

An Introduction to Qualitative and Mixed Methods Study Designs in Health Research

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With the recognition of different population behavior and relevance of socio-cultural factors in health, health services and public health program contexts, qualitative research is increasingly being used in health research, including clinical trials. Qualitative research follows an inductive framework to explore and gain an in-depth understanding of the phenomena, especially why and how aspects, through techniques including interviews, focus groups and observations. It analyzes the textual data collected following one of the common analysis approaches: grounded theory, phenomenology, ethnography or participatory action research. Despite the divergence in principles, mixed methods research designs systematically combine the quantitative and qualitative methods for a comprehensive understanding on the issue. The commonly used mixed methods designs variably combine the purpose, priority, sequence, embedding and data integration. Mixed methods analysis requires strategic synthesis of the results to gain comprehensive knowledge for appropriate clinical or public health action.

Keywords: *Focus group, Implementation, Interviewing, Participatory research, Social research.*

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Traditional clinical research is dominated by quantitative study designs that document different variables (exposure, outcome and confounders) as measurable parameters and examines the relationship between them using statistical analysis principles. Much of the clinical and public health research happens within the clinical, social, population and interpersonal context, where the numeric data and statistical methods may be inadequate to document the patients, public and healthcare provider's experiences about the care and services. It is commonly observed that the outcomes and degree of associations vary across different populations or individuals, which are not explainable quantitatively. The quantitative study is unable to tell about 'why' people behave in the observed manner and the reasons thereof. It is important to move beyond 'what works' documented in quantitative research and understand 'what works for whom, why, how and when' to improve or customize the interventions or processes, and this is where qualitative research comes into play. The individual and population characteristics, experiences, behaviors and practices play a significant role in health and clinical practice. For documenting the possible reasons and identifying potential solutions for the observed patterns, qualitative research is needed. Moreover, qualitative research is critical for exploring new areas or issues of research, and identification of items of enquiry for documentation and quantification.

QUALITATIVE RESEARCH

Qualitative research is the systematic enquiry to obtain an in-depth understanding on the nature of phenomena in their natural setting, which may include but is not limited to, people's experience, individual and/or group behavior, and organizational function [1]. Several definitions for qualitative research have been proposed (**Suppl. material**). Qualitative research explores people's perceptions, experiences, attitudes, behavior, and inter-actions with others related to the phenomena or topic under study in the specific context. The researcher is the key instrument for data collection. It does not attempt to generalize the findings to the larger populations or other phenomena.

It was initially used by sociologists and anthropologists to study cultures and practices in their own and foreign contexts. Over the last few decades, it is increasingly used in clinical and public health research. As qualitative research does not attempt enumerating and generalizing the findings, some view this as the opposite of quantitative research. Although the methods are contrasting, the two research methods may overlap somewhat and complement each other. The key differences between quantitative and qualitative research are summarized in **Table I**. Qualitative research has been used in clinical trials and intervention studies to optimize interventions, trial procedures, improving the external validity, facilitating the interpretation of the findings, making trials human sensitive, and assisting in improving the

Table I Some Differences Between Quantitative and Qualitative Research for Various Domains

<i>Quantitative research</i>	<i>Qualitative research</i>
<i>Theory orientation</i>	
<ul style="list-style-type: none"> Deductive; tests to confirm hypothesis about phenomena 	<ul style="list-style-type: none"> Inductive; generates theory or explores phenomena
<i>Epistemology orientation</i>	
<ul style="list-style-type: none"> Positivism; only includes scientifically verifiable ones 	<ul style="list-style-type: none"> Interpretivist; interprets the meanings that humans attach to their actions
<i>Ontology orientation</i>	
<ul style="list-style-type: none"> Objectivism; asserts the validity of objective phenomena over subjective experience 	<ul style="list-style-type: none"> Constructivism: allows people to actively construct their own knowledge Reality is determined by researcher's experiences
<i>Methods</i>	
<ul style="list-style-type: none"> Follows designs and tools fixed prior to data collection 	<ul style="list-style-type: none"> Allows flexibility in designs to emerge during study
<i>Data collection</i>	
<ul style="list-style-type: none"> Precise measurement and objective data collection Uses standardized tests, instruments and measurement tools Close ended and objective questions Often involves large sample sizes estimated by formula or software Participants selected following randomness approach Participant responses not affected by how questions are asked and sequence 	<ul style="list-style-type: none"> Accurate description of the processes and observations (words, texts, etc.) Adopts interviews, discussions, observations and document reviews Open ended questions Often involves smaller sample sizes and observations, no sample size formula Participants selected purposively Participant responses are affected by how questions are asked and sequence
<i>Interpretation</i>	
<ul style="list-style-type: none"> Conducts analysis after data collection Numerical data (assigns values to responses as numbers, scales, categories) Explores single truth and often measures single outcome Performs data analysis in prescribed and standardized method(s) Analysis attempts achieving significance level Statistics complexities Generalizes the findings from sample to population 	<ul style="list-style-type: none"> Conducts analysis during data collection Accommodates complexities and multiple realities Textual data (uses text, notes, audios/videos, observation narratives) Flexible and iterative analysis approach Can obtain multiple outcomes and accommodate multiple sources of data (triangulation) Performs data analysis in creative, iterative, nonlinear and holistic manner Analysis attempts insight and metaphor Conceptual complexities Specific to the sample and context, does not generalize to the population
<i>Reporting</i>	
<ul style="list-style-type: none"> Quantifies the observations and variations Follows standardized format 	<ul style="list-style-type: none"> Describes the observations and variations Allows variability with expressive language and personal voices

Epistemology is a branch of philosophy that investigates the origin, nature, methods, and limits of human knowledge. Ontology is a branch of philosophy that explores the types, properties, and interrelationships of the entities that really or fundamentally exist for a particular domain of discourse.

effectiveness of future trials [2].

Qualitative Study Designs

The taxonomy of qualitative research has evolved over time [3-5]. In 2007, Cresswell proposed five qualitative study designs: Narrative research, Case studies, Grounded theory, Phenomenology and Participatory action research (PAR) [6].

Broadly, these are categorized into non-participatory types (the researcher only observes and does not participate in the activities) and participatory (the researcher participates in the process in the community and usually attempts to influence some activities). All study designs except PAR fall under the non-participatory category. The case studies have several subtypes: snapshot, comparative, longitudinal, pre-

post, and patchwork case studies. In health research, the grounded theory, phenomenology, ethnography and PAR are commonly used. The grounded theory explores a less-well-understood problem, situation, or context to generate a general hypothesis or explanation based on the views of a large number of participants. Phenomenology focuses on the essence of the 'lived experiences' of the person (or group), regarding an issue that becomes embedded in the consciousness and what meaning that carries for the person or group. Ethnography focuses on the cultural and social systems (structure and function) of a particular group and may cover various aspects like religion, economy, politics, environment and history. This may require immersion of the researcher in the society to study everyday life and relies on participant observation along with interviews. PAR focuses on finding suitable solutions for a social problem through researcher-community collaboration at all levels. The PAR may involve mixed (both qualitative and quantitative) methods designs.

Choosing Qualitative Study Design

Qualitative research designs do not follow strict taxonomy with fixed boundaries or strict stages like quantitative research. The data collection, analysis, research question refinement, theory modification, and addressing validity proceed more or less simultaneously and each step influences the others. The researcher has the flexibility to revise or modify the design and methods during the study based on the new developments and experiences. It does not imply a lack of study design in qualitative research, but the concept of a broader design. While choosing a study design and methods, the researchers consider various aspects including research question, context, conceptual framework, appropriate data types, validity and ethical considerations. Apart from these, the researcher's skills, participant and community concerns, piloting experience, and larger goals also influence study design selection. **Table II** summarizes the characteristics of the qualitative study designs. Qualitative research question can focus on any one or combination of these: *i*) understanding the meaning of the events, situations, and participants actions based on their lived experiences; *ii*) understanding the specific context within which the participants live and operate for their action; *iii*) identifying unknown, unanticipated phenomena and influences to generate new theories; *iv*) understanding the processes of occurrence of events and actions and their interconnections; and *v*) developing causal explanations and relationships between the different segments [7].

Data Collection Methods

The most commonly used qualitative data collection methods in health research are interviews, focus group discussions (FGDs), observations, and analysis of documents.

Qualitative interviews: These are conversations between the researcher(s) and participant(s) to gain insights into their subjective experiences, perceptions, motivations and knowledge. The interviews may be of three types: structured, semi-structured and unstructured. In structured interviews, the interviewer refers to a predetermined list of questions, which allows consistency across participants and interviewers (multiple), but limits additional exploration. In semi-structured interviews, the interviewer(s) refer to some questions but have the flexibility to adapt and add questions based on the responses and context, which allows more intuitive and natural conversations with the participants. Unstructured interviews aim to gather in-depth information from key informants and usually do not have a pre-planned set of questions and are instantaneously generated during the interview. Thus, it resembles more with free-flowing conversation than an interview. The semi-structured and unstructured interviews are also known as in-depth interviews (IDIs). For conducting IDIs, the interviewers must be researchers themselves or have a good understanding on the topic. The topics, questions, sub-questions and probes are developed based on the available literature, previous research and piloting, which may be revised during data collection. Interviews must primarily focus on being interactive and allowing unexpected issues to emerge and be explored. The interviewer can audio- or video-record the conversation with the consent of participants for transcription later [5,7,8].

Focus group discussion: This involves discussion among the participants (preferably of similar background) to explore their experiences, perceptions, knowledge and how and why people behave in certain ways. AFGD usually involves 6-10 people and is facilitated by an experienced moderator using a topic guide. Topic guide or interview guide is compilation of the list of topics or questions that the interviewer plans to cover during an interview. It is called a guide, because it is used to guide the interviewer, but not rigid like the questionnaire in quantitative studies. Topic guide include the topics or open-ended questions organized like a funnel; starting with warm-up discussion and easy questions, more detailed exploration, key areas of discussion, pulling out the essential insights, summarization. Additional observers and note-takers may be involved to record the verbal and nonverbal expressions. The discussions preferably are audio- or video-recorded with participants' permission and transcribed later [9]. To review the quality of conversation, moderator's technique and compare between FGDs, a sociogram for each FGD is drawn. Sociogram reflects the flow of discussions in the group [10]. FGDs allow obtaining information from many people quickly representing the community view and supplement the interviews. FGD may be inappropriate for exploring sensitive topics.

Table II Qualitative Study Designs and Their Characteristics

<i>Study designs</i>	<i>Type of research question</i>	<i>Context</i>	<i>Unit of analysis</i>	<i>Data collection forms</i>	<i>Data analysis strategy</i>
<i>A. Non-participatory research</i>					
Narrative research	Questions about the life experiences of an/few individuals and how they unfold over time	Stories to understanding the problem	One or more individuals	Interviews, document review; chronological, story-oriented	Chronology, story elements Little set structure
Case study	Questions about developing an in-depth understanding about how different cases provide insight into an issue or a unique case	Explores a case bounded by time, place that inform a problem	An event, program, activity One or more individuals	Interviews, observations, documents, artefacts	Case description, themes of the case and cross-case themes; Some structure
Grounded theory	Questions about experiences over time or changes that have stages and phases	No theory exists or existing ones are inadequate	Process, action or interaction involving many individuals	Interviews, may include others	Open coding, axial coding and selective coding; High level structure
Phenomenology	Questions about what is at the essence that all persons experience about a phenomenon	To understand the lived experiences of persons about a phenomenon	Several individuals with experience	Interviews, documents, observations, other items	Statements textual description on phenomenon; Structured approach
Ethnography	Questions about the structure and function of a group of people	Cultural and social system of a group; natural setting	Group of population	Observations, interviews, documents, immersion	Themes, statements; textual description; High level structure
<i>B. Participatory research</i>					
Participatory action research	Questions about how changes occur in a community	To address community issues for bringing change	Entire community, multiple stakeholders	Interviews, documents, observations, other items	Combination of different options; Little set structure

Adapted from Cresswell, et al. 2007 [7]

Observation: This involves documentation of activities, behaviors, conversations, organization or community processes or other aspects of observable human experiences [11]. Observation may be reactive (with participant's knowledge) or non-reactive (without participant's knowledge). Observation is critical in both interviews and FGDs to identify nonalignment between verbal and nonverbal data. Observation can also be a stand-alone method with or without the participation of the researcher. Observation provides information about the setting, context and actual behavior, which may not be possible in reported behavior or opinions. Observations can be either participant (observer is part of the observed setting) or non-participant (observer neither participates nor influences the setting) in nature. While observation allows deeper insights into the real-world setting and capturing issues not already considered, it also has the risk of the Hawthorne effect with the presence of an observer [12].

Written or audio-visual documents: These may be reviewed to gain information about the issue under study [9].

Qualitative research assumes no objective hierarchy of evidence and methods and the selection of methods (single or combined) must be based on the research question and suitability and feasibility of method(s) for the question and setting. The selection of method must be justified and documented. The use of multiple methods may allow a more comprehensive understanding of the issue under study and comparison between findings from different methods, which is referred as triangulation.

Sample Size and Sampling

Unlike a quantitative study, qualitative research follows no fixed rule for sample size. The data collection usually continues until data saturation, i.e., no new information or opinion emerges. The sample size depends on the richness

and type of participants. Usually, 15-20 participants per stakeholder category may be adequate, but the number may be decided depending on the research issue, context, stakeholders, anticipated differences in that phenomenon, and data saturation achieved during data collection [13]. The researcher may choose a small homogenous sample for in-depth study on the group and particular subgroups [11]. Sampling is usually non-probability and purposive. In qualitative research, the researcher attempts to gain in-depth understanding of the issues and dependent on the richness of the information shared by the participants/informants, not generalizability. Thus, the research selects the participants subjectively rather than random selection according to the likelihood of obtaining rich and in-depth information. The researchers often use purposive sampling and choose participants based on the specific expertise or insight regarding the phenomenon of interest.

Data Management and Analysis

The field notes and recordings of interviews, FGDs, observations are transcribed verbatim and checked for accuracy with the source documents. As needed, the narratives may be translated into the language of analysis, but care must be taken to ensure no loss of the essence and meanings.

Qualitative data analysis involves reading the texts and understanding its essence from the participant's perspective. The raw data (statements or segments of narratives) are coded either manually or using software. Coding is the process of organizing the sections of the data according to their meaning, sentiment and relationships. The codes bearing similar meanings are grouped into conceptual codes and categories. Linkages and connections between the conceptual codes and categories are explored (axial coding). Based on the emerging hypothesis, the conceptual codes and categories are organized under few themes (selective coding). The data is presented under the themes identified and compared across the data collection methods, stakeholders and contexts to identify the similarities and differences along with the potential reasons. The coding and data organization is an iterative process till an agreement between the researchers is achieved. The results are organized under the themes as the headings, the codes as the sub-headings with the researcher's interpretation and statements or narratives as 'quotable quotes'. Apart from textual format, data can be displayed in any form: boxed display, decision tree model, flow chart, ladder, matrix, metaphorical display, modified Venn diagram, network and taxonomy [14].

Use of Software and Challenges

Several free and license-based software programs

(Ethnograph, NVivo, Atlas-Ti, NUD.IST, WinMAX, MAXQDA, HyperRESEARCH, HubSpot, FreeQDA, RQDA, etc.) are available [14]. International Clinical Epidemiology Network (INCLEN) qualitative data analysis software (IQDAS) is an in-house program and is being used by us. Although software programs improve the efficiency of data management, purists claim it to distance the researcher from the data.

Biases

Qualitative studies are at risk of biases from the data collection method, selection of participants or analysis based on the researcher's knowledge, preconception, theory and values. Although rigorous and standardized training may improve the quality of data collection, the influence of researcher and data collector cannot be eliminated [7].

Validity Tests

Validity of the data and credibility of the interpretation can be increased with: *i*) repeated observation over a longer period; *ii*) in-depth exploration using probes; *iii*) respondent validation (soliciting feedback on the conclusions from the study population to avoid misinterpretation); *iv*) data triangulation (comparison across participants, settings and methods); *v*) comparison (with the control group) [7].

Quality Assurance

Quality assurance is a systematic approach to review the practices and procedures followed in a research to document whether things are being done according to the standards/best practices as well as they could/should be and identify possible improvements. It is a continuous and on-going process throughout the study and dissemination. Rigorous quality assurance measures must be adopted at all levels including *i*) selection of appropriate research methods and data collection techniques; *ii*) selection and appropriate training of the research team; *iii*) audio- or video-recording of the interviews and FGDs; *iv*) correct and complete transcription and translation; *v*) data analysis by multiple researchers and discussion to generate consensus on the code mapping; and *vi*) adopting validation methodology.

Ethical Issues

Although qualitative methods appear harmless compared to the biological sample collection, they may have unintended consequences at individual, group, organizational and societal levels. Thus, anonymity and confidentiality of participants must be ensured.

Some examples of qualitative research are given as Supplementary material.

MIXED METHODS RESEARCH

Mixed methods research (MMR) combines the quantitative

and qualitative methods (questions, data collection, analysis, interpretation) in the same study. Despite the contrasting assumptions, principles and cultures, increasingly both quantitative and qualitative research methods are being used to complement and supplement the hypothesis and findings. Several definitions for this have been proposed (Supplementary material). For denoting the emphasis and contribution of research method types, the components are indicated as QUAL or qual and QUAN or quan (capital indicates primacy) for qualitative and quantitative research, respectively. The purposes of using mixed methods research include: complementarity, completeness, triangulation of results; development (one method informs the other), initiation (discovers new perspectives), explanation, expansion (expands the breadth and range of inquiry), instrument development, credibility

and contextualization [15,16].

Designing Mixed Methods Research

Four issues must be addressed for planning mixed methods research: theoretical basis, priority, data collection sequence and data integration. The theoretical basis and research question inform the dominance, sequence and integration of methods. Based on the dominance, MMR may be considered as qualitative dominant, quantitative dominant or equal status. MMR may use the methods in either a sequential or concurrent manner, based on the need. The qualitative and quantitative approaches may integrate at five possible points: planning, research question, tool development and data collection, analysis and result presentation [17,18]. The mixed methods research framework is summarized in **Table III**. MMR is broadly divided into six

Table III Mixed Method Research Design and Integration Framework for Each Level

<i>Levels and types</i>	<i>Characteristic</i>
<i>Conduct</i>	
Concurrent	Data collection and analysis for both methods done concurrently.
Sequential	Data collection and analysis of one method precedes the other.
Multistage	Multiple stages of data collection, variable combinations of methods.
<i>Priority/Dominance</i>	
Dominant	One method is dominant based on the research question.
Equal	Both methods contribute equally according to the question.
<i>Intervention</i>	
Observational	No intervention.
Interventional	Intervention.
Hybrid	Observation and intervention combined variably.
<i>Study designs</i>	
Triangulation	Comparison and/or validation of the quantitative results with qualitative data or expand quantitative findings with qualitative data; Includes data transformation: one type of data is converted into the other type and integrated/compared with the data not transformed for analysis. Second method helps to explain the findings from first method.
Explanatory	Results of first method (usually qualitative) informs the second method (identify variables, develop instrument).
Exploratory	Second method (qualitative/quantitative) is needed to answer a research question within larger quantitative or qualitative study.
Embedded/ Nested	One type of data is converted into the other type and this data is integrated with the data not transformed for analysis.
<i>Database linkages</i>	
Connecting	One database is linked to the other through sampling.
Building	Results from one database informs the data collection approach of the other.
Merging	Both databases are brought together for analysis.
Embedding	Data collection and analysis are linked at multiple points.
<i>Interpretation</i>	
Narrative	Describe findings from both methods in same report. - Weaving: both findings presented together, either theme- or concept-wise. - Contiguous: findings presented in separate sections. - Staged: findings presented step/stage wise as conducted.
Transformative	One type of data is converted into the other type or consolidated into new variables for analysis.
Joint display	Data from both components integrated and presented together in figure, table, matrix or graph.

types: three concurrent or convergent (triangulation, embedded/nested and trans- formative) and three sequential (explanatory, exploratory and transformative). Additionally, sequential embedded and multiphase mixed methods research designs may also be adopted. The architecture of these mixed methods research study designs is shown in **Fig. 1**. These designs are selected according to the research purpose, conduct, priority, analysis, integration and presentation. Mixed methods research design involves several steps and considerations which guide the selection of the type of study design: research question, the purpose of mixed methods research, method priority, data collection sequence, embedding and data integration [19,20]. **Fig. 2** shows the steps in mixed methods research study design selection. Mixed methods research is being used in health behavior, implementation researches and clinical research [2]. Some examples of MMR are given in the supplementary material.

CONCLUSIONS

Qualitative research has a unique position in socio-behavioural research in health and significant value addition if used with the quantitative research. Qualitative research would enhance the etiological, risk factor and health behaviour understanding in clinical practice and public health programs. Qualitative research involves critical thinking and much dependent on the competence of the researcher(s). Despite the contrasting methodologies and

dissimilarities, mixed methods research designs enable combining the qualitative and quantitative study designs in a meaningful and symbiotic manner to address the questions. While combining and selecting these study designs, careful planning must consider the research purpose, data dominance, dependence, sequence, sampling, data integration and analysis. While the research purpose and theoretical conceptual framework are the primary drives, the practical aspects like timing, context, sampling, feasibility and competency of the research team are to be considered.

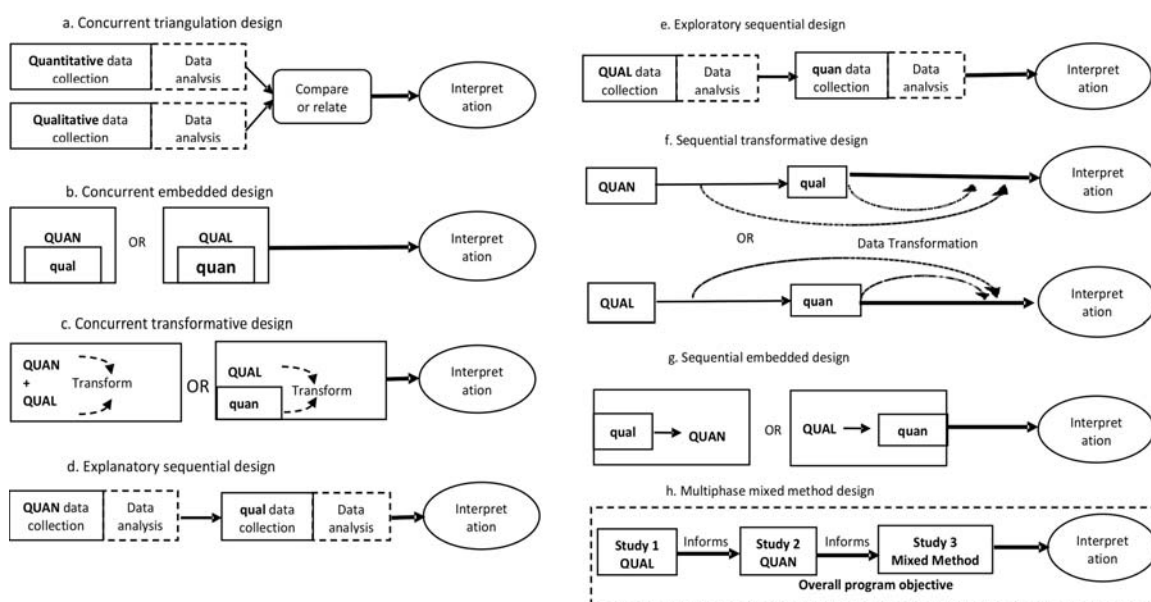
Note: Supplementary material related to this manuscript is available with the online version at www.indianpediatrics.net

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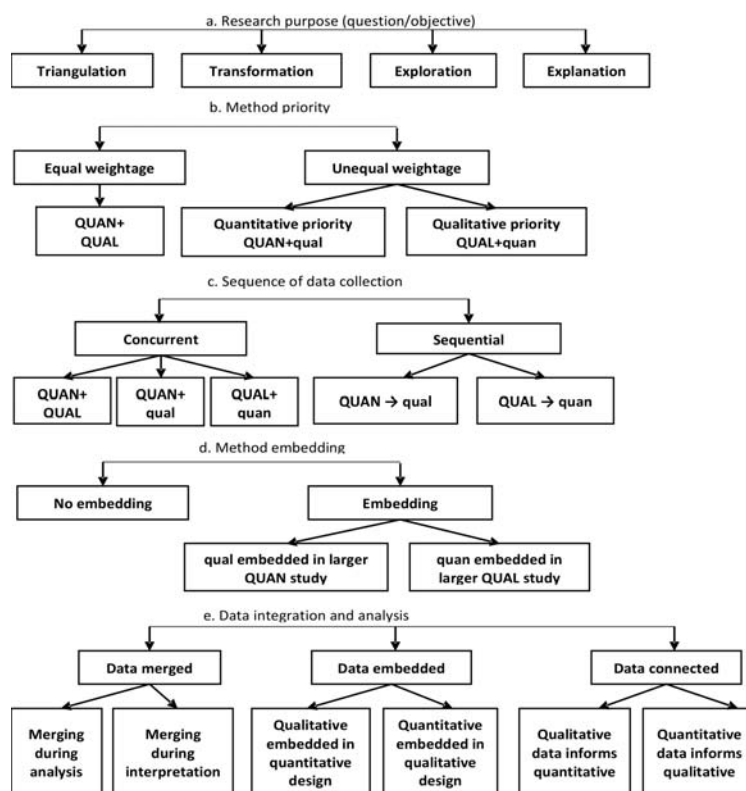
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QUAL: qualitative data is given higher priority; qual: qualitative data is given lower priority; QUAN: quantitative data is given higher priority; quan: Quantitative data is given lower priority.

Fig. 1 Types of mixed method research study designs (adapted from Cresswell, et al. [17] with permission).



QUAL: Qualitative data is given higher priority; *qual*: Qualitative data is given lower priority; *QUAN*: Quantitative data is given higher priority; *quan*: Quantitative data is given lower priority.

Fig. 2 The steps in mixed method research design selection.

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Supplementary Document 1

The available definitions of qualitative research

“Qualitative research involves any research that uses data that do not indicate ordinal values” (Nkwi PN, Nyamongo IK, Ryan GW) (1). “Qualitative research is a situated activity that locates the observer in the world. It consists of a set of interpretive, material practices that makes the world visible. These practices transform the world. They turn the world into a series of representations, including field notes, interviews, conversations, photographs, recordings, and memos to the self. At this level, qualitative research involves an interpretive, naturalistic approach to the world. This means that qualitative researchers study things in their natural settings, attempting to make sense of, or to interpret, phenomena in terms of the meanings people bring to them” (Denzin NK, Lincoln YS) (2). “Qualitative researchers are interested in understanding the meaning people have constructed, that is, how people make sense of their world and the experiences they have in the world” (Merriam SB, Tisdell EJ) (3).

“Qualitative research is research using methods such as participant observation or case studies which result in a narrative, descriptive account of a setting or practice. Sociologists using these methods typically reject positivism and adopt a form of interpretive sociology” (Drislane R, Parkinson G) (4). “Qualitative research as an iterative process in which improved understanding to the scientific community is achieved by making new significant distinctions resulting from getting closer to the phenomenon studied” (Aspers P, Corte U) (5).

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Supplementary Document 2

Examples of published literature using Qualitative Research Method

Case study 1: Qualitative research using in-depth interviews and observations

Perceptions of the parents of deceased children and of healthcare providers about end-of-life communication and breaking bad news

Parents of dying children face unique challenge and expect compassionate support from health care providers (HCPs). There is limited documentation from Indian context on the experiences of the parents and HCPs on end-of-life care for dying children and breaking the bad news around death. This study explored the experiences of the parents and HCPs about the end-of-life care and breaking bad news and related positive and negative factors in Indian context. This qualitative study was conducted at a tertiary care hospital. The data collection included in-depth interviews with the parents ($n=49$) and family members ($n=21$) of the children died at the hospital and HCPs ($n=16$; 6 doctors, 6 nurses and 4 support staffs) were conducted. The events and communication around death ($n=8$) for the children were observed. Data were inductively analysed using thematic content analysis method to identify emerging themes and codes.

The study observed that the doctors were the lead communicators for end-of-life communication. Majority of parents perceived the attitude, communication and language used as by resident doctors as brief, insensitive and sometimes inappropriate or negative. They perceived that the attitude and communication by senior doctor's as empathetic, positive and complete. Parents recalled the death declaration by resident doctors as non-empathetic, blunt and cold. Most parents received no emotional support from HCPs during and after death of their child. All doctors

expressed that death of their patients affected them and their emotions, which they coped through different activities. The overcrowded wards, high workload, infrastructural limitation and no formal communication training added to the emotional stress of the HCPs.

The study highlights the communication by HCPs and support for parents during the end-of-life communication and breaking bad news. Majority of the communication by the HCPs during the hospitalisation and end-of-life period were perceived as suboptimal by the parents. The HCPs were emotionally affected and faced end-of-life communication challenges. There is need for adoption of context specific communication protocol and materials and training of HCPs in communication to improve the quality of care and communication during the crisis periods.

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Case study 2: Multisite qualitative research using in-depth interviews, focus-group discussions and informal interactions to explore the determinants of undernutrition

The high levels of under-nutrition in India persists despite economic growth and multiple multisectoral interventions and continue to challenge political leadership and policy makers. This multisite qualitative research was conducted to map the perceptions of mothers and other key stakeholders, to identify emerging drivers of childhood undernutrition.

This multi-centric qualitative research was conducted across six states of India with high burden of undernutrition. The study sample included 509 in-depth interviews with mothers of undernourished and normal nourished children, policy makers, district level managers, implementer and facilitators. Sixty six focus group discussions and 72 non-formal interactions were conducted in two rounds with primary caretakers of undernourished children, Anganwadi Workers and Auxiliary Nurse Midwives.

Based on the perceptions of the participants, a model was inductively developed showing core themes as drivers of under-nutrition. The most forceful emerging themes were: multitasking, time constrained mother with dwindling family support; fragile food security or seasonal food paucity; child targeted market with wide availability and consumption of ready-to-eat market food items; rising non-food expenditure, in the context of rising food prices; inadequate and inappropriate feeding; delayed recognition of under-nutrition and delayed care seeking; and inadequate responsiveness of health care system and Integrated Child Development Services (ICDS). The study emphasized that the persistence of child malnutrition in India is also tied closely to the high workload and consequent time constraint of mothers who are increasingly pursuing income generating activities and enrolled in paid labour force, without robust institutional support for childcare.

The models identified from the data are shown in Figure 1 and 2.

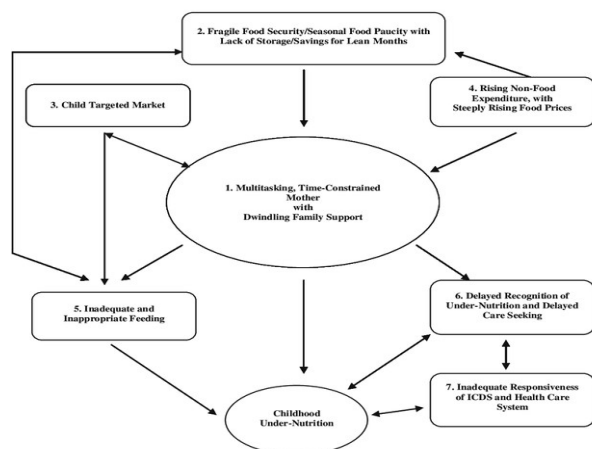


Fig. 1 Emerging model of childhood under-nutrition.

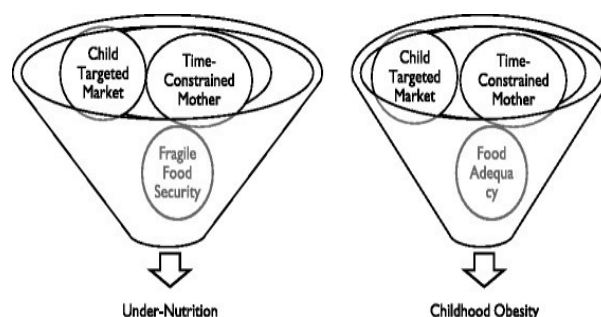


Fig. 2 The linkages between childhood under-nutrition and obesity (double Burden) with changing economic condition and food security at household level

The study findings identified the factors beyond the health sector with influence of the business and contextual issues on the food behaviour of the families and societies, which contribute to persistence of the child undernutrition burden.

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Case study 3: Using qualitative research for improving implementation of complex community intervention

The lay health workers (LHWs) are increasingly engaged to complement health services at community level. Their perceptions of the interventions they implement and their experiences in delivering community based interventions in India have been infrequently studied. A LHW led intervention was implemented to improve anemia cure rates in rural community dwelling children attending village day care centers in South India. To improve the implementation, a qualitative study was undertaken to understand the LHWs' acceptance of and perspectives regarding the intervention, particularly in relation to factors affecting daily implementation. The study used focus group discussions (FGDs) were conducted with the trained LHWs assigned to deliver the educational intervention. These were complemented by non-participant observations of LHWs delivering the intervention.

The study identified several factors related to the implementation of the intervention effort including pre-implementation training modules, intervention simplicity, and ability to incorporate the intervention into the routine work schedule. LHWs felt that the intervention impacted negatively on their preexisting workload. Fluctuating relationships with mothers weakened the LHWs position as providers of the intervention and hampered efficient implementation, despite the LHWs' highly valued position in the community. Modifiable barriers to the successful implementation of this intervention were seen at two levels. At a broader contextual level, hindering factors included the LHW being overburdened, inadequately reimbursed, and receiving insufficient employer support. At the health system level, lack of streamlining of LHW duties, inability of LHWs to diagnose anemia and temporary shortfalls in the availability of iron supplements constituted potentially modifiable barriers.

This qualitative study identified some of the practical challenges as experienced by LHWs while delivering a community health intervention in India. Methodologically, it highlighted the value of qualitative research in understanding implementation of complex community interventions.

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Shet A.S., Rao A., Jebaraj P., Mascarenhas M., Zwarenstein M., Galanti M.R., Atkins S. Lay health workers perceptions of an anemia control intervention in Karnataka, India: a qualitative study. *BMC Public Health* 2017; 17: 720. Doi: 10.1186/s12889-017-4758-x

Case study 4: Using photovoice for capturing the community perceptions on child health

The Sundarbans (West Bengal, India) has several inhospitable terrain and is at risk for frequent climatic shocks which challenge the access to healthcare for the inhabitants. Community members, and women in particular, have few means to communicate their concerns to local decision makers. Photovoice is one way in which communities can raise their local health challenges with decision makers. This study attempted to capture the mothers' voices on the determinants of their children's health to inform local level decision-making.

A photovoice action research was conducted in three blocks in the Sundarbans region. The project involved eight groups of eight to ten mothers who had at least one child below 6 years of age across four villages. The mothers were trained on photo documentation and ethical concerns before taking two rounds of photographs within 6 months, interspersed by fortnightly group meetings facilitated by researchers. Photographs and key messages were communicated to local decision makers during block and village level interface sessions with the mothers and researchers.

Mothers' photos focused on specific determinants of health, such as water and sanitation; health status, such as malnutrition and non-communicable diseases; service accessibility; climate conditions; and social issues such as early marriage and recurrent pregnancy. Some issues were not captured by photos but were discussed in group meetings, including domestic violence and the non-availability of medical practitioners. Differences in perceptions and photographs taken were observed according to the mother's educational status, livelihood and caste identity.

Photovoice has the potential to capture the voices of vulnerable and special group communities regarding their perceived health needs and challenges, which can help communicating these to the local decision makers for health policy and planning.

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Ghosh, U., Bose, S., Bramhachari, R., Mandal S. Expressing collective voices on children's health: photovoice exploration with mothers of young children from the Indian Sundarbans. *BMC Health Serv Res.* 2016; 16: 625. Doi: 10.1186/s12913-016-1866-8.

Supplementary Document 3

Examples of published literature using Mixed-Method Research

Case study 1: The relevance of qualitative research The poliomyelitis eradication effort in India

As a commitment under the Global Polio Eradication Initiative (GPEI), India accelerated its effort towards improving oral polio vaccine coverage through the routine immunization and Supplementary Immunization Activities (SIA, also known as the pulse polio immunization). With these intensified immunization efforts, the number of reported acute flaccid paralysis (AFP) cases decreased from 134 in 2004 to 66 in 2005. However, the cases resurged in 2006 and concentrated in western Uttar Pradesh and Bihar. The routine vaccination coverage with 3 doses of OPV was low in the polio-endemic states (Bihar, 27%; western UP, 38%; and eastern UP, 45%). (1)

The causes of the social resistance and low coverage of OPV vaccines could not be identified through the quantitative research approach. To document the determinants of social resistance and low OPV acceptance in the western UP districts, a qualitative research was conducted. This qualitative research used in-depth interviews (IDIs, with mothers, healthcare providers and community leaders), focus group discussions (FGDs, with mothers and healthcare providers), non-formal interactions (with community leaders, parents, businessmen, journalists, mobilizers, vaccinators and supervisors) and observations of the vaccination and mobilisation. The researchers documented a distinct machination of social resistance and rumors against OPV during the SIA in some minority dominated areas. While, most parents in minority areas supported the SIAs, a few clusters from extremely marginalized sections continued to evade SIAs, with an endemic pattern. The rumors circulated through various channels reached majority community as well parents (2).

The findings of this research was used for appropriate programmatic modification and adoption of strategic communication approach targeting the resistant communities and pockets. With these refinements in the communication and community mobilisation approaches, the polio eradication was achieved in the country.

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1. Centers for Disease Control and Prevention. Progress Toward Poliomyelitis Eradication - — India, January 2005—June 2006. *Morb Mortal Wkly Rep.* 2006;55(28):772–6.
2. Chaturvedi S, Dasgupta R, Adhish V, Ganguly KK, Rai S, Sushant L, et al. Deconstructing social resistance to pulse polio campaign in two North Indian districts. *Indian Pediatr.* 2009;46(11):963–74.

Case study 2

Sequential mixed-method research- quantitative research followed by qualitative research and

Integrationat interpretation phase

Documenting the performance of electronic health records app and barriers in implementation

Electronic health record (HER) capturing is being promoted to improve the health services delivery, documentation and planning. A study documented the performance of “Comprehensive Public Health Management” application (CPHM App) in Karnataka forcing on the family based maternal and child health (MCH) services and the challenges.

This research compared the completeness and consistency of selected MCH indicators from paper-based records and the CPHM App and also the implementation enablers, barriers, and suggested solutions from the user perspective. A sequential mixed-method study design was followed. The first phase involved quantitative research focusing on the consistency of selected MCH indicators followed by in-depth interviews of healthcare providers (users). The quantitative research findings for consistency was expressed as percentages. In the qualitative phase, IDIs with various cadres of healthcare providers (ANMs, MHW, ASHA, and administrator) were conducted. The findings were integrated at the analysis phase to triangulate the findings from quantitative and qualitative phases and identify the potential reasons for the gaps and challenges faced by the users (3).

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Shilpa D, Naik P, Shewade H, Sudarshan H. Assessing the implementation of a mobile App-based electronic health record: A mixed-method study from South India. *J Educ Health Promot.* 2020;9(1):102.

Case study 3:

Sequential mixed-method research- qualitative research for tool development followed by quantitative research

Development of a composite Slum Adversity Index and factors affecting the mental health of individuals living in slums

The persons staying in slums are exposed to several adversities and have higher risk of common mental disorders (CMDs). There was no suitable tool and index to capture the risk for developing these CMDs in Mumbai slum. This mixed-method research used qualitative research (focus group discussions and in-depth interviews) to develop the tool and indices for slum adversity quantitative survey. The quantitative survey used the slum adversity questionnaire along with the other standard tools, which were used to create a composite Slum Adversity Index (SAI) score. The qualitative data were also used to identify the potential factors and their sources contributing and triggering the psychological distress in the inhabitants (4).

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Subbaraman R, Nolan L, Shitole T, Sawant K, Shitole S, Sood K, et al. The psychological toll of slum living in Mumbai, India: A mixed methods study. *SocSci Med.* 2014;119:155–69.