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in Learning!*

Qualitative Research in TB Dx

An introduction & argument for its relevance

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Outline

1. Examples of qualitative research
2. Why is qual research important for TB Dx?
3. Paradigms, methods of qualitative research
4. What qual methods are already being used in areas related to Dx 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)

1. Examples of qualitative research



Social Science & Medicine 74 (2012) 1528–1535



Contents lists available at SciVerse ScienceDirect

Social Science & Medicine

journal homepage: www.elsevier.com/locate/socscimed



‘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

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- In many settings in Cameroon RD underused, overuse of antimalarials patients are still being prescribed

Chandler et al. 2012: examined **how and treatment is dealt with in practice**

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:

- show a divide between parasitebased guidelines initiated in Geneva & 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

Results from focus group discussions (Chandler et al., 2012)

'When we do the malaria test and it comes out negative, it does not prevent the patient from having his malaria ... We continue with the antimalarial treatment.' (P11, FGD305 Yaoundé, mission facility midwives/nurses)

- Malaria is well-known, common & serious in Cameroon
→ presumptive treatment, even when lab results are negative
 - Malaria defined by clinical symptoms & experience, not just lab test
- role of individual experience of clinician neglected in guidelines

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

Implications for scale-up of Malaria RDTs (Chandler et al. 2012)

- Rapid scale-up of RDTs more complicated than expected
→ healthcare is a complex social process
- Don't overrule social functions, but support health workers in them
 - Raise consciousness of the reasons for and consequences of certain practices & stimulate problem-solving among healthworkers w/o compromising clinical outcomes (placebos)
 - Encourage experimentation with new tools in practice & assessing patient's responses
 - Support communication skills of health workers

→ Qual research helps understand complex setting & can support scale-up of existing diagnostic test



Original Article

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

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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,



New Tests: designing a 'product in a box' (Engel, 2012)

- 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



New Tests: designing a 'product in a box'

- PATH India: Designing a 'product in a box' which is tested in community last
 - "When the kit is ready, we need to talk to the patients also. Maybe there will be some cultural issues on that. We don't know. We don't know how the community responds to this test." (Interview, int. NGO programme manager -3, Hyderabad, 27.11.2008)*
 - field conditions act as test for acceptance, not as component in development stage *'technology diffusion perspective'*
- *The way standardization is done excludes non-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



Who should be included in development of diagnostics? (Engel, 2012)

- Constructivist view on science: relevant social groups have different forms of expertise → none is a priori superior over the other (Bijker, 2009)
 - Considerable *scientific uncertainty*: Room to deliberate freely among scientists without involvement of interest groups (Bijker, Bal & Hendriks, 2009)
 - not given → local scientific expertise excluded
 - Designing a product in a box involves also *political, operational & cultural uncertainty* → more than scientific expertise is needed
 - often local non-scientific expertise is excluded
- → 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 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”)



ELSEVIER

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

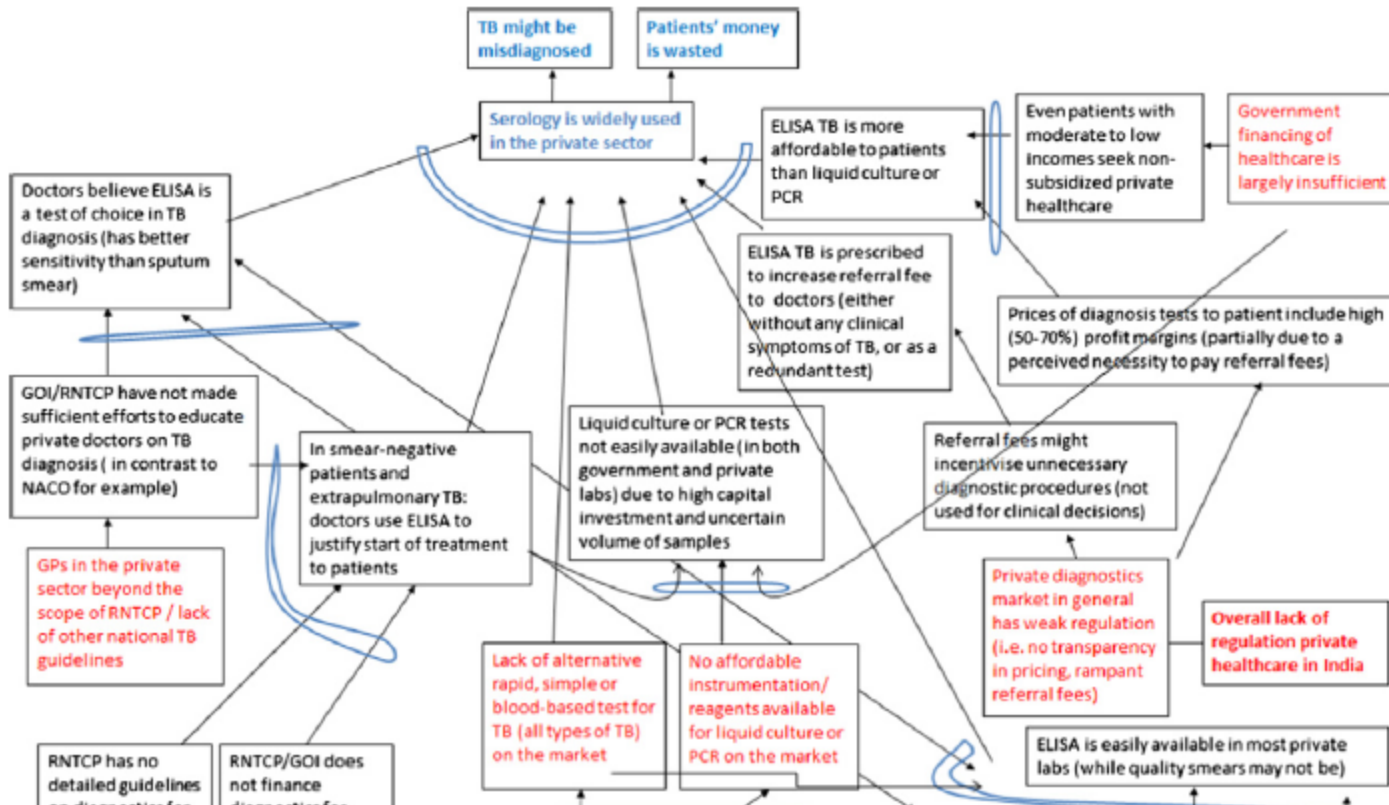
Szymon Jarosławski ^a, Madhukar Pai ^{b,*}

^a *Institute of Bioinformatics and Applied Biotechnology, Bangalore, India*

^b *McGill University, Montreal, Canada*

Example #3

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



(Jaroslowski & Pai, 2011)

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** questions in **evaluation of interventions** (combined with RCT and quantitative methods)
- ..support **design process** of medical device
- ..answer questions about **technology-in-use**

Diagnosis is central to medicine

- Diagnosis validates what counts as disease; offers explanations and coherence to patients' symptoms; legitimates illness, enabling patients to access the sick role; provides means to access resources and facilitates their allocation; and forms the foundation of medical authority. (Jutel & Nettleton, 2011)
 - Change in nature of diagnostic process
 - Diagnosing is now more complex: New categorizations of potential diseases and risk factors
 - patients bring expertise, knowledge and expectations
 - Progress in biotechnology, RDTs, self-testing
- qual research good at examining processes

Future of diagnostic research (editorial of Journal of Epidemiology & Community Health, 2002)

- Distinction in practice:

performance of diagnostic tests



comprehensive patient care

- Is mirrored in research: the part that a diagnostic test is supposed to play in patient-practitioner encounter is hardly researched (diagnostic decision-making, diagnostic processes)

→ qualitative research & active participation of clinicians are essential

Qual research supports market & product requirement documentation (Weigl et al., 2012)

- If you do not innovate incrementally (build on existing platform) but innovate a new platform or setting of use (POC)
- You need to:
 - develop and clinically validate a new device
 - Identify simultaneously potential end-users
 - Formulate reimbursement approaches
 - educate medical and diagnostic establishment
 - develop use algorithms

→ academic, nonprofit, or commercial start-up diagnostics R&D settings not equipped to do that

Why is qual research important for you?

- As a lab scientist you might not think in these terms

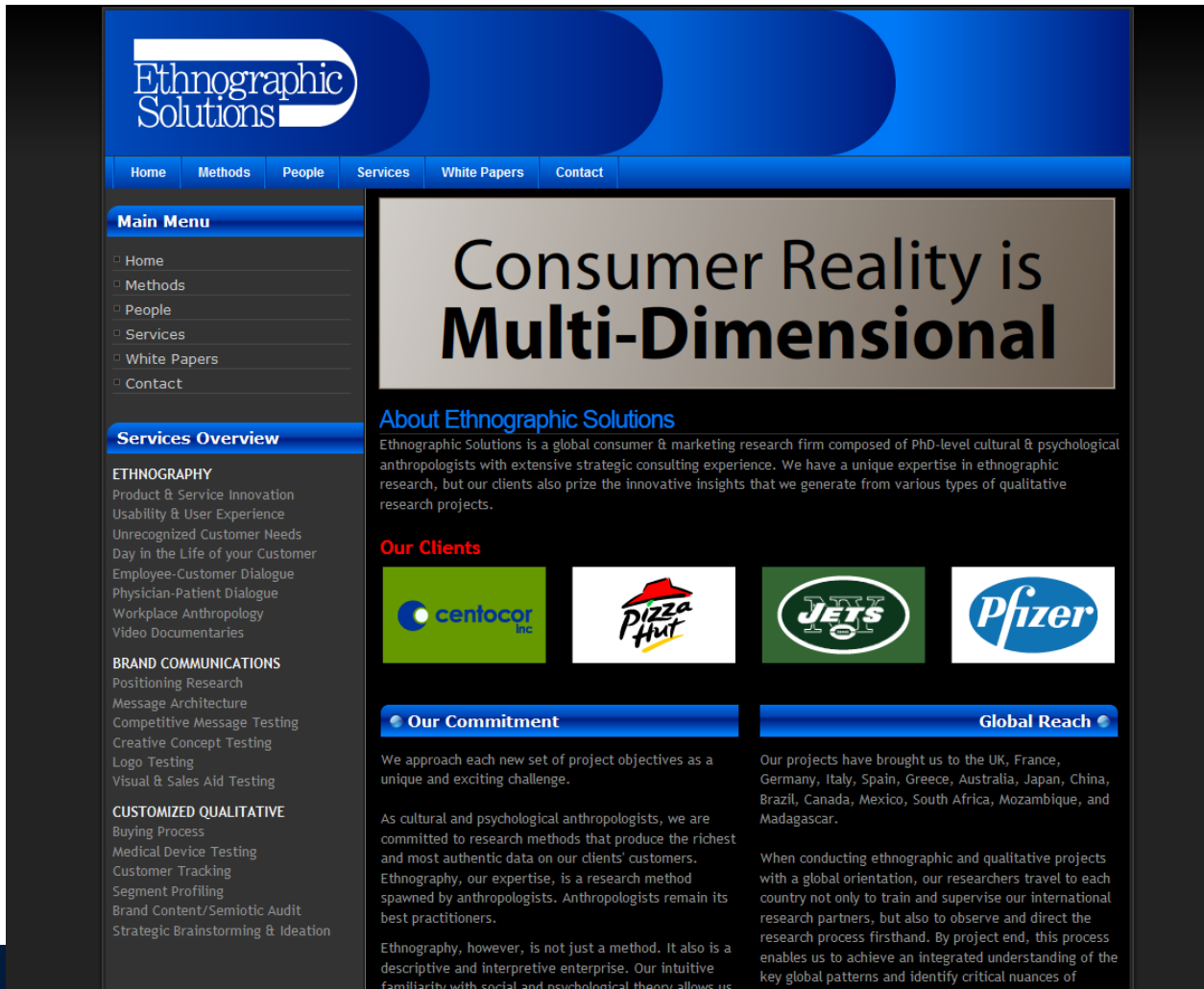
But qualitative research will..

- ..help you to develop better products: create better fit with local contexts, user needs and support scale-up to different contexts,
- ..support 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...



The screenshot shows the website for Ethnographic Solutions. The header features the company logo and a navigation menu with links for Home, Methods, People, Services, White Papers, and Contact. A main menu on the left lists these categories. The central content area has a large heading: "Consumer Reality is Multi-Dimensional". Below this is a section titled "About Ethnographic Solutions" which describes the firm as a global consumer & marketing research firm. A "Our Clients" section displays logos for Centocor Inc., Pizza Hut, the New York Jets, and Pfizer. At the bottom, there are two columns: "Our Commitment" and "Global Reach".

Ethnographic Solutions

Home Methods People Services White Papers Contact

Main Menu

- Home
- Methods
- People
- Services
- White Papers
- Contact

Services Overview

ETHNOGRAPHY

- Product & Service Innovation
- Usability & User Experience
- Unrecognized Customer Needs
- Day in the Life of your Customer
- Employee-Customer Dialogue
- Physician-Patient Dialogue
- Workplace Anthropology
- Video Documentaries

BRAND COMMUNICATIONS

- Positioning Research
- Message Architecture
- Competitive Message Testing
- Creative Concept Testing
- Logo Testing
- Visual & Sales Aid Testing

CUSTOMIZED QUALITATIVE

- Buying Process
- Medical Device Testing
- Customer Tracking
- Segment Profiling
- Brand Content/Semiotic Audit
- Strategic Brainstorming & Ideation

Consumer Reality is Multi-Dimensional

About Ethnographic Solutions

Ethnographic Solutions is a global consumer & marketing research firm composed of PhD-level cultural & psychological anthropologists with extensive strategic consulting experience. We have a unique expertise in ethnographic research, but our clients also prize the innovative insights that we generate from various types of qualitative research projects.

Our Clients

centocor inc. Pizza Hut JETS Pfizer

Our Commitment

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

Global Reach

Our projects have brought us to the UK, France, Germany, Italy, Spain, Greece, Australia, Japan, China, Brazil, Canada, Mexico, South Africa, Mozambique, and Madagascar.

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

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)

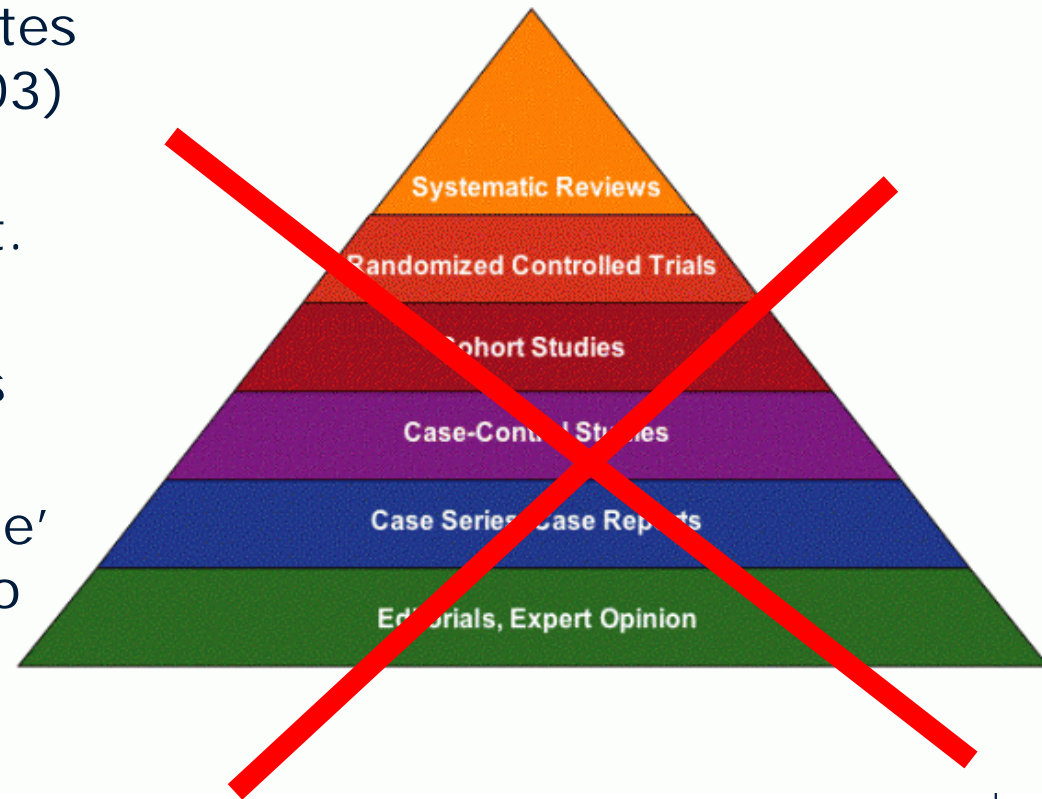


Quant vs. Qual:

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

→ rather: what information is relevant in what situation?

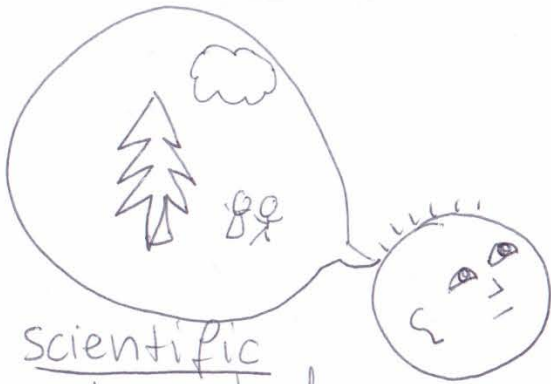
- instead of making 'ultimate' judgments about what is to be considered as 'best' evidence for policymaking, and which kind of data are 'better'.



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!

Positivism



scientific knowledge
= superior:
not colored
= exact picture



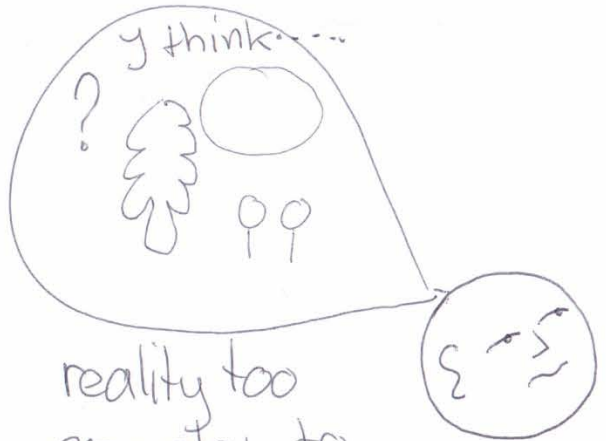
normal individual

lay understanding
= trial + error
= common sense
= colored
= imperfect

reality can be known if not blurred by subjectivity/emotions etc. →

strict rules on methods
guarantee true knowledge

Post-positivism



reality too complex to know it all

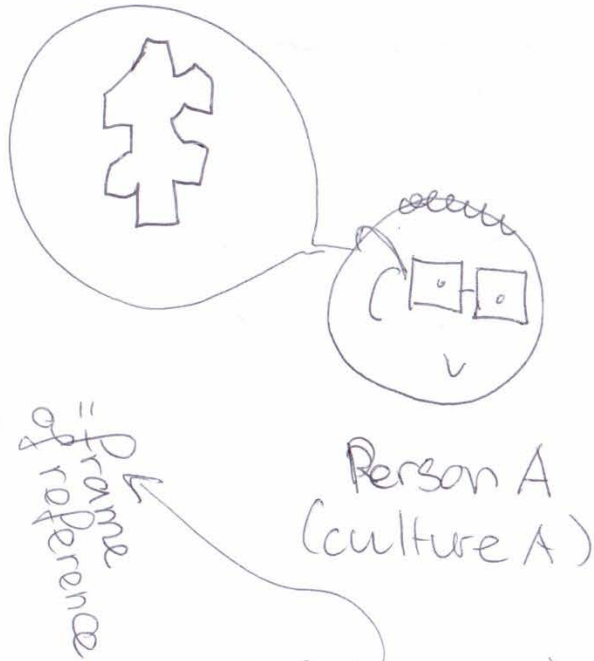
↓
reduced (simplified) to theory
"for now"

striving for perfect knowledge →



← methodology not too strict
falsification
still superior to lay-knowledge

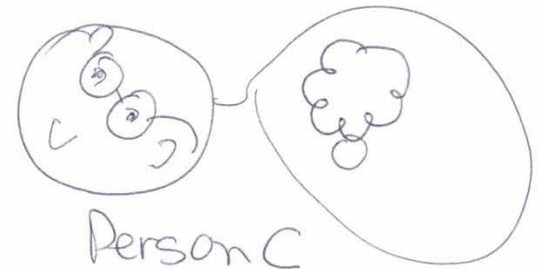
Interpretivism



we need 'glasses' to see reality,
without them we're blind.
They shape our understanding
our interpretations of reality

methodology: relativist claim not
too strict: 9LR!!

(culture B f.i. science)

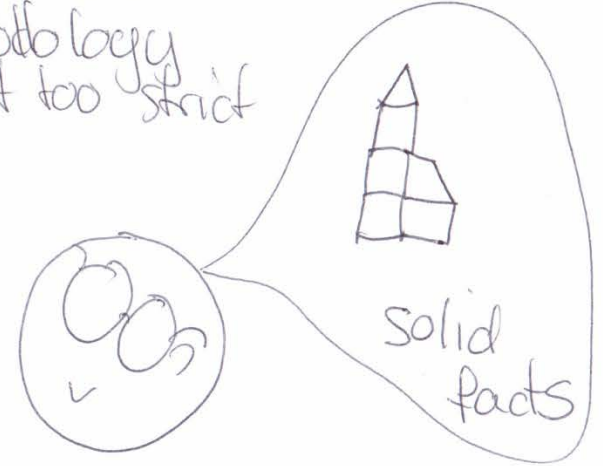
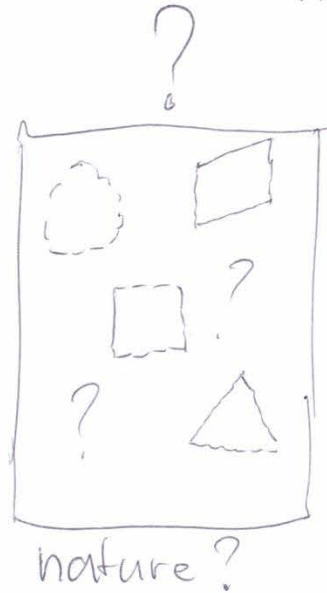
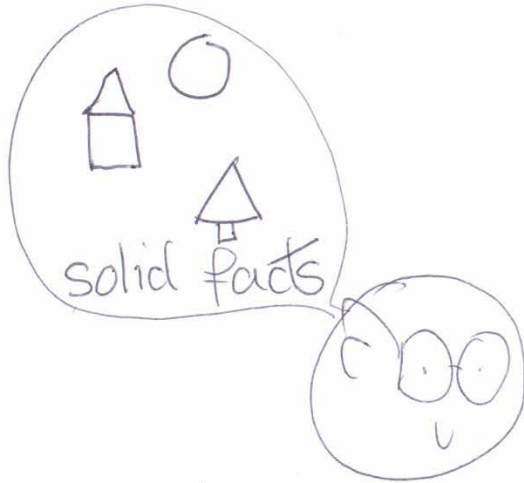


→ knowledge is always
subjective

understanding people is
understanding their perc.

Constructivism

knowledge claim
relativist:
methodology
not too strict



person A
creates solid facts
fact = construction:
mix of reality/norms/values
etc.

person B
scientist: facts
more widely
accepted
but still mix of
reality norms + values

QLR: to deconstruct =
study process of construction
+ implication +

QLR: to ~~research~~ study these processes!

Critical theory

Knowledge is power?

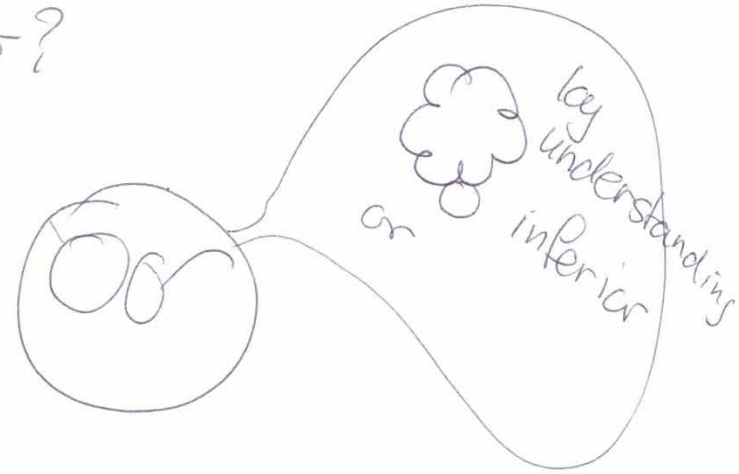


underlies social difference

science = at the side of the dominant - seen as superior



knowledge claim: relativist / dialogical



determines chances + possibilities of ordinary people

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; photography; maps; genealogies; 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 interaction and dialogue

ethnomethodology; discourse analysis

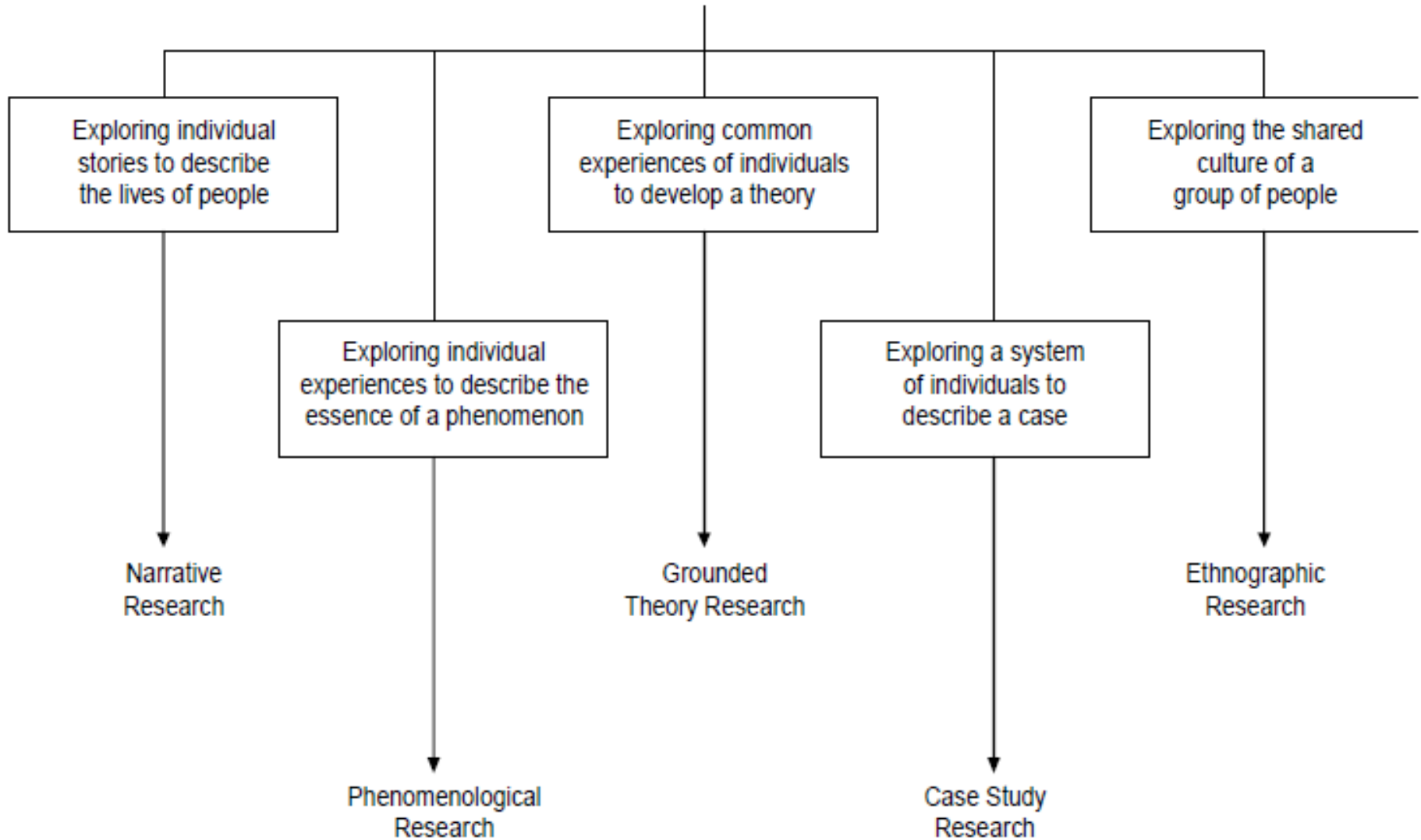
semiotics

dialogue (audio/ video recording)

observation; field notes

(Denzing & Lincoln, 1994)

Qualitative Research Designs



Data collection techniques

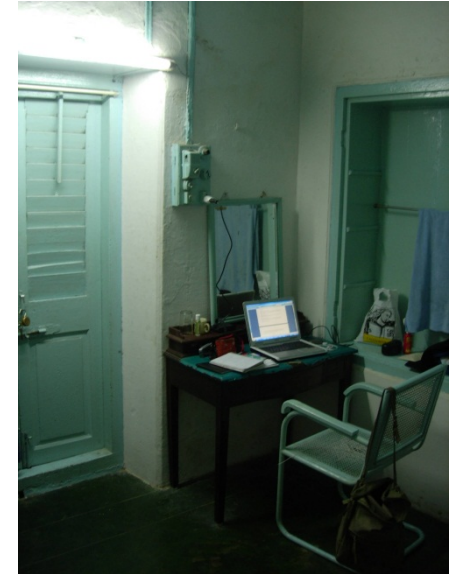
- Interviews (semi-structured, structured),
 - Focus group discussions,
 - Participant observation,
 - Text/discourse analysis,
 - Conversation/video analysis
- Assess data collection: describe context & structure of the situation, record observations of participants, assess quality of the data, evaluate usefulness of questions, acknowledge areas of difficulty
- → going back & forth between data and questions and theory

Qualitative fieldwork example (9 months)

Over 100 semi-structured interviews practitioners, public health experts, policymakers, members of civil society, microbiologists, WHO, donors, pharmaceuticals, health staff, community workers, patients

Document research
government documents,
conference proceedings,
research articles, news items
and the Internet

Sites: hospitals, government buildings, research institutes, pilot sites, policy meetings, patients' home, rural & urban health facilities, community projects, conferences



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)

Example focus group study:

- Hsieh et al., 2010: explore the perceptions of the ideal types and characteristics for STI POCTs for use in clinics and other care settings, FGDs with clinicians, opinion leaders, and public health professionals
- Chandler et al., 2012: FGDs on how Malaria, its diagnosis and treatment is practiced & contrasts to WHO guidelines on RDTs

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

Data analysis: Software

- Nvivo, Atlas.ti, Ethnograph, Kwalitan
 - Allows to
 - enter texts, audio, video
 - assign codes to sections (referring to concepts)
 - Search & retrieve codes, sections
 - categorize codes
 - Make field notes (memo's)

Coding

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

The screenshot shows the ATLAS.ti software interface. The main window displays a text document titled 'P23: Report 11.rtf' with the following text:

21.10.2003

Vo Tanh

5 fishermen (Mr. Diep)

Some 500 fishing boats with many big trawling (24000 \$). It takes them government loans. The million VND (???)

They use mainly drag nets. There is a law that prohibits to break the law and go fishing trips to fishing fishing trip last for about 4 days. Fish catch is down from 100% 10 years ago to 30%. 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. Then they would even invest in bigger boats.

I've been invited on a fishing trip for 4 days after TED New

The Code Manager window is open, showing a list of codes:

- Community organization to protect coastal resources
- Conflicts between fishermen and authorities
- Corruption
- Crab fishing
- Culture and values
- Decline of coastal fishery resources
- Decline of traditional fishing methods/gear net

The code tree on the right side of the interface shows a hierarchical structure:

- Off shore fishing/ Drag net
- Loans and banking
- Income
- Fishing regulations/ fishing area
- Off shore fishing/ Drag net
- Decline of coastal fishery resources
- Local INRM approaches/ Off shore fishing development

was, van het moment dat ge net onderzuggena probeeren vraag naar euthanasie weg. Maar meestal is nu, het moet geen arts zijn, het is zijn. Het mag ook eum verpleging zijn. Eum is gevallen vergeeten. Dat was ook heel recent. Huisdokter mij gebeld omdat de familie daar ad en hij zei "ik ben daar niet in beslagen. Wilt u gaan uitleggen?" En dat heb ik dan gedaan. Dat is in de thuis situatie. Maar eum ik zeg genlijk nogal zeer strikt wat er volgens de wet. En ik vind het heel belangrijk dat men de er hoort. Dat ge kunt (nadruk) uitleggen dat er dingen zijn. Dat er iets is tegen de pijn, dat er onrustigheid. En dat men heel bewust kan n als men bepaalde medicamenten gebruikt. En ind verliest enzo want daar hebben heel veel van. En als mensen dan toch uiteindelijk bij ven naar euthanasie en die is ook terecht gezien tand, dan vind ik dat men dat moet volgen of lijk moet zijn. Ik heb heel veel respect voor de zegt "Nee, ik doe dat niet". Ik heb geen respect s zeggen "Ik ga u helpen" en die het et doen. Dat vind ik heel erg. Daar heb ik echt peet voor en zo lopen er ook nogal wel wat vind ook niet dat ge iedereen op dezelfde t krijgen. Binnen een verpleegequipe die d worden met zo'n geval. Bestaan nogal wat e moet het kunnen uitleggen en ge moet respect edereen zijn mening maar ge gaat nooit een pe op een lijn krijgen daarvoor. En daar moet n praten. En er moet tijd voor genomen zien mijn functie en gezien mijn statuut in het a ik dat. Ik kan mij dat permitteren om daarbij twee uren, drie uren als het moet zijn. Maar dat ind ik. Ook voor die mensen omdat één of sen daarna verder moet. En als ge daar uw tijd nt en ge hebt heel veel dingen niet aangeraakt ken, dan gaat het voor die mensen achteraf zeer. Dat is mijn persoonlijke visie daarover. Dus, ge < tijd nodig voor dat aan te raken. En bepaalde n meer als een keer besproken geweest zijn.

→ geïnformeerde n.
 nettel. proced.
 palliat. filter
 E alternatieven

arts - kritische
 adviseer.

duidelijkheid!
 is belangrijk.

praten
 tijd nemen.

Daar:
 medewerking

conver. in HV be
 als in fam. at
 in pt.

Quality assurance

Traditional criteria (quant. research)

- Objectivity
- Validity
- Reliability

Specifically for qual. research

- Triangulation
- Reflexivity
- Credibility & plausibility

Good qual. research = good science

TABLE 8.1 Components of Rigor

<i>Terms</i>	<i>Verification</i>	→	<i>Validation</i>	→	<i>Validity</i>
Process	Strategies internal to inquiry		Within project evaluation		Outcome
Means	Design Bracketing Saturation Methodological cohesion		Inter-rater reliability Member → checks Audit trail Computer-assisted analysis		Trustworthiness
Source	Investigators		Investigators		External judges and standards

(Meadows & Morse, 2001)

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)

4. What qual methods are already being used in areas related to (TB) Dx research?

What qual methods are already being used in areas related to TB Dx research?

1. Sociology of diagnosis
2. Qualitative methods in clinical trials, testing interventions
3. Qualitative methods in medical device design (design ethnographies)
4. Qualitative methods in evaluation of health technology (Health Technology Assessment)

Review Article

Sociology of diagnosis: a preliminary review

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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**
 - Nichter, M. 1994. Illnesses of the weak lungs/TB complex
 - Bennstam, A.L., et al 2008. Democratic Republic of Congo
- **Social process** of diagnosis
 - Watkins, R. E. & Plant, Tuberculosis in Bali
 - Rintiswati, et al. 2009. Jogikarta
 - Sagbakken, M., et al. 2008. Perception and Management of Tuberculosis Symptoms in Addis Ababa, Ethiopia
 - Sagbakken, M., et al. 2010. Experiences of being diagnosed with TB among immigrants in Norway - diagnostic delay

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
 - 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

Sociology of diagnostic technology (Science and Technology Studies' view)



We see & talk about the device, healthworker & patient, but hardly: necessary infrastructure, training, maintenance, regulation, monitoring, quality assessment, etc.

STS accounts make all those things and the work around them visible (and with it the uncertainties & responsibilities involved (de Vries, 2008))

Sociology of diagnostic technology (Science and Technology Studies' view)

- shows that diagnostic instruments do not exist independently of practitioners but they are a central part of and transformed through their application (Jutel & Nettleton, 2011)
 - society & technology influence each other
- Study technology-in-use & innovation processes
 - Pasveer, B. 1989. Knowledge of shadows: the introduction of X-ray images in medicine
 - Mueller-Rockstroh, B. 2007. Ultrasound Travels: The Politics of a Medical Technology in Ghana and Tanzania
 - Engel, N. 2012. New diagnostics for multi-drug resistant Tuberculosis in India

Some important concepts

- Local explanatory models, different perspectives on disease & diagnosis
- „Culturalism“ (Lock & Nguyen) in health services turns attention away from the socio-economic & political aspects
- „Structural violence“ (Farmer): relationship between poverty, marginalisation & disease
- Examining disease (control) in practice (Nichter, Mol)
- Technology & society co-evolve, mutual shaping (Jasanoff, Bijker)

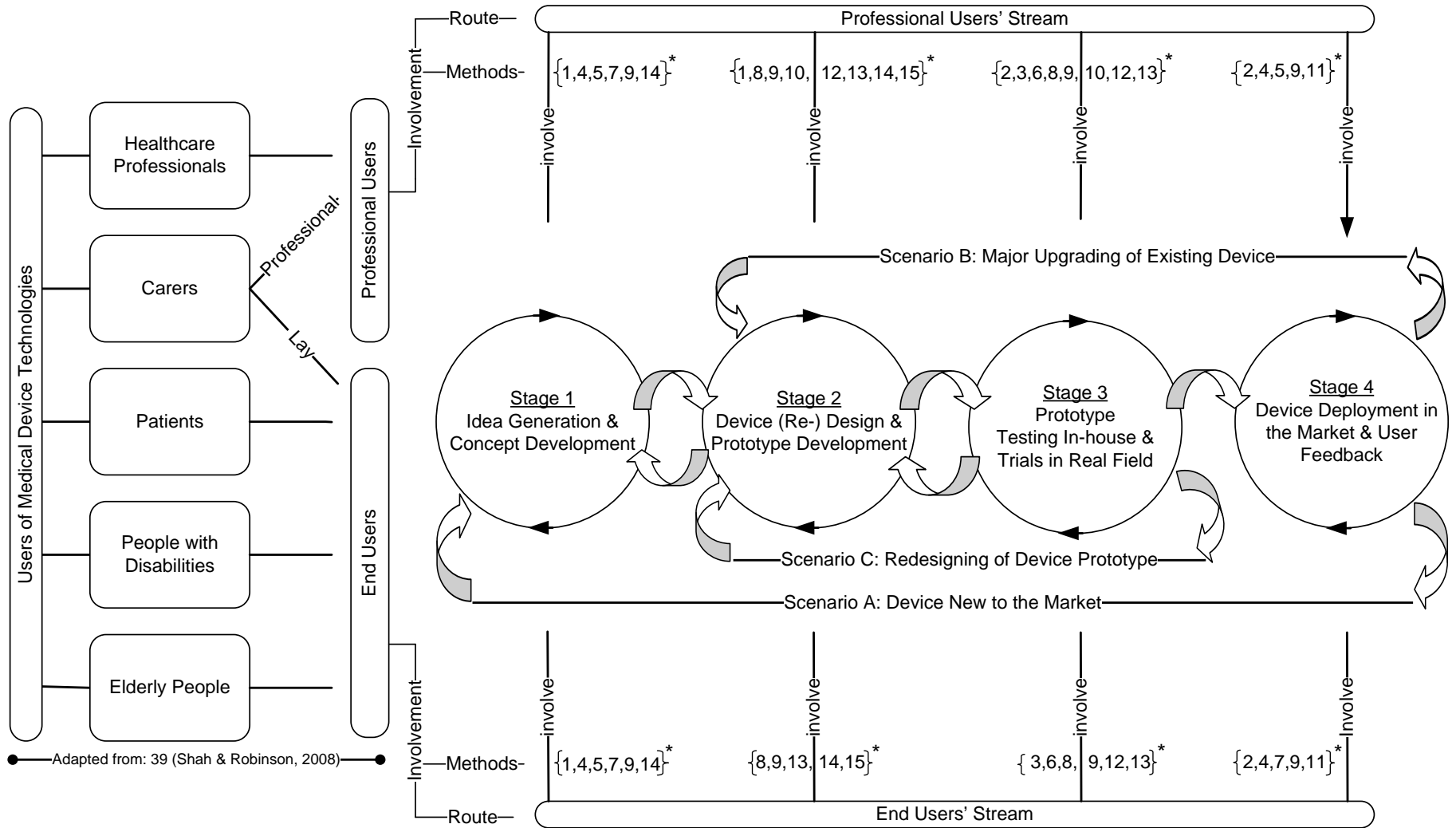
3. Qualitative methods in medical device design (Shah et al 2009)

- 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)

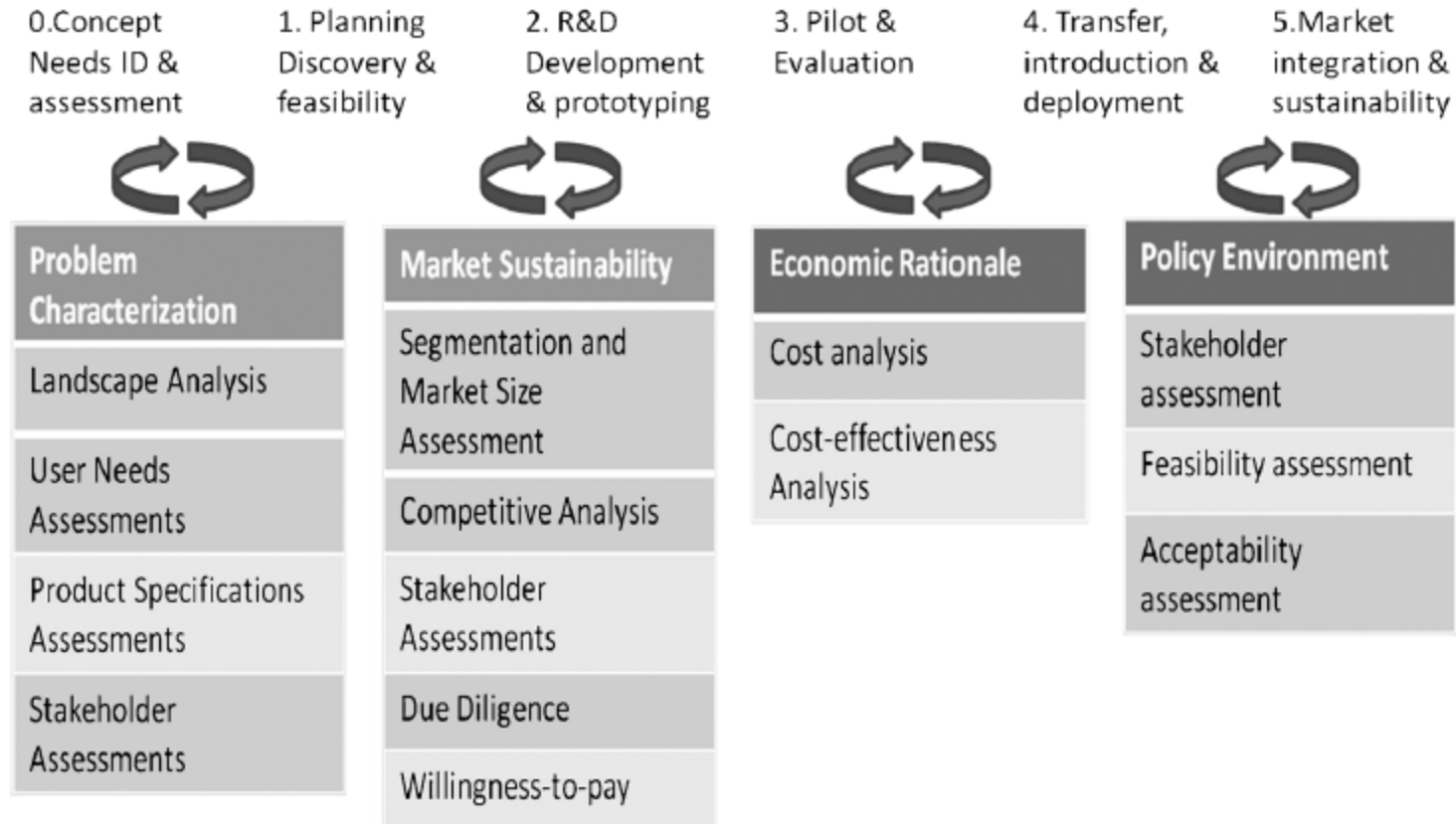


- *{User Involvement ⇌ Methods
- 1. Brainstorming sessions
 - 2. Cognitive walkthrough
 - 3. Discussion with users
 - 4. Ethnography
 - 5. Expert users meetings
 - 6. First human use
 - 7. Focus groups
 - 8. In vitro tests
 - 9. Interviews
 - 10. Observations
 - 11. Surveys
 - 12. Think aloud method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

Clinical Needs Assessment for POC R&D

(Weigl et al., 2012)

CNA-Guided Product Development



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



4. 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)

Why is qual research important for you?

- As a lab scientist you might not think in these terms

But 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 introduction of existing products (implementation)
- ..evaluate what products do to the context

→ reach out to social scientists & qualitative researchers!!

(medical anthropologists & sociologists, design ethnographers, science & technology studies scholars)

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Thank You!
Questions?
Suggestions?

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