Qualitative Research in TB Dx
An introduction & argument for its relevance

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Qualitative research =?

Not one clear definition. Usually definitions have these elements:

- “Qualitative researchers study things and social relations in their natural settings attempting to make sense of, or interpret phenomena in terms of the meanings people bring to them [and how they act upon them].
- The word ‘qualitative’ suggests an emphasis on processes and meanings that are not rigorously examined or measured in terms of quantity, amount, intensity, or frequency (“numbers”).
- Most analysis is done with words.” (Leys, 2003b, p.323)
1. Examples of qualitative research on TB Dx
Review Article

Sociology of diagnosis: a preliminary review
Annemarie Jutel

School of Midwifery, Otago Polytechnic, New Zealand

Abstract
Diagnoses are the classification tools of medicine, and are pivotal in the ways medicine exerts its role in society. Their sociological study is commonly subsumed under the rubrics of medicalisation, history of medicine and theory of disease. Diagnosis is, however, a powerful social tool, with unique features and impacts which deserve their own specific analysis. The process of diagnosis provides the framework within which medicine operates, punctuates the values which medicine espouses, and underlines the authoritative role of both medicine and the doctor. Diagnosis takes place at a salient juncture between illness and disease, patient and doctor, complaint and explanation. Despite calls for its establishment, almost two decades ago (Brown 1990), there is not yet a clear sociology of diagnosis. This paper argues that there should be, and, as a first step, draws together a number of threads of medical sociology that potentially contribute to this proposed sociology of diagnosis, including the place of diagnosis in the institution of medicine, the social framing of disease definitions, the means by which diagnosis confers authority to medicine, and how that authority is challenged. Through this preliminary review, I encourage sociology to consider the specific role of diagnosis in view of establishing a specific sub-disciplinary field.

Keywords: medicalisation, diagnosis, history of medicine, classification
1. Sociology of Diagnosis (Jutel, 2009)

- Diagnosis as categorisation, a social process & as a label with consequences (Jutel & Nettleton, 2011) (= a category & a process)

- Sociological scholars have researched how diseases are identified and classified (categorisation),
- they have researched how diagnosis is reshaped by different factors, the experience of diagnosis and illness and
- the consequences of diagnosis on people’s life, social movements around contested diagnosis, lay epidemiology, sociology of science and technology, and medicalisation
Some examples from the field of TB Dx

- Diagnosis as categorization:

- Social process of diagnosis:
  - Murray, E. J., et al. 2013. High levels of vulnerability and anticipated stigma reduce the impetus for tuberculosis diagnosis in Cape Town, South Africa.

Sagbakken et al, 2008: how symptoms of TB are perceived and managed → explain diagnostic delay, **Interviews & focus groups** at different treatment stages to examine (a) symptom identification and interpretation; (b) interaction with health personnel; (c) social support factors; and (d) financial and structural barriers

→ Health personnel confirms health beliefs (sin, punishment) to interact with patients
  → reinforce stigma & blaming
Some examples from the field of TB cont.

- **Consequences** of diagnosis
Pressing questions of the TB Dx community (Engel & Pai, 2013)

1. How to take into account complex diagnostic ecosystems?
2. How to scale-up and combine new and existing diagnostic tests in routine programs?
3. How to actively manage and foster innovation for POC diagnostics at the country level?
4. How to assess tests and evaluate their impact?

→ Potential of qualitative research to find answers to these questions is underused!
Face-to-face/telephone interviews with 41 stakeholders: private doctors, hospital laboratory staff, private stand-alone laboratories, test distributors, test manufacturers, hospital doctors, NGOs

Questions focused on: reasons for use of ELISA, interests of stakeholders, cost, experiences
Qual research helps you to understand & navigate through complex environments

(Jaroslawski & Pal, 2011)
Qual research on barriers to POCT - ongoing

**Aim of the project:**
- Identify the biggest barriers to successful implementation of point-of-care test (POCT) programs in different settings (South Africa & India)
  - Home, Community, Clinic, Peripheral Laboratory & Hospital
  - Focus on major infectious diseases (HIV, TB, Malaria, Syphilis, Hep.)
- Identify target product profiles for TB

*Where in public/private, urban/rural settings is POCT happening? if not, why it is not done?*
Study design

- **Semi-structured interviews** with healthcare providers (doctors, nurses, specialists, trad. healers, quaks), patients, community health workers, test manufacturers, laboratory technicians, managers, policy-makers
- **FGDs** with groups of patients, CHWs, nurses, laboratory technicians
  - **South Africa**: 100+ interviews, 7 FGDs
  - **India**: 72 interviews, 13 FGDs

- **Topics explored**: diagnostic processes & challenges therein, understanding of diagnosis, visions of an ideal test
- **Team**:
  - PI: Madhukar Pai, funded by BMGF
  - Malika Davids, Keertan Dheda, University of Cape Town
  - Mamata Patil, Devadasan, Institute of Public Health, Bangalore
Differences in diagnostic set-up

- **South Africa**: samples/reports/materials/communication travel between laboratories and providers via courier, fax, internet, telephone, paper record, SMS

- **India**: patients travel between laboratories and providers as carriers of samples, reports, communication between providers, history, results

→ Qual research helps you to understand the context, meaning and materiality of complex diagnostic eco-system
‘As a clinician, you are not managing lab results, you are managing the patient’: How the enactment of malaria at health facilities in Cameroon compares with new WHO guidelines for the use of malaria tests

Clare I.R. Chandler\textsuperscript{a,*}, Lindsay Mangham\textsuperscript{a}, Abanda Ngu Njei\textsuperscript{b}, Olivia Achonduh\textsuperscript{b}, Wilfred F. Mbacham\textsuperscript{b}, Virginia Wiseman\textsuperscript{a}

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In many settings in Cameroon RDTs for Malaria have been underused, overuse of antimalarials remains and patients are still being prescribed antimalarials.

Chandler et al. 2012: examined how a disease, its diagnosis and treatment is dealt with in practice.

Results:

- Divide between parasite-based guidelines (WHO) & how local clinicians deal with patients, how healthcare is organised, doctors roles & responsibilities
- Overprescription of antimalarials is part of how Malaria diagnosis and treatment is done in practice
- Richness of medical decision-making crucial to understand how guidelines are dealt with

Focus group discussions with 146 health workers involved in clinical care from 49 health facilities. open-ended questions on the role of antimalarial drugs and tests in participants’ practice, reliability and logistics.
Quotes from focus group discussions cont.  
(Chandler et al., 2012)

‘According to me, most of the times I will send the patient for a malaria test just for the psychology of the patient, just to please the patient...’  
(P4, FGD107 Bamenda, mission facility medical doctors)

‘some patients, when you tell them it is negative, he puts in his mind that he has lost his money whereas when it is positive, he is happy.’  
(P3 FGD302 Yaoundé, public facility nurses)

- Antimalarial prescriptions, drugs & tests have multiple functions, also psychological & social
- Health worker respond to entire situation of patient (ability to pay, social context, perceived needs)
- juggling patients’ desires, clinical guidelines and protecting medical reputations

→ Multiple roles of health workers, tests & treatment neglected in guidelines
Original Article

New diagnostics for multi-drug resistant tuberculosis in India: Innovating control and controlling innovation

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www.palgrave-journals.com/biosoc/
Researching innovation dynamics  
(Engel, 2012)

- Research around a demonstration study of a new diagnostic test & efforts of smaller players innovating MDR-TB Dx

- TB programme: need for standardization of diagnostic process → 'product in a box'

Semi-structured interviews, observations & document research with practitioners, policymakers, civil society, microbiologists, donors, pharmaceuticals, health staff, patients → Topics investigate: diagnostic and innovation processes, challenges,

- FIND demonstration study: ‘product in a box’ from Europe does not fit local context: requires changes in the laboratories: in their hierarchies, environment and culture (existing manpower is not prepared or qualified)

- Smaller players in medical colleges: no means, capacities & political relations to develop a commercially viable ‘product in a box’

→ Way standardization is done might not fit local context
→ need for standardization excludes local scientific expertise
Researching innovation dynamics
(Engel, 2012)

- Research around a demonstration study of a new diagnostic test & efforts of smaller players innovating MDR-TB Dx

- TB programme: need for standardization of diagnostic process → 'product in a box'

**Results:**

- Central role of standardization for innovation process
- No open negotiation of those needs, not all potentially relevant actors participate
  → participation should be assessed depending on the degree & form of inherent uncertainty in the innovation situation
Implications of results

Qual research is able to unravel complexity of innovating diagnostics.
This has implications...

→ for design of demonstration & evaluation studies
→ for implementation strategies of tests
→ but also for design of diagnostic test itself (which is more than the technique but a “product in a box” and should be able to address complexity of diagnostic eco-system)
2. Why is qual research important for TB Dx
Pressing questions of the TB Dx community (Engel & Pai, 2013)

1. How to take into account complex diagnostic ecosystems?
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Qualitative research is useful to..

- help in **explorative** stage of a research project: clarify/set research questions, conceptualize, generate hypotheses
- support **interpretation**, qualification, illumination of quantitative results (answering how and why questions)
- understand **social context** of biomedical interventions → improve **implementation**
- Support **clinical trials** (how trialists **experience** & why they stop to participate, improve trials in real time)
- answer **why** & **how** questions in **evaluation of interventions** (combined with RCT and quantitative methods)
- support **design process** of medical device
- answer questions about **technology-in-use**
Qualitative methods in medical device design (Shah et al 2009)

- End-users discard devices that do not fulfill their personal expectations
- Competing perspectives of developers, users, manufacturers, regulators

User involvement necessary:
- **Concept stage**: interviews, focus groups, brainstorming sessions & users-producers seminars
- **Design stage**: interviews, usability tests, & users' feedback
- **Trials stage**: usability tests, interviews, & discussion at testing
- **Deployment stage**: ethnography, interviews & surveys
User involvement in medical device design (Shah et al., 2009)

Adapted from 39 (Shah & Robinson, 2008)

**Scenario A: Device New to the Market**
- Stage 1: Idea Generation & Concept Development
- Stage 2: Device (Re-)Design & Prototype Development
- Stage 3: Prototype Testing In-house & Trials in Real Field
- Stage 4: Device Deployment in the Market & User Feedback

**Scenario B: Major Upgrading of Existing Device**
- Professional Users: \{1,4,5,7,9,14\}*
- End Users: \{8,9,13,14,15\}*

**Scenario C: Redesigning of Device Prototype**
- Professional Users: \{1,8,9,10,12,13,14,15\}*
- End Users: \{2,3,6,8,9,10,12,13\}*

**Methods**
- 1. Brainstorming
- 2. Cognitive walkthrough
- 3. Discussion with users
- 4. Ethnography
- 5. Expert users meetings
- 6. First human use
- 7. Focus groups
- 8. In vitro tests
- 9. Interviews
- 10. Observations
- 11. Surveys
- 12. Think aloud method
- 13. Usability tests
- 14. Users - producers seminars
- 15. User feedback

*User involvement in medical device design (Shah et al., 2009)
Clinical Needs Assessment for POC R&D (Weigl et al., 2012)

CNA-Guided Product Development

0. Concept Needs ID & assessment

1. Planning Discovery & feasibility

2. R&D Development & prototyping

3. Pilot & Evaluation

4. Transfer, introduction & deployment

5. Market integration & sustainability

Problem Characterization
- Landscape Analysis
- User Needs Assessments
- Product Specifications Assessments
- Stakeholder Assessments

Market Sustainability
- Segmentation and Market Size Assessment
- Competitive Analysis
- Stakeholder Assessments
- Due Diligence
- Willingness-to-pay

Economic Rationale
- Cost analysis
- Cost-effectiveness Analysis

Policy Environment
- Stakeholder assessment
- Feasibility assessment
- Acceptability assessment
Design ethnography

• Observation of device in use

• identify challenges, discover latent needs, document usability, workflow, collect design criteria inputs, time metrics, personnel interaction, and emotional state (Hägen, 2012; Ball & Omerod, 2000)

• Challenge: to translate observational analysis into actionable design criteria (Kjeldskov & Stage, 2012)

Source: www.farmpd.com
Qualitative methods in Health Technology Assessment (Reuzel & van der Wilt, 2000)

- ‘Is this diagnostic technology better than the technology currently used?’
  - usually with accuracy studies
  - some argue experience and clinical judgment should also be evaluated (decision analysis) and impact on patient outcome (Mrus, 2004)

- Main users of HTA: policymakers & practitioners
- → strong focus on cost-effectiveness & effects (does the technology live up to my expectations?)
- → less attention to legal, ethical, psychological, societal aspects or programmes, organizational & support systems
- → qual methods can help (f.ex. goal-free evaluation, responsive evaluation, illuminative evaluation, pluralistic evaluation, fourth generation evaluation)
Qualitative methods in Health Technology Assessment (Murphy et al. 1998)

Qual methods needed (f.ex. goal-free evaluation, responsive evaluation, illuminative evaluation, pluralistic evaluation, fourth generation evaluation):

- Detailed evaluations of processes
- Examination of how & why questions (explanations)
- Facilitation of scale up to other contexts by providing comprehensive analysis of each site
- Discovery of alternative or existing natural solutions to problems
- Evaluation for community development: Sensitivity to local cultures, negotiating concerns with all stakeholders, shared ownership of data
Why is qual research important for you?

Qualitative research will..
- ..help you to **develop better products**: create better fit with local contexts, user needs and support scale-up to different contexts,
- ..support **scale-up & introduction** of existing products (implementation)
- ..**evaluate** what products do to the context

→ **reach out to social scientists & qualitative researchers!!**
(f.ex. medical anthropologists & sociologists, design ethnographers, science & technology studies scholars, political scientists)
You could also purchase qualitative research skills in the private market, f.ex...
3. Paradigms, methods of qualitative research
# Quantitative and qualitative methods

## Quantitative methods
- Useful for generating numerical findings for statistical manipulations
  - Statistical generalizations
  - Predictions
  - Estimations of causal explanations
  - Hypothesis-testing

## Qualitative methodology
- Useful for understanding processes, context & considering experiences or perspectives
  - Analytical generalizations
  - Interpreting or explaining numbers & causal events
  - Theory-building
Quant vs. Qual:

- Qual researchers emphasize “… evidence is developed in order to answer specific question(s), which may privilege certain stakeholders. The nature of a question (of the decisionmaker as well as the researcher) and how questions are asked, have an impact on developing evidence.” (Leys, 2003)
Quant vs. Qual:

- Hierarchy of evidence creates false dichotomy (Leys, 2003)
- Results of qual. research equally important as quant.

→ rather: what information is relevant in what situation?
- instead of making ‘ultimate’ judgments about what is to be considered as ‘best’ evidence for policymaking, and which kind of data are ‘better’.
General characteristics qual. research

- Open data collection techniques
- Aimed at unraveling complex **processes and mechanisms** that constitute contexts
  AND/OR
- Focus on (construction of) **meaning/perceived truths (facts), interpretation and experience**
- Variety of methods
- Digs deep
- Reflexive
  → Can be used with different philosophical paradigms! (post-positivism, interpretivism, constructivism, critical theory)
<table>
<thead>
<tr>
<th>Type of Research Questions</th>
<th>Strategy</th>
<th>Paradigm</th>
<th>Method</th>
<th>Other Data Sources</th>
</tr>
</thead>
<tbody>
<tr>
<td>Meaning questions—eliciting the essence of experiences</td>
<td>phenomenology</td>
<td>philosophy (phenomenology)</td>
<td>audi-taped “conversations”; written anecdotes of personal experiences</td>
<td>phenomenological literature; philosophical reflections; poetry; art</td>
</tr>
<tr>
<td>Descriptive questions—of values, beliefs, practices of cultural group</td>
<td>ethnography</td>
<td>anthropology (culture)</td>
<td>unstructured interviews; participant observation; field notes</td>
<td>documents; records; photography; maps; genealogies; social network diagrams</td>
</tr>
<tr>
<td>“Process” questions—experience over time or change, may have stages and phases</td>
<td>grounded theory</td>
<td>sociology (symbolic interactionism)</td>
<td>interviews (tape-recorded)</td>
<td>participant observation; memoing; diary</td>
</tr>
<tr>
<td>Questions regarding verbal interaction and dialogue</td>
<td>ethnomethodology; discourse analysis</td>
<td>semiotics</td>
<td>dialogue (audio/video recording)</td>
<td>observation; field notes</td>
</tr>
</tbody>
</table>

(Denzing & Lincoln, 1994)
Data collection techniques

- Interviews (semi-structured, structured),
- Focus group discussions,
- Participant observation,
- Text/discourse analysis,
- Conversation/video analysis

→ Assess data collection: describe context & structure of the situation, record observations of participants, assess quality of the data, evaluate usefulness of questions, acknowledge areas of difficulty

→ → going back & forth between data and questions and theory
Duration

- Fieldwork duration varies: from 1 month - 3 years
- Rule of thumb:
  - 1 day preparation
  - 1 day per interview and transcription
  - 1 day analysis
  (excluding write-up)
Data collection questions asked in qual. methods

- **Aim**: to elicit participants’ perspective, experience, meaning, practices, processes and reason for action
- **Open-ended**
  - Tell me what it was like when you first had symptoms
  - Tell me about getting a diagnosis
- **How questions**: examples rather than opinions
  - Angotti et al., 2010 how do HIV testing counselors translate global guidelines? dont ask: how do you understand the guidelines, but what are your experiences with counseling/testing → examples, practices, stories, iconic events, keep close to real life
- **Follow-up questions: probe** (when? where? why?)
- Different questions for different participants, no set order, questions are likely to change throughout the research
Focus group discussion

- **Introduction** of participants, general purpose of meeting & ground rules of discussion
- **Predisposition phase**: to establish what particular problems participants experience or define with regard to main topic
  - Introduce topic of discussion
  - Short silence in which participants write down ideas
  - Individuals present ideas
  - Summary of ideas
- **Group discussion** on the questions you prepared between leader and participants as well as among participants
- Summarize results
- Short survey among participants (do they have comments, anything to add)
- Participant observation
- Text/Discourse analysis
- Conversation/video analysis
Data collection: types of data

Written texts
- Transcripts (interviews, FGDs)
- Summaries (interviews, FGDs)
- Narrative stories (e.g. about events)
- Diaries
- Life histories
- Formal documents (minutes of meetings, reports, articles)
- Local tales
- Social media, websites, online discussion boards

(Audio/) visual materials, e.g. pictures, videos, films, artefacts
Data analysis

- No ‘right way’, yet: systematic approach
  - Careful reading of material, make notes, code, reflect (keep framework, questions in mind)
  - Look for patterns, regularities, recurrent themes
  - Label categories, use overarching concepts
  - Look for relations between concepts, comparisons, contrasts
  - Relate back to theoretical framework, adapt theory

- Theory based (deductive) – building theory (inductive)

- Analysis (incl. hypothesis development) and data collection go hand in hand
Analysis: Developing themes, narratives & descriptions (Rubin & Rubin, 2005)

- **sorting & summarizing**: write a summary of the data units for each code, list main points (no judgment) → what seems to be missing? why? what is present? why?

- **sorting & ranking**: within one code summary, some aspects of a problem/phenomenon might be considered minor other major → why? who is affected how? which ones are addressed?

- **sorting & comparing**: sort again, now by source and see whether different actors highlight concepts, themes, events in different ways → look for differences & commonalities, why?

- **weighing & combining**: combine different views/definitions of the same concepts, or combine explanations of processes from different actors, weigh contrasting versions of same process (back up with additional sources, look for contradictions, credibility)

- **integrate, check, modify**: check summary themes against other coded data, double check if you side with one group, make sure you are able to document every step if you identified causal relations
Sources qual. research handbooks

  free download of the 2003 edition available: Download Nursing Research: Principles and Methods (Nursing Research: Principles & Practice) http://mihd.net/q0enrc
  Password: econiches
Sources qual. research design

Sources data collection & analysis

Sources analysis & writing up

Sources Nvivo

Basics of coding: [http://www.youtube.com/watch?v=O9eTvP3E5TE](http://www.youtube.com/watch?v=O9eTvP3E5TE)


References


Thank You!
Questions?
Suggestions?

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