



# EXCHANGE

## newsletter

## Introduction

Illness is a risk to people's livelihoods and a cause of impoverishment in many settings. Health policy interventions that protect households from high illness costs and impoverishment, for example through the removal of user fees, or the introduction of social health insurance or community prepayment schemes, have become a key focus of international health policy debates. Yet we have only limited knowledge of household experiences of illness costs and impoverishment, their uptake of policy measures aimed at protecting their livelihoods, and in particular the factors that increase susceptibility to impoverishment or enable resilience. The second research objective of the Consortium for Research on Equitable Health Systems (CREHS) is to evaluate the implications for the poorest of current and evolving financing arrangements, and identify how cross-subsidies in their favour can be developed.

One of the first CREHS activities in support of this objective was to organise a workshop which was held in Kilifi, Kenya from 13-16 June to bring together work done by CREHS-related researchers on the subject of household experience of ill-health and risk protection mechanisms. A series of papers were presented which adopted a variety of quantitative and qualitative methodological approaches including cross-sectional surveys, longitudinal case study methods and anthropological approaches such as family portraits, with many studies using mixed methods. Theoretical perspectives also varied, with papers drawing on concepts such as sustainable livelihoods, microeconomic models of household resource allocation, and household cost burdens and catastrophic healthcare payments. Taken together, these studies increase understanding of household decision-making at times of illness, and the treatment actions and illness costs that contribute to impoverishment, as well as casting light on policy measures that protect the poor. The strength of this group of studies is the comparative international experience from a range of different country contexts (Kenya, Tanzania, Nigeria, South Africa, Thailand, Lao, and India) where similar issues arise, such as the need to reduce out-of-pocket payments, ineffective implementation of exemptions, and the importance of both formal and informal social support (social grants, social networks) in enabling household resilience. In the coming months workshop participants will be finalising their papers which we hope to bring out as a journal collection. In the meantime, the summaries provided below give a flavour of the methods and findings.

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### **SACOCO - Falling through the social welfare net? Public health services, social grants and illness induced impoverishment in rural South Africa**

Poverty reduction is at the heart of the international development agenda. Health policy debates have focused attention on how to promote affordable public health services that do not trigger impoverishment due to treatment costs. The removal of user fees and other financing sources (prepayment schemes, social insurance or taxation) are advocated as a means to spread risks and minimise cost burdens (Gilson, McIntyre et al 2006). Social grants are seen as enabling uptake of health services when households face the combined burden of income losses due to ill health and the costs of seeking treatment (Chapman 2006).

A small but growing literature has documented the level of the cost burdens household face, but greater understanding is required of how household experiences mediate the effects of formal policy on the ground, and the factors that determine

a household's vulnerability or resilience to illness induced impoverishment. This paper presents the first detailed report of South African household experiences, and is one of a very limited number of papers internationally to draw on in-depth, longitudinal qualitative data to examine these issues. As South Africa has a number of relevant policy interventions, including free public primary care services, exemptions for the poor from public hospital fees, and social grants, it is an interesting setting in which to examine experience.

In a rural Health and Demographic Surveillance Site in one of the poorest provinces in South Africa, the study conducted a survey of 280 households. 30 households were studied for 10 months, using quantitative data collected in household diaries, and in-depth qualitative interviews to understand the household decisions and events determining cost burdens and impoverishment.

Free public primary care, hospital exemptions and social grants combined to protect some poor households from illness induced impoverishment. Households with a more secure livelihood had fewer, less complex illnesses, with free care at public primary health clinics providing effective relief. If a more complex illness occurred, exemptions and higher household income enabled regular visits to a public hospital. In vulnerable households limited resources and a greater number of illnesses led to either non-consultation despite ill health, or high cost burdens, and in some cases livelihood decline. When faced with health system weaknesses (such as lack of drugs, ambulances, insufficient explanation of the illness and its treatment), patients often chose not to use limited funds to return to a facility that had 'failed' to provide relief but resorted to 'healer shopping'. Treatment patterns combining private allopathic providers, traditional and religious healers generated high cost burdens often leading to livelihood decline.

High cost burdens did not automatically lead to decline. With sufficient understanding of the treatment, and convinced of its efficacy, households mobilised gifts and loans from the family and community to pay for treatment. However, without the financial support of strong social networks, sustained treatment seeking in vulnerable households was not possible.

Social grants were a key factor in explaining the experiences of secure and vulnerable households. Secure households were often headed by a person receiving a social pension. Access to exemptions at public hospitals was easier because the individual was receiving a pension. Households without a pensionable adult were more vulnerable due to lower grant income, greater difficulty in obtaining exemptions at public hospitals, and greater likelihood of costly long term infectious diseases such as TB and HIV.

The South African experience highlights some key problems: a) when access to exemptions at public hospitals is facilitated by other components of the social welfare system some intended beneficiaries may not receive exemptions; b) although equitable financing mechanisms and grants increase the use of services and reduce poverty, the provision of effective care that doesn't generate high cost burdens is equally important; c) both social grants and social networks are central to the resilience and survival of vulnerable households. Policy interventions need to enable households to make greatest use of the synergies between different types of social protection.

This study was funded by the Wellcome Trust.

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## Understanding resilience pathways in malaria case management in the light of rural livelihood: The case of Kilombero district, Tanzania

This exploratory study employed a resilience approach in the context of the Sustainable Livelihood Framework (SLF) to illustrate how people gain access to resources in order to access treatment for malaria in a risk prone environment. Resilience is broadly conceived as the strengths of risk-exposed individuals in terms of adjustment outcomes and assets/protective factors that promote positive adaptation. Using the SLF we explore households' livelihood strategies and the accessibility of households to five forms of capital that make their livelihoods possible and also enhance their ability to manage malaria episodes. These resources include human capital (such as the physical ability of individuals); social capital (social networks and affiliations); natural capital (such as land); physical capital (infrastructure and machinery); and financial capital (cash and credit). The SLF also considers the role of policies and institutions (norms and rules) in shaping access to resources needed in pursuit of intended livelihood options.

The study was undertaken in two villages of Kilombero District, Tanzania between November, 2006 and February, 2007. To develop household portraits of experiences in malaria case management, data were collected through intensive

interactions with households at both primary residence and farming fields houses (*shamba* houses). Community focus group discussions were held to supplement the information collected from the case households.

The livelihood strategies of households were found to be clearly shaped by seasonal mobility to the *shambas* where the majority of households stay in temporarily built houses. This period of the year is characterized by spatial and temporal isolation, coupled with intensive use of financial and time resources for farming activities, leaving little time for proper child care or participation in off-farm income generating activities. As a result of being away from the primary residence, more time is needed to mobilize the resources needed to seek health care. Due to a lack of preparedness strategies, most children who were sick at the *shamba* houses only received treatment between the third and fifth day after falling ill, compared to children who were at their primary residence, of whom more than 50 percent received treatment within 24 hours. This led the children to be severely ill by the time they reached the health facility.

Creating resilience avenues for malaria case management is a process developed and supported by the individuals, communities, and external factors operating in the livelihood system. Resilience could be understood *ex ante*, that is preparedness for the "most likely shock" and *ex post* when the household has been exposed to malaria. At the primary residence, households keep a stock of anti-pyretic drugs to treat fever and money to meet unforeseeable future events, but only a few households visited in the *shamba* houses had stocked anti-pyretic drugs. Despite some differences between primary and *shamba* residences, resilience avenues *ex post* include financial resources, physical infrastructure such as passable roads and access to bicycles for transport from the *shambas* to the sources of health care. Social networks that facilitate mobilization of people for taking care of the sick or transporting them to the sources of care, and money for bicycle renting and treatment costs are also important.

The strength of the approach employed in this paper lies in its ability to explore and link livelihood options, resources, and institutions in understanding the adaptive system of the households that enables and supports effective malaria case

management. In order to create an adaptive system, layers of resilience have to be drawn together. These range from what the household and community members can do to transform the prevalent resilience avenues into use, and how this is facilitated by the health system and policy environment. Future resilience is therefore contingent on the ability of households to generate income needed to access malaria treatment and physical assets such as bicycles; other potential avenues of support include promotion of community based networks and initiatives to contribute to health system accountability, and information campaigns that stress the preparedness component of the national malaria strategy.

This study was undertaken as part of the ACCESS program, funded by the Novartis Foundation for Sustainable Development.

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## SACOCO – A relationship between mental health, poverty and livelihood vulnerability

The WHO's investigation on mental health found that close to 20% of primary health care patients has a mental problem, yet until recently mental health has not been recognised as a public health issue. Studies have been done in both developing and developed countries looking at the relationship between poverty and its effect on mental functioning. In a rural area of South Africa, 30 households were followed up over a period of 10 months to study the interaction between poor households and the health system. Among other information collected was an assessment of minor psychological disorders, measured using the WHO Self Report Questionnaire (SQ20). The results of this questionnaire were used in conjunction with other household data collected to analyse the relationship between socio-economic status of the household and mental health. Three levels of socioeconomic status were defined: highly vulnerable (not meeting basic needs such as food, school and health care), vulnerable (meeting basic needs but livelihood not secure) and secure (households who meet basic needs and whose livelihood will not be disturbed in any near future).

The results of our exploratory analysis were similar to those from other studies conducted in similar contexts using a similar tool (WHO SRQ20). Poor mental health was found to be closely associated with low SES and low levels of education. No relationship with gender was found, though this may be due to the predominance of women in our sample (200 out of 270 female).

Three main patterns emerged from the analysis of the in-depth data:

*Secure households with good mental health:* Chronic illnesses were well managed and they used both public and private health providers. Their social networks were more extensive in that they went beyond family and neighbours, and included links with the church and moneylenders.

*Vulnerable households with good mental health:* These households were characterised by ill health, no regular income, and at times death, which together placed their livelihood at risk, but they scored high in the mental health tool. This appeared to be due to the strong social network to which they had recourse, which provided financial support in times of need.

*Vulnerable households with poor mental health:* These households also had little income, and on-going illnesses. However, the lack of strong and extensive social networks meant that little support was available, and meeting basic needs on a daily basis was a constant worry that depleted the respondent's mental resilience.

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## What happens to poorer households in Thailand when renal replacement therapy has been excluded from a national benefit package?

A decision of the Thai government not to include renal replacement therapy (RRT) into the benefit package of the universal coverage health insurance scheme (UC scheme) in 2001 led to a situation in which access to RRT depends on ability to pay of individuals, and types of health insurance coverage. A longitudinal household study conducted in a province of the North-eastern region of Thailand explored differentials in access to and utilization of RRT, coping strategies, and health expenditure borne by end-stage renal disease (ESRD) patients with different socio-economic status. The investigation attempts to elaborate the impact on poorer and richer households of excluding expensive medical care like RRT from the benefit package of the public-financed health insurance scheme.

Three qualitative approaches including semi-structured and in-depth interviews and direct observation, were used to investigate 20 households with ESRD patients. Poorer and richer households located in both urban and rural areas of Nakorn Ratchasima province were purposively selected. Four investigating tools were employed: 1) roster of household members and relationships; 2) life-line and life history; 3) illness narratives; and 4) household records on monthly income and expenditure. This study was conducted from January to March 2005, and each household was visited every two weeks for three months. Interviews were transcribed and analyzed using a thematic approach. Notes from direct observation were kept throughout fieldwork and analyzed using content analysis.

Results revealed that the exclusion of RRT from the benefit package of the UC scheme resulted in financial barriers to this service, particularly for poorer households. Health expenditure for RRT ranged from 25-68% of household income and 31-52% of household expenditure, which resulted in catastrophic health expenditure for all ESRD patients in poorer households. Poorer ESRD patients could not afford costs of RRT and consequently did not obtain regular treatments. None of them could afford erythropoietin injection, an expensive medical treatment for anaemic problems, and blood transfusion was used as an alternative for poorer patients. In contrast, richer ESRD patients could access and utilize RRT as well as erythropoietin injection regularly and effectively, which resulted in higher survival rates and quality of life, compared to their poorer counterparts. To reduce household expenditure, three major coping strategies were adopted by poorer households: 1) reduction in the frequency of access to RRT; 2) using blood transfusion to treat anaemic problems rather than using expensive medical injection (erythropoietin); and 3) reducing other flexible household expenditure such as transportation, food expenditure, and education of children in some households.

Financial consequences from using RRT manifested themselves as a high level of household debt with high interest rates, especially in poorer households. Other family members, such as patient's offspring or parents usually had to bear costs of RRT for ESRD patients, and consequently faced catastrophic health expenditure.

This study has raised public concern over what criteria and principles should be used for prioritising health services included into the UC benefit package. To rely on economic analyses or the concept of maximization of resources might not be sufficient to achieve policy objectives of universal coverage in protecting households from health care costs and improving equitable access to health services.

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## Coping with the costs of illness: The role of shops and shopkeepers as social networks in two low-income community in coastal Kenya

Studies of ability to pay for health care have shown that social networks are key factors in determining household ability to cope with illness costs. Although the role of shops/shopkeepers as an important first response to many illnesses is well documented, little effort has been directed towards exploring the additional role that shops and shopkeepers may play in terms of wider social and economic support to households. They may do this, for example, by helping households to meet the direct and indirect costs of illness, and to cope with other day-to-day needs.

Using data from a cross-sectional survey in a rural and an urban setting (n=294 rural; 576 urban) in Kenya, interviews with shopkeepers (n=22 rural; 104 urban) and longitudinal case studies with rural households (n=15), this paper demonstrates the role of shops/shopkeepers as members of social networks that assist households to cope with the costs of illness. Case study households were categorized into three groups on the basis of their socio-economic status and asset ownership (highly vulnerable, vulnerable and least vulnerable), and their use of social networks (including shops and shopkeepers) to manage the costs of illness and other needs was studied over a period of 10 months.

The results revealed that shops/shopkeepers are a key resource for both the poor and less poor. Their role was clearly demonstrated in the rural setting. Shops enable households to cope with illness costs directly through providing an alternative treatment to 'unaffordable' care for the poor and indirectly through enabling households to smooth consumption in difficult months and in so doing releasing funds to be spent on health care and/or in asset

accumulation. Specific roles played by shops include: providing credit to purchase goods (drugs and household items), acting as 'saving' schemes, providing loans, and holding funds on behalf of households to allow use for purchase of basic commodities. They played an important role in smoothing access to basic needs for households with unpredictable work and when significantly high costs of illness were incurred in a month, in extending support to households who depended on remittance from income earners living elsewhere, primarily in town. Whether or not households had access to these services from shopkeepers was determined by a household's wealth status, trust that repayment would be done on time and whether or not one was a regular customer. Clearly all of these influences are inter-related. Most households had some degree of access to the additional services available from shops, and an indicator of a particularly vulnerable household was one which could not access any support from a shop.

Shopkeepers can provide useful information to identify and support the poor and vulnerable because of their experience in terms of offering credit and other assistance. The findings highlight the potential of working with shops/shopkeepers to design and implement interventions that reach the poor and vulnerable, but also the dilemmas and challenges involved in such resource constrained contexts.

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## Household responses to health risks and shocks: A study from rural Tanzania raises some methodological issues

Households have limited resources to allocate to various expenditure items. When an individual within a household falls ill, some additional resources may be allocated to health related expenditure. These decisions around treatment seeking and its associated costs will have welfare impacts in the short and long run. In the short run, illness may cause households to substitute consumption away from other items (such as food) to health, whilst longer run consequences include reduced investment in productive activities and increased vulnerability. Authors have argued that households behave strategically when making decisions about how to cope with an illness in order to minimise treatment seeking costs whilst accounting for the risks associated with different symptom sets. One aim of these strategies is to minimise the impact of the health shock on consumption and welfare.

This paper aims to identify the impact of a health shock on short run household welfare by exploring the relationship between the presence of a malarious/feverish individual within a household and household consumption patterns.

Data for the study were collected within the umbrella of the Ifakara Demographic Surveillance Site in south-eastern Tanzania. Information on household consumption patterns in the month before interview was collected and consumption expenditure was categorised into six mutually exclusive and exhaustive groups: protein, other food, general household consumables, luxury items, health care, and other. During interviews households provided information on whether anyone in their household had experienced a bout of malaria or fever in the two weeks

before interview. This measure is often used in surveys interested in the costs associated with malaria, given that it is the perception of illness that determines individual's behaviour, particularly around treatment seeking (Mugisha et al. 2002). A system of demand equations, using both absolute consumption and the budget share of each group, was estimated to investigate the effect of malarial illness on household consumption.

After controlling for the level of total consumption by a household, the presence of a self-reported malarious individual in a household reduces consumption on luxury items and increases consumption of health care and health products such as medicines. The results from the budget shares equations indicate that the presence of a malarious individual increases the budget share of health care, and this increase is spread evenly across remaining budget items.

The findings from this analysis, notably the surprising lack of association between malaria and consumption patterns, raise important methodological issues. Long run risk mitigation strategies employed by households are a key impediment to dissecting the impact of a health shock on household welfare. In an area of high risk (for example from diseases and crop failure) households will implement strategies aimed at smoothing consumption, which will mediate acute impacts associated with any one illness bout. It is important to acknowledge and account for the fact that households are being strategic when making decisions around illness.

Cross sectional studies are unable to identify how these risk mitigation strategies mediate the direct impact of disease observed in any one time period. They are also unable to identify whether the strategies implemented during an illness bout are effective at maintaining household welfare in the medium to long run. Authors such as Chuma et al. (2006) have found that the economic impact of illness can be felt for many months and years after an illness episode. As such, cohort studies looking at the strategies that households implement (particularly around how to manage their budgets) may provide useful information that cannot be gained through a cross sectional approach.

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Mugisha, F et al. 2002. Examining out-of-pocket expenditure on health care in Nouna, Burkina Faso: implications for health policy. *Tropical Medicine and International Health*; 7(2): 187-96.

## Determinants of health care seeking behaviour and the extent of catastrophic health expenditure of urban households in Tamil Nadu, India

In India 75% of health expenditure is financed by the private sector and 25% by the public sector. About 97% of the private sector funds come from the household sector in the form of out-of-pocket expenditure (OOPE). The low level of public investment in health and the unpredictability of illness increase vulnerability, particularly among those too poor to afford private treatment. High levels of OOPE are capable of altering the consumption pattern of the entire household and could also result in impoverishment. In this paper we study the patterns of health care seeking behaviour, the extent of out-of-pocket payments and catastrophic health expenditure among urban households in Tamil Nadu, India.

The study uses data collected by the National Sample Survey Organisation (NSSO) for the year 2004-05. The socio-economic and demographic determinants of household health care seeking behaviour were analyzed using multivariate logistic regression. The extent and composition of out-of-pocket payments and the extent of catastrophic health expenditure (defined as more than 10% of household consumption expenditure) were analyzed by quintile of monthly household consumption expenditure. Out of total (26,566) urban households surveyed by NSSO for all states of India, 2599 households of Tamil Nadu State were considered for the analysis.

The analysis showed that about 1341 spells of illness were reported during the past 15 days (including hospitalization) from the urban households. Treatment or medical advice was sought for 84% of these. The major types of ailments reported were fever of unknown origin followed by diabetes mellitus, hypertension and joints and bone disorders.

Among those who sought care, 24% used the private sector and 74% used the public sector. OOPE on medical care was analyzed for both outpatients (past 15 days) and inpatients (past 365 days). Mean total expenditure was Rs 66 (\$1.60) for outpatient care in public sector and Rs 407 (\$10) for outpatient care in the private sector. For inpatients it was Rs 1652 (\$41) in the public sector and Rs 16,018 (\$393) in the private sector. The largest components of total expenditure were drug costs, food and travel in case of public inpatients while for private inpatients spending was high for fees for hospital staff, drugs

and bed charges. The burden of drug costs was particularly high in the lowest socioeconomic quintile among both the private and public inpatients. For the outpatients in public sector the major expenses were on medicines purchased outside the hospital and travel costs, while for private sector outpatients the major expenditures were on medicines from outside the hospital and fees for hospital staff.

Improving access to government medical services and increasing the quality of services are the options needed to reduce the incidence of catastrophic expenditure both on inpatients and the outpatients. Policy options could also consider various coping mechanisms including mobilizing out-of-pocket payments as prepayments through community based risk-pooling schemes.

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## **Issues in equitable health financing: socio-economic and geographic differences in illness cost-burden on households and policy makers' views on the protection of the poor**

Effective health care delivery in developing countries depends on the availability of resources for health expenditures and the effectiveness of policies designed to protect the poor from financial risks during illness episodes. There is ongoing global debate on abolition of user fees, use of health insurance schemes to ensure risk protection of the poor and improvement of equity in financing of healthcare. It is important therefore to know the cost burdens of ill health on households in Nigeria as well to ensure that policy makers have the right perceptions of the best ways of assuring financial protection of poor households.

This study sought to assess the levels of expenditure on illness by different socio-economic and geographic groups of households as well as the views of policy makers and other relevant stakeholders in the health sector on the burdens placed by current financing mechanisms on poor households.

The study covered two urban and four rural areas in two states in South-eastern Nigeria. A cross-sectional survey used interviewer-administered questionnaires to elicit information on household socio-demographic characteristics, healthcare seeking and expenditure on illness. A socio-economic status index developed using principal component analysis was used to examine levels of inequity in health care costs. In-depth-interviews targeted at policy makers, heads of health facilities and health and social workers were conducted and following transcription, categories were related according to coded thematic areas covered by the study.

Poor households were found to be paying significant amounts and primarily paying out of pocket. Those who are unable to pay don't seek care at all. Households in the urban area spend an average of N2517.6 (\$20.14) monthly while those in the rural area spend N1147.6 (USD \$9.20). When compared with a monthly minimum wage of N7500 (\$60), this gives an expenditure/income proportion of 16.8% and 33.6%, respectively. Among those households with illness in the previous month, urban households and households of higher socioeconomic status were more likely to have incurred expenditure in treatment seeking.

The current policy environment does not seem to be addressing this problem. A former system of exemptions and waivers has been replaced with a series of cost recovery mechanisms such as drug revolving funds (DRF) without provisions for exemptions. There is evidence of informal mechanisms at facility level but these seem to be at the discretion of individual health workers or social workers and are very rare.

There is a diversity of opinions among stakeholders about the need to address this problem. For instance, health workers and social workers are more aware of the burdens that payment places on households and the consequences for delayed treatment seeking. Facility managers, however, feel that people have to pay and that even the poor households can manage to mobilise the needed resources through their families and social networks. Policy makers feel that there are no resources to fund exemptions and they are also of the view that even poor patients can manage. They are also concerned about the practicalities of operation of exemption mechanisms such as identifying the poor.

There is a gap between the reality and the policy debate which needs to be bridged if public systems are going to protect the poor. While households are in reality weighed down by heavy cost burdens, policy discussions assume that households have the capacity to cope with prevailing payment strategies. There is a need to reduce out-of-pocket payments as this will increase healthcare seeking and utilization by the poor. Payment strategies that will assure financial risk protection of poor households such as prepayment mechanisms and exemptions with budgetary provisions need to be designed and implemented. Policy makers need to be more aware of and more sensitive to the actual burdens faced by households in accessing healthcare. This will ensure evidence-based decision making.

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## Considering biomedical and social science ethical frameworks: dilemmas and potential responses for multi-disciplinary health research in Africa

Multi-disciplinary, multi-method studies have numerous advantages in answering many health related research questions or problems, but also pose particular challenges, including reconciling the differing notions of research ethics in the social sciences and in biomedicine. These challenges may be particularly acute in cross-cultural research, or where research is being carried out in low-income settings by researchers/funding bodies from more wealthy countries.

Emanuel et al (2004) have synthesised the numerous guidelines, recommendations and interpretations that currently exist for clinical research into 8 principles and 31 corresponding benchmarks. For developing countries, special attention is given to the principle of collaborative partnership; equal partnerships between investigators and sponsors in developed countries with local researchers, policy makers and communities in developing countries. The available literature suggests that these principles are relevant for social science health research, but that the emphases, application and review processes may differ (Wassenaar, 2007; ESRC, 2005). In particular there is generally less codification in social science ethics, and greater emphasis on the power differences between researchers and research participants. There are also strong differences within both traditions, especially between those working from a positivist and naturalistic epistemological base. The latter have been particularly critical of the mechanical application of biomedical codes and regulatory systems to primarily qualitative research; arguing that valuable research can be unnecessarily and inappropriately constrained, and that protection of participants may be negatively affected through blunting researchers' sensitivities to critical issues.

We draw on the experiences of developing and carrying out two studies of very similar design and aim, to highlight the challenges met and approaches adopted in two different contexts (coastal Kenya and rural South Africa). The studies aimed at improving understanding of household health related costs and coping in order to feed into policy debates on how to protect poor households from unaffordable cost burdens. Both involved cross-sectional household surveys, focus group discussions, and the longitudinal follow-up of a sub-set of households. Our experiences suggest that:

- 1 Field staff should be selected and treated as essential members of the research team, and receive supportive training and possibly even counselling. They are often acting as cultural brokers between researchers and community members/participants, they have a key role

in shaping the nature and quality of data, particularly for qualitative research, and they often have to handle complex concepts, methods, and information and observations – with important ethical implications - away from senior researchers.

- 2 There are always consequences for individuals and communities associated with social science research. These consequences need to be anticipated, monitored and responded to throughout the research, including through being as transparent as possible about the benefits associated with the work (and the limits of these) and through constantly (re)considering the benefits to individuals, communities and the contribution of new knowledge. This requires reflexivity around the impact and implications of one's characteristics and institutional links; previous or on-going studies or development activities, and the potential ramifications of the processes undertaken to enter and leave communities.

We conclude by suggesting that in designing and reviewing all studies – both biomedical and social science elements - there should be special consideration given to **the process of research and the nature of interaction between different actors, and the factors influencing these**, as well as the design of the study and the tools. The latter is traditionally the focus of ethics committees, and the former would be very difficult for committees to evaluate and monitor. To support these suggestions we call for stronger social science capacity in ethics review committees, and we identify a series of questions for all researchers and ethics committee members to consider at different stages of research endeavour.

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