in order to shine a light on the practices of clinicians and to understand patients' pathways thereby to see how more evidence-based care can be practiced. For our part, we have contributed work articulating some of the underlying concepts in implementation science, arguing for a return to first principles, especially centred on the core ideas of diffusion, dissemination, adoption, and sustainability.(52)

We've also examined through a systematic narrative review of mainly qualitative studies how we can apply ideas from implementation science to attempt to bolster initiatives to

improve quality of care and patient safety.(219) In that last paper we uncovered eight success factors of implementation: preparing for change, capacity for implementation-people, capacity for implementation-setting, types of implementation, resources, leverage, desirable implementation-enabling features, and sustainability (Figure 22).

Figure 22. Success factors for implementation

Source: Braithwaite, Marks, and Taylor(219)

Taken together, these approaches help show how taking a qualitative-minded approach to problems of getting evidence into practice provides context, texture, and theoretical richness. This helps generate an understanding of the scope of, and challenges to, implementation which quantitative studies cannot uncover.

In regard to the patient pathways concept, qualitatively-trained researchers have contributed ideas, frameworks and studies which have teased out the dimensions of the problematics of getting more evidence into practice, taking the perspective of patients and their journeys. These include a qualitative investigation of the views of healthcare professionals about improving outcomes and making recovery after surgery more efficient.(220) In this study, enabling factors which supported the implementation of enhanced recovery after surgery included leadership, teamwork, and patient involvement.

In another study Blevins et al.(221) examined four case studies, each predicated on creating collaborative implementation as a partnership between clinicians and researchers in the US. The studies were attempting to achieve four disparate goals: one, improve patient adherence with medications and medical appointments; two, support military veterans' engagement with Post Traumatic Stress Disorder (PTSD) care; three, enhance veterans' involvement with Cognitive Behavioural Therapy; and four, provide additional levels of care for mental health patients. Using survey data and qualitative focus group data, Blevins et al. found that while collaboration between clinicians and researchers was important, the results (achieving longer-term clinical effects as a result of the initiatives) were inconsistent. Only one intervention achieved such gains. Clearly, simply arguing for the importance of clinician-researcher partnerships is insufficient. We need to appreciate the context within which studies are taking place, how shared leadership between groups of clinicians and researchers is enacted, and what mechanisms are in place to engender collaboration between clinicians and researchers. These are qualitative, not quantitative questions.

Another benefit from qualitative research emerges from work which synthesises what we know into a model or graphical depiction of what needs to be done to be effective in implementation, as shown in the Braithwaite et al. model above. The framework provided by Greenhalgh et al.(222) from an extensive review of the literature on innovation in healthcare brings to our attention the variables, factors, influences, and connections between the variables in order to articulate innovation processes (Figure 23).

Figure 23. Determinants of diffusion, dissemination, and implementation of innovations in health services
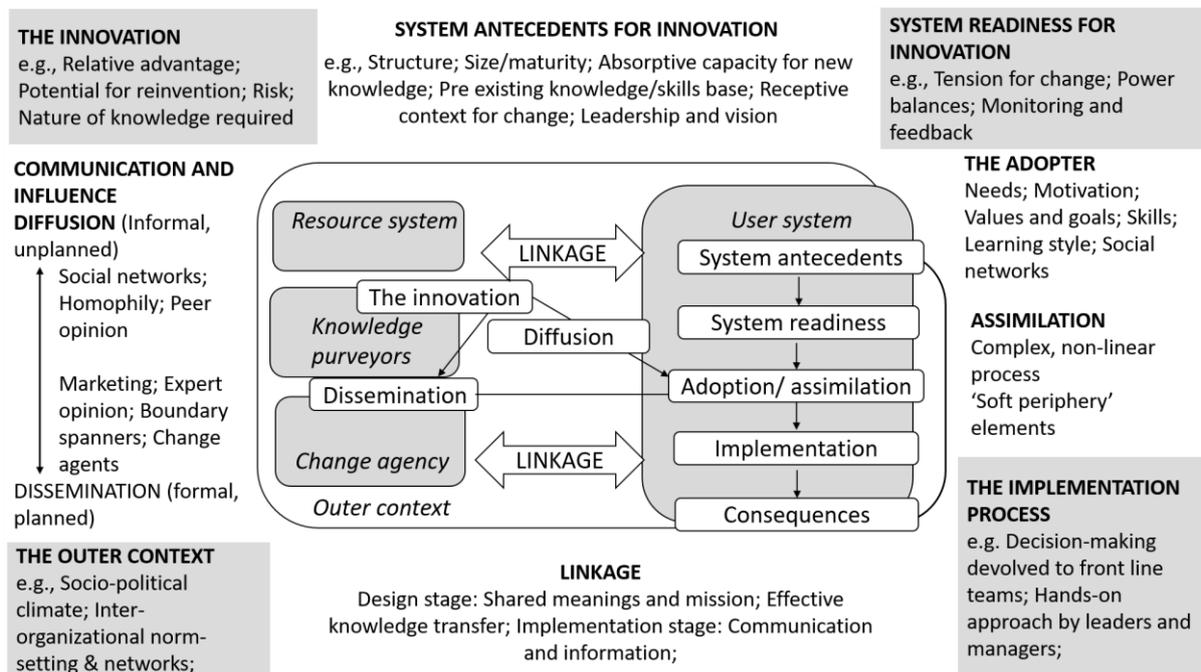
Source: Greenhalgh et al.(222)

All-in-all, qualitative research on implementation science and efforts to get more evidence into practice has helped illuminate facets of care and the caring process that would otherwise remain opaque. This includes helping to understand how care is actually delivered by practitioners (and partnerships of clinicians and researchers in some cases) and where there are challenges in the processes, systems and pathways of care.

Implications of qualitative methods for improving healthcare systems

A close cousin of the implementation science movement is improvement. Whereas implementation experts have narrowed their focus to creating a science centred on the evidence basis for clinical practice, improvement is much broader, both conceptually and in the topics it researches. There are many aspects of improving health systems to which qualitative researchers have uniquely contributed. They span the macro, meso and micro levels of health systems.

At the macro, whole-of-system level, various improvement theories and perspectives, underpinned by qualitative data, have shown how health reform works in practice, and have highlighted the messiness and uncertainty which permeates the policy process. Despite the challenges in making progress in systems-level reforms, however, many countries are making gains by adopting a continuous improvement appetite. For example, in our recent book on health reform in 60 low-, middle- and high-income systems(223) the Spanish health system, recognising that organ shortage in Spain was not due to a lack resources but rather ineffective organisational measures, led the successful establishment of the National Transplant Organization (ONT). Spain is now one of the world's most successful countries for high rates of organ donation.(223, 224) Meanwhile, in an accompanying chapter, Jordan implemented the national Health Care Accreditation Council (HCAC) and sponsored effective accreditation and regulatory standards.(223, 225) This initiative enhanced national healthcare quality in a country with limited resources and huge regional challenges.(223) Many other examples drawn from this book in the health reform series showed a multiplicity of success stories, again largely qualitative case studies, of how reformers, improvers and change-agents effected innovation across their health system to the benefit of providers, or patients, or both.

In a related book (that the last-listed author in the White Paper edited), we looked at the future of reforms in the health systems of 152 countries. Evocative examples of systems improvement include how in the health system of Guyana, community-based mental health models were integrated into primary healthcare systems, to provide a more holistic and modern approach to healthcare;(226) in Malaysia an improved antenatal care system was built out of an earlier system in need of renewal;(227) and in Portugal, the National Program for the Prevention of Antimicrobial Resistance was created—antibiotic resistance is a primary concern not only for Portugal, of course, but the EU and the WHO, and indeed, the world.(228)

Turning to the meso level, qualitative research has asked how and why patients and carers seek emergency ambulance care in the UK. This was a systematic review of qualitative studies or mixed-methods approaches, locating 33 studies which illuminated this question. In this review, Booker et al.(229) discovered that patients' decisions about what constitutes an emergency call for an ambulance were not solely dictated by physical symptoms but by complex socio-emotional factors. The rationale to call an ambulance was at least in part attributable to control over the situation as it was to do with the patient's perceptions of their condition.

Another study examining a meso-level matter conducted 183 interviews with 37 teams delivering care to heart failure patients in Canada.(230) It uncovered a dichotomy of relationships across the teams. One was a pattern of convergence in which teams pulled together in order to deliver care in complex settings. The second was a divergent pattern where teams pulled apart. Clearly the convergent pattern would be preferred in most cases, but the researchers argued that divergence is an underlying feature inherent in complex adaptive systems where healthcare teams are not unitary and tightly-bound but are constituted amongst distributed individuals.(231) Thus, it is not tenable to think that cohesive teams are always, or can be always, the answer.

In other research investigating the front-lines of care, studies of coal-face providers in services and teams have shown that taking a 'micro-systems' view can be useful. Johnson(232) has argued strongly for many years for instance, based on multiple qualitative studies, that organising around the microsystem rather than formal units such as departments, is a logical, flexible and appropriate way to conceptualise care and deliver it effectively.

In yet other research, this time spanning the UK and Australia, Rapport's work on breast cancer patients,(34) embracing an innovative multi-methods approach to understanding the journey such patients take, showed that risk is interpreted differently by patients compared with the ways that clinical providers mobilise their ideas about it. Without understanding these differing views of risk, we run into problems when patients are given statistical information to inform them about risk in an abstract way, when what they need is personalised non-statistical information about the course of their treatment, explained in clear, terms with little or no jargon or statistical inferences.

What studies such as these have drawn attention to is the vexed and vexing nature of improvement. Simplistic ideas such as 'plan-do-check-act' (PDCA) cycles are just that—simplistic. Real world, qualitative research has uncovered the problematics inherent in providing care—it's cultural complexity, the on-the-ground difficulties faced by participants, and its political-social-cultural dynamism. This uncovering of the social-political aspects of improvement by qualitative researchers, the deconstruction of cultural features of caring environments, makes improvement work more, not less, difficult.

We are not apologists for this. We would like to make the telling point that it is much better to know about the intricacies and challenges of the caring enterprise than not.(231, 233-236) Our work applying complexity science to clinical endeavours has just this goal. Understanding how hard it is to do improvement is a step forward. Surely, we believe, forewarned is forearmed.

"I am a compulsive observer of bodies in pain. His ease of movement, once again, reminds me of the resistance I experience each morning as I negotiate the terms of engagement for the day with my own lower back".

Andrew C. Sparkes, Bodies, Identities, Selves, 2003

PART V – The Future

Implications of qualitative methods for improving our understanding of health services culture and behaviours

By providing an understanding of the 'how' and the 'why', rather than just the 'what' of a research scenario, qualitative research can encourage researchers to reveal work processes and patterns of working that support the design of effective improvement interventions within, in this case, healthcare settings. Understanding the culture of an organisation or team may also assist in determining the barriers and enablers associated with implementing new procedures. In complex adaptive systems such as healthcare,(237) WAD by clinicians when caring for patients can be very different from 'work-as-imagined' (WAI) by managers and healthcare executives.(238)

This can result in incomplete or even incorrect assumptions within the organisation of how processes and tasks are conducted, and drive improvement designs that are poorly matched to the needs of clinicians and patients. A qualitative exploration of workplace culture will enable us to adjust interventions appropriately before they are implemented, resulting in improved uptake and fewer workarounds.

The role of qualitative methods in the future of health services research

As this monograph has indicated, and readers will have noticed through the case study examples presented, the field of qualitative methods in health services research is rapidly changing. Not only are topic areas, within which qualitative methods feature, expanding in scope, but qualitative methods are gaining recognition worldwide for their ability to uncover processes, and in turn influence professional behaviour, change policy or inform care delivery.(239, 240) Clearly, as evidenced in this White Paper, there is a pressing need for patients to receive individualised care. This includes clearer information and guidance on appropriate treatments and care pathways. But there is also a new breed of healthcare professional; willing to work less authorially and starting to consider the patient's views through the application of person-focused care delivery models.(241) Indeed, a groundswell of opinion from researchers globally suggests professionals are listening more intently to patients.

This is filtering through to policy initiatives, including the infusing of procedures, operating plans and clinical guidelines with patients' views, while professionals working across primary, secondary and tertiary care levels are much more able, and likely, to share information with one another. While there is still a long way to go before patients transition across sectors and services in a streamlined manner, professional investment is taking hold, with the multidisciplinary service delivery arrangement a growing reality. This promises a more consistent approach to patient care and transitioning, while ensuring patients do not lose faith in the system as can be the case in the current healthcare climate.(52)

Thus, as never before, qualitative methods are being put to the test and surpassing expectation. They are being applied successfully and found capable of illuminating how care is being delivered, thereby enabling change in the complex world of healthcare systems and services, at both strategic and practical levels. Qualitative methods are increasingly being sought out across medical settings, and used not only in observational and exploratory studies, but also as embedded arms of randomised controlled trials, having their own set of standard operating procedures.(152) They allow trialists to go inside the black box of their RCT, to understand the processes taking place.

Qualitative studies are being recognised for their ability to enhance data capture and analysis and to underpin a more rigorous *modus operandi* that stimulates implementable study outputs. They assist researchers in realising which interventions are implementable and which are not and can tease out the finer details of study questions that satisfy the knowledge-deficit currently in evidence in some clinical areas of guidelines development, protocol compliance, and behaviour-change.

Added to this, there is a sea-change underway in opinion on the value of causal explanations and standardised outcomes in and of themselves. Qualitative methods are frequently being adopted to supplement causal explanation, offering a more nuanced understanding of caregiving, and explaining notions of health and illness and patient experience that causal explanations cannot satisfy. In the future, we envisage: a) a greater qualitative scrutiny of clinical and system-wide data, and b) new and unique methods of inquiry, that encapsulate more nuanced understanding of clinical processes and patient experience. New ways of interpreting data will also be needed, that match a newfound desire for inter- and intra-

methods designs (described earlier in this monography), and as we move forward with this, we believe this will herald a new research era – the era of the 'Third Research Paradigm'.

We forecast that this new paradigm will bring a seismic shift in the world of health services research, that neither favours qualitative nor quantitative methods. The Third Research Paradigm will remove exclusivity and hierarchy from methodological development, while perceptions of a dominant positivistic position or a submissive 'soft' option, will be a thing of the past. As the Third Research Paradigm takes centre-stage, fewer academics will dismiss qualitative methods as secondary to quantitative methods, welcoming the consistency that mixed methods promise, equalising but also essentialising for both qualitative and quantitative findings, and ensuring corroboration over undercutting.(104) The work of the Third Research Paradigm will be underpinned by intra- and inter-methods triangulation,(242) and in their various guises, intra- and inter-methods will be written into every new research design as a tried and tested approach when used wholly in combination, with a sustained effect on service improvement.

In 2004, Gareth Williams(3) described the ways in which we examine (and to a degree we are still continuing to examine) explanations and understandings, according to methodological silos or: "bunkers" (see Illustration 10). This, he said, was a way of seeing the world that was: "impoverished, desiccated and confined",(3(pxvii)) resulting from a desire to:

"... dig a hole, stick the name of a discipline or a method on it, get into it, and talk only to those who want to get into the hole with us; [who] are only allowed in once they have learned the methodological rules".(3(pxvii))

Illustration 10. Methodological silos or "bunkers"

Source: Crash Macduff(243)

Since then, progress has clearly been made to get out of the holes we have dug for ourselves, but nevertheless 'change is still a-coming'. We need to create a climate where researchers are less fearful of: "using [their] imaginations"(3(pxvii)) and where they find it easier to understand a) the best way to gain new insights, b) search for links between methods and philosophical contexts, and c) apply themselves fully to achieving richer perceptions of the world in which we live. Now, even more so than in 2004, there is the pressing need to push methodological thinking forward. We are at the crux of a paradigmatic breakthrough, and the sooner we recognise this, the sooner we can move on to understand the perceptible world from a range of angles, using a battery of methods that translate understanding into practical applications to make a real difference to people's lives.

While there is an ever-growing strain on healthcare resources globally, resulting from depleted medical infrastructure, financial 'belt-tightening', measures of austerity, rising costs, and more mobile workforces, we need solidarity and commitment to match the demands of an ageing population. As populations grow, and ageing populations grow ever-older with their multi-morbidities to challenge health professionals and put pressure on governments and policy

makers globally, there is work to be done. Rather than playing: "according to the rules"(3) we need to defy expectation, encourage researchers to allow their imaginations to run wild, employ ideas beyond the constricts of disciplinary boundaries, ask research questions that intrigue as much as offer clear solutions, and move on from well-worn problems. As we see a resurgence in interest in the 'spoken word', the future holds exciting opportunities to test new ways of literary explication and presentations of oral testimony. We will continue to embed imagery into text, and yet bio-photographic methods that work on an equal footing have yet to reach their zenith. The case we have made here surely tells is that we will delve more expansively into methods conducted on the hoof ('mobile-methods'),(244) search out technological breakthroughs, turn to social media forums for rich data, and develop more automated techniques for managing 'big' qualitative datasets.

The future of qualitative research is one of ever-greater adaptation, a search across disciplinary boundaries for new ways of mapping and plotting patient pathways, and a hunt for new literary turns of expression. We predict larger, more complex, and ambiguous datasets to work with, and the need to reformulate our approach to data analysis. Mixing methods will mean mixing teams and building organisations around new configurations, with outputs responsive to one another inter-textually. The greatest challenge will still be methodological – how to make mixed methods work, how to develop new theories within a Third Research Paradigm, how to be more equalising in our treatment of data, how to absorb complex findings into a coherent whole, how to formulate new research questions using best evidence. To manage these challenges, we will need to make forays into the unknown world of other disciplines, borrowing mapping techniques from human geographers, for example, and visual presentations from anthropologists and sociologists. But in turn we will give back methodological know-how. We will be called upon to help others theorise experiential knowing and will share our knowledge widely. The next frontier, moving beyond the confines of academia, is to captivate business and industry partners. Both giving and taking, but neither to the exclusion of the other, is the way forward, as we search out new ways of knowing the sweet individuality of the human condition.

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