Qualitative Research in TB Dx & Barriers to POC testing in India (& South Africa)

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Outline

1. Short primer in qualitative research
2. Why is qual research important for TB Dx?
3. Qualitative research in TB Dx
4. Results: Qual research on barriers to POCT in India & South Africa
1. Primer in qualitative research
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)
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<td><strong>phenomenology</strong></td>
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<td>audiotaped; “conversations”; written anecdotes of personal experiences</td>
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<td>Descriptive questions—of values, beliefs, practices of cultural group</td>
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<td>“Process” questions—experience over time or change, may have stages and phases</td>
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<td>Questions regarding verbal interaction and dialogue</td>
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(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
‘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,}\textsuperscript{*}, 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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\textsuperscript{b}The Laboratory for Public Health Research Biotechnologies, University of Yaoundé, Cameroon
• In many settings in Cameroon RDTs for Malaria have been underused, overuse of antimalarials remains & RDT neg. 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 parasitebased 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

17 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
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? don’t 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)
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
Vo Thanh
5 fishermen (Mr. Diep)

Some 500 fishing boats with many big trailing (24000 $). It takes their government loans. The million VND (??). They use mainly dragnet, is a law that prohibits breaking the law and go fishing trips to fishing fishing trip last for about a rich catch is down from 100% 10 years ago to 50%

In November people go fishing for lobster fry and can make up to 50 million VND a night. Some people own small boats and go fishing with gill nets. "Every job in town is related to fishing"

Their vision is that the government builds a harbour to protect their boats against the rainy season storms and the big waves. Besides that it would ease to load and unload the boats, which takes long time and costs substantial amounts of money. The

I've been invited on a fishing trip for 4 days after TED New
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) \( \rightarrow \) 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 \( \rightarrow \) 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 \( \rightarrow \) 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
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
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 & Pai, 2011)
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’.
2. Why is qual research important for TB Dx?
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)

Professional Users’ Stream
- 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

End Users’ Stream
- Scenario A: Device New to the Market
- Scenario B: Major Upgrading of Existing Device
- Scenario C: Redesigning of Device Prototype

User Involvement Methods
1. Brainstorming sessions
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

Adapted from: 39 (Shah & Robinson, 2008)
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 Assessment
- Product Specifications Assessment
- 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)

• → 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: answer how & why questions (f.ex. goal-free evaluation, responsive evaluation, illuminative evaluation, pluralistic evaluation, fourth generation evaluation) (Murphy et al 1998)
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. Qualitative research on TB Dx
1. Sociology of Diagnosis (Jutel, 2009)

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

- **Consequences of diagnosis**

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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
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!
4. Qualitative research on barriers to POC testing in India & South Africa
Qual research on barriers to POCT - ongoing

Aim:
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.)

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

Team India (IPH):
Mamata Patil
Vijayashree
Gayatri Ghanesh, Devadasan

Team South Africa:
Malika Davids (Keertan Deda’s team, UCT)
Nadine Blankvoort (UM)
Diversity of target product profiles, users, and settings (Pai et al., 2012)

**TPP1: HOME**
- **Self-testing** (home-based)
  - **User:** Lay person
  - **Device:** RDT (pregnancy test) or dipstick
  - **Purpose:** Self-assessment and referral

**TPP2: COMMUNITY**
- **Testing in the community by health workers**
  - **User:** Village workers, paramedics
  - **User:** Minimally trained health worker
  - **Device:** RDT
  - **Purpose:** Triage and referral

**TPP3: CLINIC / HEALTH POST**
- **Testing in the clinic by healthcare providers**
  - **User:** Doctors, nurses
  - **Device:** RDT, handheld instruments
  - **Purpose:** Diagnosis and treatment

**TPP4: PERIPHERAL LAB**
- **Testing in the peripheral laboratory**
  - **User:** Lab tech
  - **Device:** RDT, molecular tests, ELISA, microscopy, etc.
  - **Purpose:** Diagnosis, treatment monitoring

**TPP5: HOSPITAL**
- **Testing of in-patients in hospitals**
  - **User:** Hospital staff
  - **Device:** RDT, molecular, smears, etc.
  - **Purpose:** Diagnosis, treatment monitoring

Disease profiles:
- **HIV self-testing**
- **Malaria, HIV, dengue**
- **HIV, malaria, syphilis, dengue, Strep A**
- **TB, HIV, malaria, HBV, C.diff, CD4, HCV, MRSA, flu, UTI, viral loads, etc.**
- **TB, HIV, malaria, HBV, HCV, flu, MRSA CD4, Strep A, C. diff, etc.**
Diagnostic "eco-system" in India

Doctor orders test

Correct test is ordered

Patient gets it done

Lab performs test

Results get reported quickly

Results do not get reported in time; no standards; no quality assurance; POC tests are not used at POC

Lab performs test

Cannot do it well; charges a lot of money; need to give kickbacks to doctors; imported tests are expensive; half-volume testing; kitchen sink testing

Doctor acts on the results

Doctor does not act on results (quality, lack of trust); has already given empiric therapy

Doctor orders inappropirate or inaccurate tests; orders unnecessary test for kickbacks; has own lab that needs business

Correct test is ordered

Cannot afford the test; does not believe in testing; unhappy with doctors who ask for tests; wants quick therapy

Patient gets it done

Impact on patient outcomes

No impact on patient outcomes

Impact on patient outcomes

Underuse or overuse of diagnostics; empiricism; access to labs; patient’s SES; easier to give antibiotics; medical training

Slide from M. Pai, 2010 Advanced TB Diagnostics Course, McGill, Montreal
Study Design

Semi-structured interviews with healthcare providers (doctors, nurses, specialists, trad. healing, informal providers), patients, community health workers, test manufacturers, laboratory technicians, managers, policy-makers

FGDs with groups of patients, CHWs, nurses, laboratory technicians on major challenges in diagnosing in their specific setting

- South Africa: 100+ interviews, 7 FGDs in Cape Town, Durban & Eastern Cape
- India: 74 interviews, 13 FGDs in Bangalore & a rural district in Karnataka

Topics explored: diagnostic processes & challenges therein, understanding of diagnosis, visions of an ideal test
Major difference in diagnostic process

**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, of reports, communication between providers, history, results

→ Major challenges to POC are linked to this difference

→→ private sector responds to these challenges:

**SA:** optimize transportation of samples & communication between providers

**India:** optimize coordination between providers (opening hours, kick-backs/tie-ups, settings nearby)
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Where does POC testing happen in India?

- Successful POC testing hardly occurs in any of the five settings.
- Available rapid tests currently not translated into rapid treatment decisions.
- Most of the rapid tests are used in clinic and hospital labs → too long TAT → patients have to come back next day.
- In settings with shorter TAT, rapid tests are unavailable (public) or their cost is too high (small private labs).
- Private providers find alternative measures to ensure the POC continuum with older testing methods (coordination, kick-backs).
Tests in use & POCT at 5 different settings India

- **Home**: diabetes monitoring in affluent areas
- **Community**: symptom screening, Malaria slide & sputum sample, and referrals by CHWs; ANMs: pregnancy, glucometer/urine albumine & sugar, HB with Sahli's haemoglobinometer (Malaria RDT if endemic) → follow up at clinic?
- **Clinic**: small PHC labs: Malaria smears, BP, HBsAg card, Dengue NS1 card, Syphilis card, (AFB), glucometer, urine dipstick, pregnancy, HIV, urine sugar (Benedict) → TAT challenges POCT
  - GPs: pregnancy, glucometer → POCT with lab nearby
- **Peripheral lab**: urine dipstick, sugar, typhoid slide, blood grouping, Malaria smear, HB; some Dengue, Syphilis, HEP, Mantoux, renal & lipid function (exp), most don’t do AFB, often older & cheaper methods than rapid tests → TAT: same day
- **Hospital**: wards: glucometer, urine dipstick, pregnancy, HIV, ECG; hospital labs use many rapid card tests (Malaria, Dengue, HBsAG, Syphilis, pregnancy, HIV (separate labs)) → TAT challenges POCT
Diagnosing in the community

**CHWs**: symptom screening, Malaria slide & sputum sample, and referrals;

**ANMs**: pregnancy, glucometer/urine albumine & sugar, HB with Sahli's haemoglobinometer (Malaria RDT if endemic)

- Stock-outs and shortages of funds
- Referrals to clinic?: onus is on patient
- CHWs struggle to convince & support patients → manpower, transportation, safety constraints
Diagnosing at public clinics

small PHC labs: Malaria smears, BP, HBsAg card, Dengue NS1 card, Syphilis card, (AFB), glucometer, urine dipstick, pregnancy, HIV, urine sugar (Benedict)

- Limited funds for rapid tests
- Available rapid tests done in small labs
- → too long TAT (docs & labtechs have workload, manpower & infrastructure constraints)
Diagnosing at private clinics

**GPs: pregnancy, glucometer**

- Ensure POC with lab nearby (adjusted opening hours, kick-backs)
- Prefer older methods over rapid tests (too expensive for patients, doubt accuracy)
- Different strategies to avoid losing patients
Diagnosing at private labs

**Small labs:** urine dipstick, sugar, typhoid slide, blood grouping, Malaria smear, HB; some Dengue, Syphilis, HEP, Mantoux, renal & lipid function (exp), most don’t do AFB

- Small labs cannot afford rapid kits and their reagents
- Small volumes → ensure quick TAT with older, cheaper methods
Diagnosing in hospitals

**Wards:** glucometer, urine dipstick, pregnancy, HIV, ECG;

**Hospital labs:** use many rapid card tests (Malaria, Dengue, HBsAG, Syphilis, pregnancy, HIV (separate labs))

- Majority of rapid tests in labs → too long TAT (half a day/next day)
- HIV & TB testing in different locations → potential for loss to follow-up
- Lack of manpower to interact with lab & to act on results (OPD) → delay
Major barriers to POCT in India

1. Infrastructure: Material, money & manpower
2. Relationships: Interaction, coordination & patient-initiative
3. Adapting behavior & practices: emp. treatment vs. investigation
Material:
• Poorly equipped lab facilities, lack of tests & consumables, inadequate space & insufficient transport infrastructure for samples & staff
• Poor sample quality (targets)
  → delays or send patients away

Money:
• Cost of rapid tests (>2USD is too much)
• Cost to patients to get tested (transport, fees, loss of income, assoc. costs)
  → Long TATs raise costs further

Manpower:
• does not match workload, lack of training
• CHWs: irregular & low wages, no transport
  → backlogs, frustrations, discourages ordering investigations
Often *we do not get those [test] materials*, [so] *we have to send them [the patients] away, refer them to another hospital or they go to private.* (medical officer 1)

*They send samples because they are target oriented.* So at the end of each month, (...) doctors, staff, field workers, they refer lots of cases, even if it’s not a good [valid] case (program officer 3)

*They [medical officers] are loaded with programs, financial work, administrative work, that training, this training, so they will not have time [for testing patients]...* (program officer 3)
Relationships: Interaction, coordination & patient-initiative

- More interaction/coordination/cooperation \(\rightarrow\) more likely POCT
- Onus always on patient to get tested & follow-through

**Private sector:** tie-ups/kickbacks \(\rightarrow\) ensure POCT, but incentivize malpractice

**Public sector:** lack of cooperation & manpower shortage \(\rightarrow\) culture of blame, dysfunctional referrals between centres \(\rightarrow\) delays, loss to follow-up

**Patient-provider:** lack of counseling and explaining, neg. results not communicated \(\rightarrow\) patients roam around, lose trust, opt out
... it is not as if we are one group, the ANMs [auxiliary nurse midwives] are separate, staff nurses are separate, lab separate, everybody is separate. If we request somebody to help us when they are free they say “we are not lab technicians.” There are so many people working but nobody is ready to support us.” (Participant 3, FGD 9 lab technicians)

In case of such type of patients [where HIV test is required] we will not disclose them you are affected by this. If the patient is illiterate, he does not understand what we do.. there is no meaning in explaining them. Unless it is positive, we do not disclose. *We will do the test, we will not tell the patient.*” (Private practitioner 5)
Adapting behavior & practices: emp. treatment vs. investigation

Lack of infrastructure drives emp. treatment (no time, no privacy, no lab)

No functioning referral system/too long TATs favor emp. treatment (avoid losing patient)

System relies on patient: providers make it more attractive to patients: no tests/fast results, instant relief (strong medication), secretly conduct HIV tests
Why does POC testing hardly occur in India?

Onus is often on the patient to ensure completion of test and treat cycles across homes, clinics, labs and hospitals, amidst a multitude of uncoordinated providers with divergent and often competing practices in settings lacking material, money and manpower.

Barriers don’t act in isolation!

Material aspects, socio-cultural relations between actors and diagnostic practices are inseparably related.
Implications for POCT

- Currently: limits to material/money/manpower new tests can rely on
- Successful POCT assumes functioning relationships!
- Tests can harm/support these relationships

How to take such complexity into account when designing POCT programmes?
→ Through such studies!
→ Examine dynamics as a whole including each actor’s rationale
Thank You!
Questions?
Suggestions?
n.engel@maastrichtuniversity.nl
Sources qual. research handbooks

  [http://mihd.net/q0enrc](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

Tutorials from NVivo directly:

NVivo Getting Started guide
References

References cont


