

Qualitative Research in TB Dx

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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)

Type of Research Questions	Strategy	Paradigm	Method	Other Data Sources	
Meaning questions eliciting the essence of experiences	phenomenology	philosophy (phenomenology)	audiotaped "conversations"; written anecdotes of personal experiences	phenomenological literature; philosophical reflections; poetry; art	-
Descriptive questions— of values, beliefs, practices of cultural group	ethnography	anthropology (culture)	unstructured interviews; participant observation; field notes	documents; records; photo- graphy; maps; genealogics; social network diagrams	
"Process" questions experience over time or change, may have stages and phases	grounded theory	sociology (symbolic interactionism)	interviews (tape-recorded)	participant observation; memoing; diary	
Questions regarding verbal	ethnomethod- ology; discourse	semiotics	clialogue (audio/ video recording)	observation; field notes	
interaction and dialogue	analysis		(Denzing &	Lincoln, 1994)	5



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
- \rightarrow \rightarrow 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^{a,*}, Lindsay Mangham^a, Abanda Ngu Njei^b, Olivia Achonduh^b, Wilfred F. Mbacham^b, Virginia Wiseman^a

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 In many settings in Cameroon RI underused, overuse of antimalari patients are still being prescribed

Chandler et al. 2012: examined hove and treatment is dealt with in production of the second s

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

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

Data collection questions asked in qual. methods

- Aim: to elicit participants' perspective, experience, meaning, practices, processes and reason for action
- Open-ended

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- 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 <u>among</u> participants
- Summarize results
- Short survey among participants (do they have comments, anything to add)



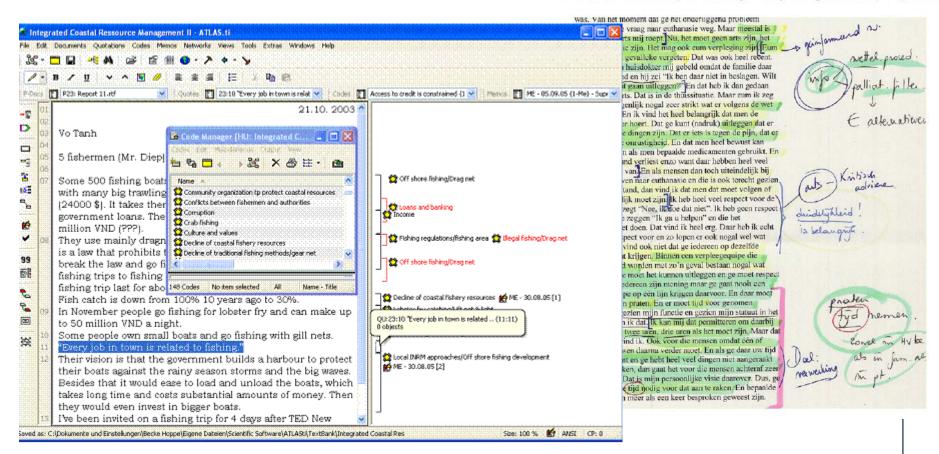
Data analysis

- 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



Coding

B. Dierckx de Casterlé et al./International Journal of Nursing Studies xxx (2011) xxx-xx





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



Quantitative and qualitative methods

Quantitative methods

Qualitative methodology

useful for generating numerical findings for statistical manipulations

- \rightarrow Statistical generalizations
- → Predictions
- → estimations of causal explanations
- → Hypothesis-testing

useful for understanding processes, context & considering experiences or perspectives

- \rightarrow Analytical generalizations
- → Interpreting or explaining numbers & causal events
- → Theory-building



Journal of Epidemiology and Global Health (2012) 2, 39-50



Why are inaccurate tube widely used in the Indian sector? A root-cause ana

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

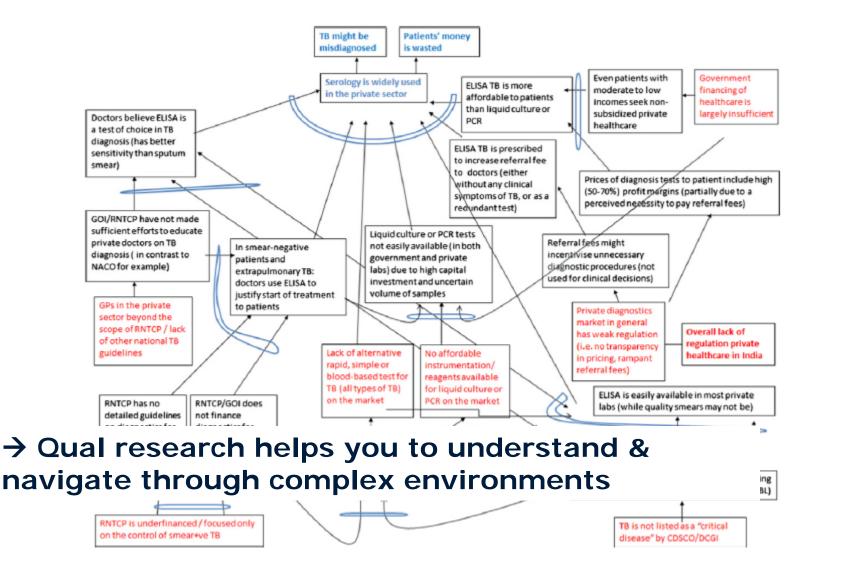
Example

ology

Szymon Jarosławski^a, Madhukar Pai^{b,*}

^a Institute of Bioinformatics and Applied Biotechnology, Bangalore, India ^b McGill University, Montreal, Canada

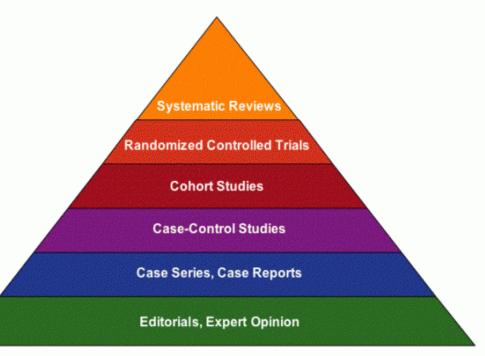






Quant vs. Qual:

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 quantiative 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



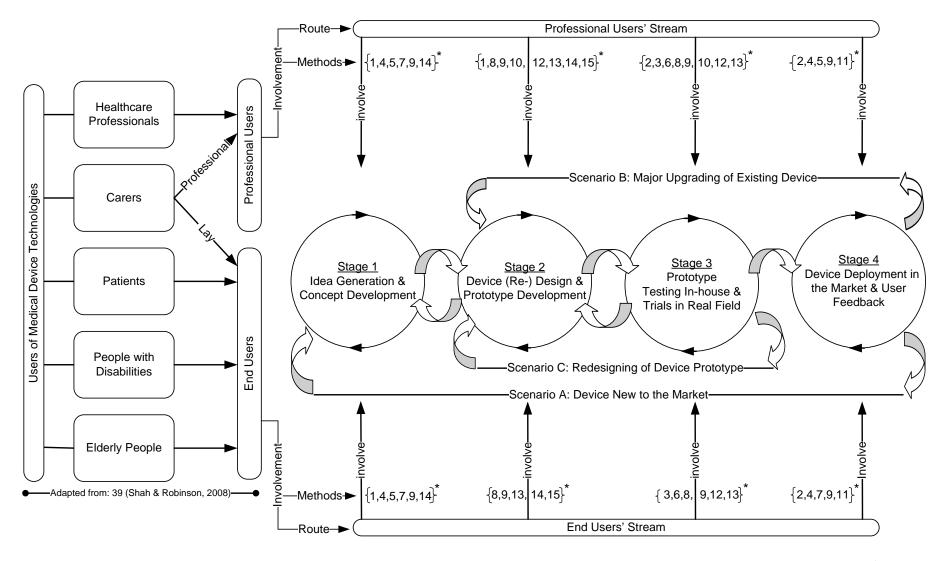
- End-users discard devices that do not fulfill their personal expectations
- Competing perspectives of developers, users, manufacturers, regulators

User involvement necessary:

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- <u>Concept stage</u>: interviews, focus groups, brainstorming sessions & users-producers seminars
- <u>Design stage</u>: 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)



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



Clinical Needs Assessment for POC R&D (Weigl et al., 2012)

CNA-Guided Product Development 0.Concept 1. Planning 2. R&D 3. Pilot & 4. Transfer, 5.Market Needs ID & Evaluation introduction & Discovery & Development integration & feasibility deployment sustainability assessment & prototyping **Policy Environment** Problem Economic Rationale Market Sustainability Characterization Segmentation and Stakeholder Cost analysis Landscape Analysis Market Size assessment Cost-effectiveness Assessment Feasibility assessment User Needs Analysis **Competitive Analysis** Assessments Acceptability Stakeholder Product Specifications assessment Assessments Assessments Stakeholder Due Diligence Assessments Willingness-to-pay



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

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- 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. goalfree 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...



Our Commitment

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We approach each new set of project objectives as a unique and exciting challenge.

As cultural and psychological anthropologists, we are committed to research methods that produce the richest and most authentic data on our clients' customers. Ethnography, our expertise, is a research method spawned by anthropologists. Anthropologists remain its best practitioners.

Ethnography, however, is not just a method. It also is a descriptive and interpretive enterprise. Our intuitive familiarity with social and psychological theory allows us

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When conducting ethnographic and qualitative projects with a global orientation, our researchers travel to each country not only to train and supervise our international research partners, but also to observe and direct the research process firsthand. By project end, this process enables us to achieve an integrated understanding of the key global patterns and identify critical nuances of

🖉 Global Reach 🌒



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 TR Dx

- Diagnosis as categorization:
 - Nichter, M. 1994. Illness sen complex in the Philippines

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- Bennstam, A.L., et al 2004.
 Congo
- Social process of diagnosis:
 - Watkins, R. E. & Plant, A. J.,
 - Rintiswati, et al. 2009. Joy/
 - Sagbakken, M., et al. 207
 in Addis Ababa, Ethiopiz
 - Murray, E. J., et al. 2013. His the impetus for tuberculosis d

Sagbakken et al, 2008: how symptoms of TB are perceived and managed \rightarrow 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

- Consequences of diagnosis
 - Ngamvithayapong-Yanai, J., et al. 2005. "If We Have to Die, We Just Die": Challenges and Opportunities for TB and HIV/AIDS Prevention and Care in Northern Thailand



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?

 \rightarrow 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, Syphillis, Hep.)

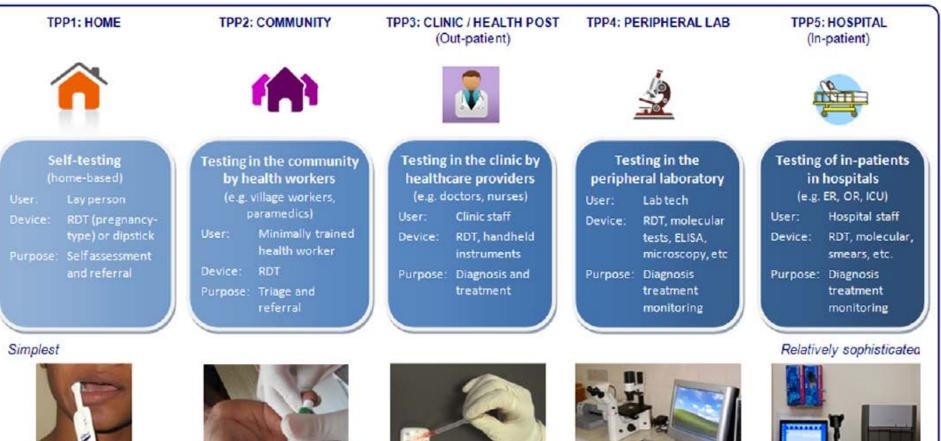
Where in public/private, urban/rural settings is POCT happening? if not, why is it not done?

<u>Team India (IPH):</u> Mamata Patil Vijayashree Gayatri Ghanesh, Devadasan

<u>Team South Africa:</u> Malika Davids (Keertan Deda's team, UCT) Nadine Blankvoort (UM)

Diversity of target product profiles, users, and settings (Pai et

al., 2012)



HIV self-testing



Malaria, HIV, dengue



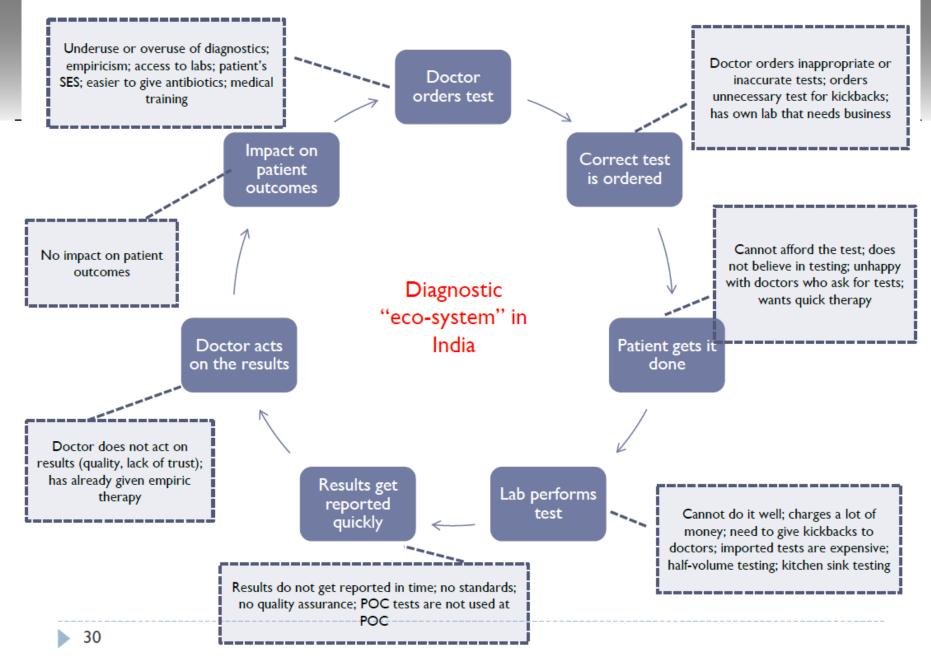
HIV, malaria, syphilis, dengue, Strep A



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.



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

Study Design

<u>Semi-structured interviews</u> with healthcare providers (doctors, nurses, specialists, trad. healers, 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

\rightarrow Major challenges to POC are linked to this difference

\rightarrow **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)











Major difference in diagnostic process

South Africa:

samples/reports/materials/communication travel between laboratories and providers via courier, fax, internet, telephone, paper record, SMS



 \rightarrow \rightarrow 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)

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: <u>small PHC labs</u>: Malaria smears, BP, HBsAg card, Dengue NS1 card, Syphilis card, (AFB), glucometer, urine dipstick, pregnancy, HIV, urine sugar (Benedict) → TAT challenges POCT <u>GPs:</u> 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: <u>wards</u>: glucometer, urine dipstick, pregnancy, HIV, ECG; <u>hospital labs</u> use many rapid card tests (Malaria, Dengue, HBsAG, Syphilis, pregnancy, HIV (separate labs)) → TAT challenges POCT



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







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)
- \Rightarrow Different strategies to avoid losing patients









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







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





- 1. Infrastructure: Material, money & manpower
- 2. Relationships: Interaction, coordination & patient-initiative
- 3. Adapting behavior & practices: emp. treatment vs. investigation

Infrastructure: Material, money & manpower

Material:

- Poorly equipped lab facilities, lack of tests & consumables, inadequate space & insufficient transport infrastructure for samples & staff
- Poor sample quality (targets)
- \rightarrow 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)
- ightarrow Long TATs raise costs further

Manpower:

- does not match workload, lack of training
- CHWs: irregular & low wages, no transport
- \rightarrow 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 & patientinitiative

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

Private sector: tie-ups/kick backs \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 midwifes] 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?

- \rightarrow Through such studies!
- \rightarrow Examine dynamics as a whole including each actor's rationale

Thank You! Questions? Suggestions?

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Sources Nvivo

Basics of coding: <u>http://www.youtube.com/watch?v=O9eTvP3E5TE</u>

Tutorials from NVivo directly: <u>http://www.qsrinternational.com/support_tutorials.aspx?productid=18</u>

NVivo Getting Started guide <u>http://download.qsrinternational.com/Document/NVivo9/NVivo9-Getting-Started-Guide.pdf</u> <u>http://download.qsrinternational.com/Document/NVivo10/NVivo10-Getting-</u> Started-Guide.pdf Nvivo 10



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