The effect of health education on women's treatment-seeking behaviour: Findings from a cluster randomised trial and an in-depth investigation of hysterectomy in Gujarat, India

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Abstract

A community-based health insurance scheme operated by the Self-Employed Women's Association (SEWA), an organisation of women workers in India, reported that the leading reasons for inpatient hospitalisation claims by adult women were diarrhoea, fever and hysterectomy – the latter at the average age of 37. In 2010, SEWA initiated a cluster randomised trial to evaluate whether community health worker-led education amongst insured and uninsured adult women could reduce morbidity, hospitalisation and insurance claims related to these three conditions.

This thesis reports the findings of the intervention evaluation and of an in-depth examination of hysterectomy, the most common cause of hospitalisation. Literature reviews were conducted on the effect of community health worker-led group health education and on the frequency of hysterectomy in low and middle-income countries. Analysis of the cluster randomised trial utilised data from SEWA's insurance database and four household surveys. Hysterectomy was explored through an in-depth qualitative study and quantitative analyses using the study cohort to estimate incidence and identify determinants of the procedure. Lastly, findings were synthesised with process data to examine the intervention process, with a focus on hysterectomy.

Statistical analyses indicated no evidence of an intervention effect on insurance claims, hospitalisations or morbidity related to fever, diarrhoea and hysterectomy. There was no evidence of effect modification by insurance status. Hysterectomy amongst women in their mid-thirties appeared to be rooted in its normalisation as a prophylactic, permanent treatment for gynaecological ailments. Incidence of hysterectomy was associated with income, age and number of children. Evaluation of the intervention process suggested that improved knowledge was necessary, but not sufficient, to change women's treatment-seeking behaviour regarding hysterectomy. Interventions to reduce hysterectomy must integrate approaches that address the structural determinants of the procedure, such as the lack of reproductive and sexual health services, providers' behaviour towards low-income women and attitudes towards the utility of the uterus.

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Acronyms

ASHA	Accredited Social Health Activist
BPL	Below poverty line
CBHI	Community based health insurance
CHW	Community health worker
DLHS	District Level Household and Facility Survey
GDP	Gross Domestic Product
HH	Household
INR	Indian rupees (Rs.)
JSY	Janani Suraksha Yojana (Institutional delivery scheme in India)
LOS	Length of stay
NFHS	National Family Health Survey
NMR	Neonatal mortality rate
NRHM	National Rural Health Mission
NSS	National Sample Survey
OOP	Out-of-pocket (expenditure)
ORS	Oral rehydration solution
RSBY	Rashtriya Swasthya Bima Yojana (National health insurance scheme)
SEWA	Self-Employed Women's Association

SECTION ONE

Chapter I. Introduction

I. Background

The World Health Organisation report on Women and Health (2009) called for

> *"…better data, for more research, for more systematic monitoring of the health of the female half of the world, and for addressing the barriers that girls and women face in protecting their health and in accessing health care and information."* [1]

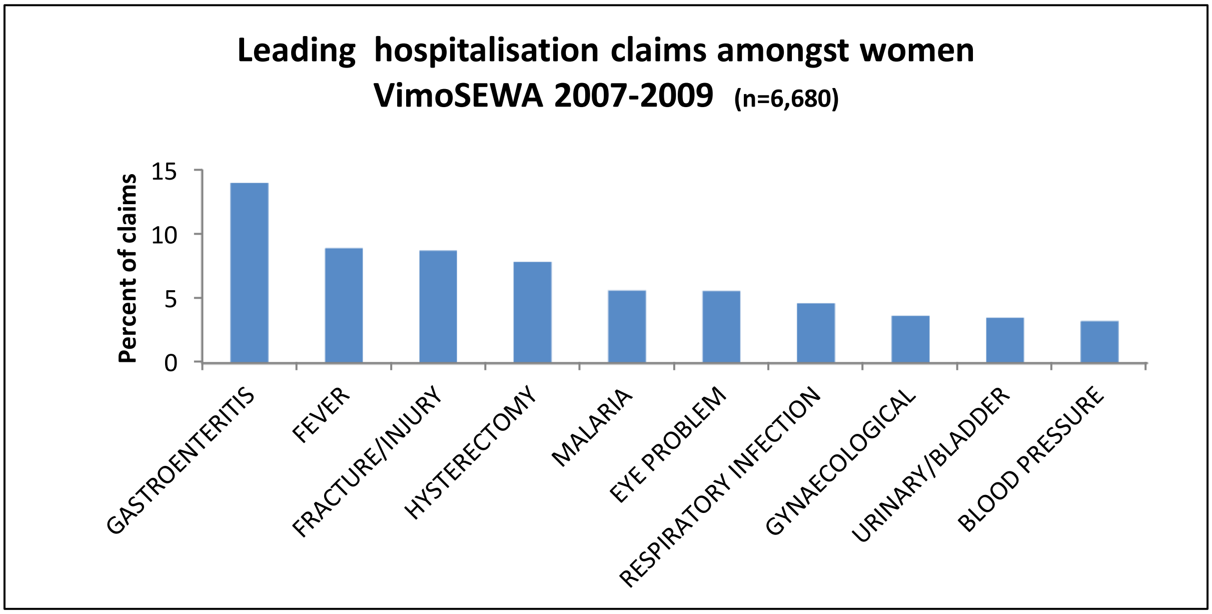
In India, three government-commissioned national surveys are the primary source of information on women's morbidity and treatment-seeking patterns. The National Sample Survey (NSS) collected data on the incidence of morbidity and hospitalisation in a nationally representative sample of households in 2004, after which it has not repeated a similar survey on health[2]. Overall, adult women reported higher incidence of morbidity in the past 15 days than men, while hospitalisation rates were largely the same for men and women, with slight differences in some age groups. The leading causes of hospitalisation amongst adults were accidents/injury (10%); fevers of unknown origin (8%); diarrhoea/dysentery; (7%); heart disease (5%); and gynaecological disorders (5%). Sex-disaggregated data were not reported for cause of hospitalisation. The other two national studies, the National Family Health Survey (NFHS) and District Level Household Survey (DLHS), conduct surveys amongst reproductive-aged women and men that focus on knowledge and practices related to maternal and child health and family planning[3, 4]. The most recent round of the NFHS (2005-6) also reported estimates of prevalence of HIV/AIDS, tuberculosis, chronic illness and violence against women. Neither survey, however, documents overall morbidity patterns or health service utilisation amongst adult women.

A search of community-based research in India on women's morbidity patterns indicated that forty percent of 556 studies focussed on women's reproductive and maternal health, and over a quarter examined chronic illnesses (Annex 1)**.** Fourteen community-based studies aimed to identify overall morbidity patterns amongst women, primarily in low-income settings. Reported prevalence of morbidity varied considerably across these studies. Regional diversity may be one explanation for this variation: two multi-site studies found that prevalence of illness varied considerably by geographic location in similar socioeconomic groups [5, 6]. Causes of illness and treatment-seeking reported by women, however, were largely similar: fever, respiratory illness and gynaecological morbidities emerged as the most common illnesses amongst adult women [5, 7-9]. Married women under 35 years ranked circulatory/respiratory illnesses as the highest burden, followed by reproductive and infectious/parasitic illnesses [10]. In addition to epidemiological studies, a range of qualitative research in India has provided further insight into women's health – and has underscored the importance of integrating multiple perspectives, particularly women's voices, to examine both the burden and experience of morbidity [11-26]. Women's perceptions of morbidity, for example, may reflect negotiations in other spheres or the dynamics of social transition [20, 27]. While both quantitative and qualitative studies in India cover a range of topics and settings, available research is far from sufficient to systematically track the overall health of India's women and girls – a gap in of itself, as well as a barrier to designing needs-based interventions.

This thesis aims to contribute to research on women's health in India, through an in-depth examination of treatment-seeking patterns and the evaluation of a women-focussed intervention in a low-income setting. My research questions emerged while implementing women's health programs with the Self-Employed Women's Association (SEWA) in India. SEWA, an organisation of low-income women workers in India's informal economy, operates a community health worker (CHW)-led health program and a community-based health insurance (CBHI) scheme, known as VimoSEWA. In 2008, while setting priorities for SEWA health programs in rural and urban Gujarat, I found the data on which health conditions women suffered from most were few, with respect to both frequency and severity. National data provided a limited, aggregate picture of adult health, and SEWA had not conducted a survey of its members' health since 1999. I thus turned to routine claims data collected by VimoSEWA on causes of hospitalisation amongst insured, low-income women workers who submitted hospitalisation claims in Gujarat. Although these data were not representative of the population, they provided insight into health services utilisation.

With few exceptions, CBHI schemes do not regularly conduct epidemiological analyses of claims; VimoSEWA had conducted such an analysis only once before[28]. In 2001, Ranson identified accidents, malaria, gastroenteritis and hysterectomy as the most common reasons for hospitalisation [29] – a similar pattern to that reported by the NSS in 2004. In 2009, we found that the over 40% of adult hospitalisation claims in 2007-2009 were for fever,[a] malaria, diarrhoeal illness and hysterectomy (Figure 1.1). Amongst rural women, hysterectomy was the primary reason for claims, at an average age of 37 years, considerably younger than in other countries where data are available[30-33].

Figure 1.1 Leading hospitalisation claims amongst women insured by VimoSEWA



When I presented these findings to SEWA members and CHWs, they hypothesised that some of these hospitalisations were unnecessary – and that a proportion could be prevented through a community health intervention. The relatively young age at hysterectomy suggested that some procedures may not have been medically indicated. VimoSEWA's management suspected that the design of its scheme may have incentivised excess hospitalisation or unnecessary surgical procedures amongst insured women, although there was no comparable data available on patterns amongst uninsured women. VimoSEWA covers hospitalisation periods that exceed a 24-hour period. For illnesses amenable to outpatient treatment, VimoSEWA suspected that women may choose inpatient care to avoid out-of-pocket (OOP) expenditure on outpatient care, while hospitalisation guaranteed revenue to providers – a potentially financially beneficial situation for both women and providers. Nevertheless, 23% of VimoSEWA members hospitalised in 2003 experienced catastrophic health expenditure, defined as annual hospital

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[a] Claims categories are based on broad classifications derived from physicians' notes and claims review. The term 'fever' is routinely used by physicians and insurance companies as reason for hospital admission and may refer to fevers caused by malaria, respiratory infection, or of unknown origin. Gastroenteritis and diarrhoea frequently overlap or are used together in claims records. Gynaecological excludes hysterectomy (presented separately) and childbirth.

expenditure greater than 10% of annual income, after reimbursement[34]. Hospitalisation also entails additional costs such as loss of income and care-giver time. Even with insurance coverage, hospitalisation remains a considerable risk to financial security for low-income women workers.

Both SEWA's CHWs team and VimoSEWA's management concluded that reduction of seemingly preventable claims was critical, both to protect women's health security and to reduce VimoSEWA's unsustainably high claims ratios. The organisation began to explore how the CHW program could work to reduce preventable claims. In March 2009, SEWA initiated the design of a CHW-led health education program that aimed to address the three leading causes of claims submission – diarrhoea, fever and hysterectomy – with the aim of reducing preventable claims and hospitalisation. Since CHWs worked in the entire community, SEWA Health decided the intervention would aim to reach all women, rather than target insured women in particular. Accordingly, a cluster randomised trial was designed to evaluate the effect of a CHW-led health education intervention on insurance claims utilisation, hospitalisation, and morbidity amongst insured and uninsured adult women in Gujarat.

II. Thesis objectives

My doctoral research was based on this evaluation study, the design of which was completed by SEWA before I enrolled in a PhD. Since there was little research on hysterectomy in India –and VimoSEWA's claims patterns suggested it was a critical, emerging women's health issue– I also examined hysterectomy through qualitative research and additional quantitative analyses. Process data collected during the trial were combined with these findings, in an intervention process evaluation that examined how CHW-led health education could affect hysterectomy. The objectives of this thesis are to:

(i) Evaluate the impact of a CHW-led health education intervention on women's insurance claims, hospitalisation, morbidity rates and expenditure related to diarrhoea, fever and hysterectomy

(ii) Examine hysterectomy in this setting through:

    (a) Exploration of the socioeconomic, individual, household and health system determinants of the decision to undergo hysterectomy

    (b) Analysis of the process by which CHW-led health education could address hysterectomy

While grounded in an epidemiological approach to evaluate the intervention, this thesis also draws from medical anthropology, economic analysis and process evaluation to understand its outcomes. Although I did not commence with an overarching epistemological framework, my approach to women's health and the synthesis of methods resonates with the basic principles of 'feminist epidemiology.' Inhorn and Whittle(2001), building on debates within modern epidemiology[35, 36][b] and the work of other feminist scholars, have defined feminist epidemiology to include: (i) engagement of women in problem definition and knowledge production (ii) examination of women's health in its totality, in both reproductive and non-reproductive roles and (iii) contextualisation of women's risk and health outcomes within the larger social, economic and political forces that affect their lives[37-39]. Feminist epidemiology focuses on women and employs multiple methodologies, with the ultimate aim of re-thinking the ways in which women and health are studied and linked to policy[37]. This thesis synthesises analyses of population-level data and women's experiences, to examine the research questions in-depth and from multiple perspectives. The findings will inform SEWA's programs, while contributing to the evidence base on women's health in India and CHW-led interventions in low-income settings.

III. Dissertation structure

This dissertation report is a combination of book-style chapters and research papers. Section One presents literature reviews on CHW-led health education interventions and hysterectomy, followed by a description of the research setting, intervention and methodological approaches, all written as chapters. In Section Two, I first present results of the baseline survey in a published research paper that describes the population and compares treatment-seeking patterns amongst insured and uninsured women. The following two book-style chapters present the evaluation findings: the intervention effect on claims, hospitalisation and morbidity related to diarrhoea, fever and hysterectomy and description of out-of-pocket expenditure on the three conditions. The next chapter is an in-depth examination of hysterectomy, comprised of two research papers that present (i) a qualitative study on hysterectomy and (ii) a mixed-methods analysis of its incidence and determinants. The final results chapter is an intervention process evaluation that brings together hysterectomy-related findings from previous chapters with process data collected during the trial, to explore how CHW-led health education can

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[b] Inhorn and Whittle identified an 'anti-feminist bias' in mainstream epidemiology, in which research conducted on women predominantly focusses on their reproductive role or issues central to men, such as chronic disease, without consideration of women's own priorities. Further, they have criticised the dominant objective of identifying individual risk or changing behaviour that neither accounts for the broader context of women's lives–such as political voice and socioeconomic structures–nor addresses gender oppression as a factor in women's health outcomes. They, like others (Freedman and Maine 2004, Kaufert 1998) build the case for a 'feminist epidemiology' that draws from approaches described as critical, popular/participatory and alternative epidemiology. This approach also echoes calls to anchor epidemiology within public health and link it within social sciences (such as those set forth by Pearce 1998, Krieger, 2000).

affect hysterectomy. I conclude with a synthesis of results, reflections on lessons learned and discussion of the contributions of this thesis to research, programs and policy.

IV. Role of candidate

I was the initial project director of the intervention and research study. As SEWA's national health coordinator at the time, I wrote the grant proposal for the intervention and evaluation, secured funding from the International Labour Organization Microinsurance Innovation Facility and managed the project for one year. When I enrolled in a PhD in September 2010, project coordination was handed over to a senior health supervisor at SEWA. I conducted all statistical analyses and qualitative fieldwork presented in this thesis and drafted research papers as first author, with guidance from my supervisor and advisory committee. Ajay Mahal acted as study advisor to SEWA during the course of the project and led the design of the trial. Tara Sinha managed the implementation of the intervention and study and conducted qualitative research on hospitalisation for diarrhoea and fever.

Chapter II. Literature Reviews

I. Literature Review on CHW-led group health education

Introduction

Since the Alma-Ata declaration for primary health care, CHWs, also known as lay health workers, health aides or auxiliary health workers, have been promoted to improve health systems[40]. In recent years, evidence on CHW interventions has been synthesised through meta-analyses, qualitative syntheses and disease-focussed reviews, highlighting their potential role in improving health outcomes [41-51]. CHW roles vary according to the local setting: from government extension worker to volunteer social activist, they can provide basic services, promote preventive health activities or mobilise community groups. Despite the considerable diversity across programs, evidence syntheses concur on the importance of CHWs in linking communities to health systems, particularly in low and middle income settings[48, 50, 51].

A 2010 Cochrane systematic review and meta-analysis of interventions involving community-based lay health workers indicated moderate evidence of their potential to improve immunisation coverage, breastfeeding and adherence to tuberculosis treatment[48]. With the exception of some chronic diseases, evidence was scarce regarding other health issues. Evaluations addressed a wide range of activities, such as home visits, counselling, telephone campaigns and health facility-based support, implemented by workers with varying degrees of training, background, payment mechanisms and structural support. The review identified a lack of evaluations in low-income settings: only 27 of 82 studies were conducted middle or low-income settings. Lehmann and Sanders, in a review of published and grey literature on CHWs, highlighted their value in improving coverage of basic health services in low-income settings, but also emphasised the need for appropriate selection and training, with consistent support, realistic planning and clear understanding of the role of community participation or mobilization[50]. Similarly, Bhutta et al synthesised literature and presented country case studies on a wide range of CHW programs related to achievement of the Millennium Development Goals[51]. While existing evidence attests to the capacity of CHWs in providing health services, improvements in the coverage, quality and impact of programs requires appropriate health system support, particularly for large scale CHW initiatives.

A 2013 Cochrane review of 53 qualitative research studies on the processes and mechanisms by which CHW-led interventions have improved health outcomes identified five critical factors: integration of CHWs in their communities; supportive working structures, particularly regarding incentives and training; affordability of services; appropriate selection criteria; and support and participation from both the health system and community. Noting that there is limited research that evaluates both the outcomes and processes of the same CHW program, recommendations for future research included inclusion of the perspectives of stakeholders such as managers and community leaders, descriptions of CHW processes in trials and measures of their role, such as the relationship between CHWs and service recipients. Each of these global reviews emphasised the need for more rigorous evaluations of CHW programs in low-income settings. Further, given the diversity of CHW programs, in-depth documentation of implementation mechanisms and barriers is required to draw generalised implications for policy or practitioners[43, 52].

Health education and behaviour change theory

This literature review and dissertation employ the term "health education" to describe the intervention. Health education has been defined as an approach to catalysing behaviour change through learning experiences. Health education aims to change health behaviour by improving knowledge and influencing attitudes, with the ultimate goal of improving the health status and quality of life of individuals and their communities[53-55]. Although health education historically has been understood as combination of strategies to influence individuals as well as their environment, it is often differentiated from health promotion, a comparatively broader approach which addresses the social context of behaviour change. Interventions that aim to change behaviour span a range of theoretical approaches, commonly known as behaviour change theory.

A recent systematic review reported that the most commonly applied theories in health behaviour intervention research are social cognitive theory, the health belief model and the trans-theoretical model[56]. Additional common approaches are theories based on reasoned action, planned behaviour and the precaution adoption model[57]. While most theoretical models share the assumption that individual attitudes and beliefs shape health behaviour, they differ on factors such as the role of environmental influences, on how an individual decides to perform a specific behaviour and on the scope for intervention.

Social cognitive theory, potentially the most comprehensive approach to behaviour change, posits that behaviour is a result of continuous and multifaceted interactions between individual and environmental factors[58]. Personal variables, such control over decision-making, influence behaviour along with external barriers or facilitating factors such as access to services. In this model, behaviour may be changed if: (i) individuals believe they have control over the outcome (ii) they can execute the behaviour and (iii) there are few external barriers. While knowledge of health risks influences behaviour, self-efficacy – an individual's belief regarding his/her own ability to perform a behaviour towards a desired outcome – is also viewed as a critical influence on behaviour[59]. In the health belief model, behaviour is linked to an individual's appraisal of barriers and benefits of an action[60]. The four constructs of this model of illness and health behaviour – perceived susceptibility, severity, benefits and barriers – may vary by demographic variables or personal characteristics. Interventions may focus on these four areas, through providing strategies for action or support to enhance self-efficacy[61]. The theory of reasoned action is rooted in an individual's intention to perform a specific behaviour[62]. Interventions address intentions through aiming to influence both knowledge and attitudes towards an action. In an expansion of this approach, the theory of planned behaviour includes perceptions of behavioural control and self-efficacy as factors that influence intention.

Approaches based on stages of behaviour change include the trans-theoretical model and precaution adoption model. The former conceptualises behaviour change as a process of six steps: pre-contemplation, contemplation, preparation, action, maintenance, and termination[63]. Interventions aim to address processes related to these stages, often through diverse methods tailored to an individual's stage. Precaution adoption process models apply a similar approach to identify how and when health protective behaviours commence, with a focus on recognising the qualitative differences within populations[64].

While empirical evidence indicates support for elements of many of these frameworks, a common weakness is the lack of recognition of the emotional influences on behaviour[54]. Theories dependent on rational processes also do not include factors such as religion and social norms that define individual behaviour[57]. Further, these frameworks have been critiqued for their inability to account sufficiently for: social, community and environmental influences ; the competing interests in an individual's life outside of the specific behaviour of interest; recognition of the origin of beliefs and how beliefs shape actions; and the role of human agency and local context[57, 65, 66]. In practice, interventions often synthesise two or more behaviour change models, based on the nature of specific health conditions and the intervention setting/context [54]. Evaluations of intervention processes, therefore, require an understanding of the theoretical basis of an intervention, how it was applied in practice and insight into the range of influences on individual behaviour.

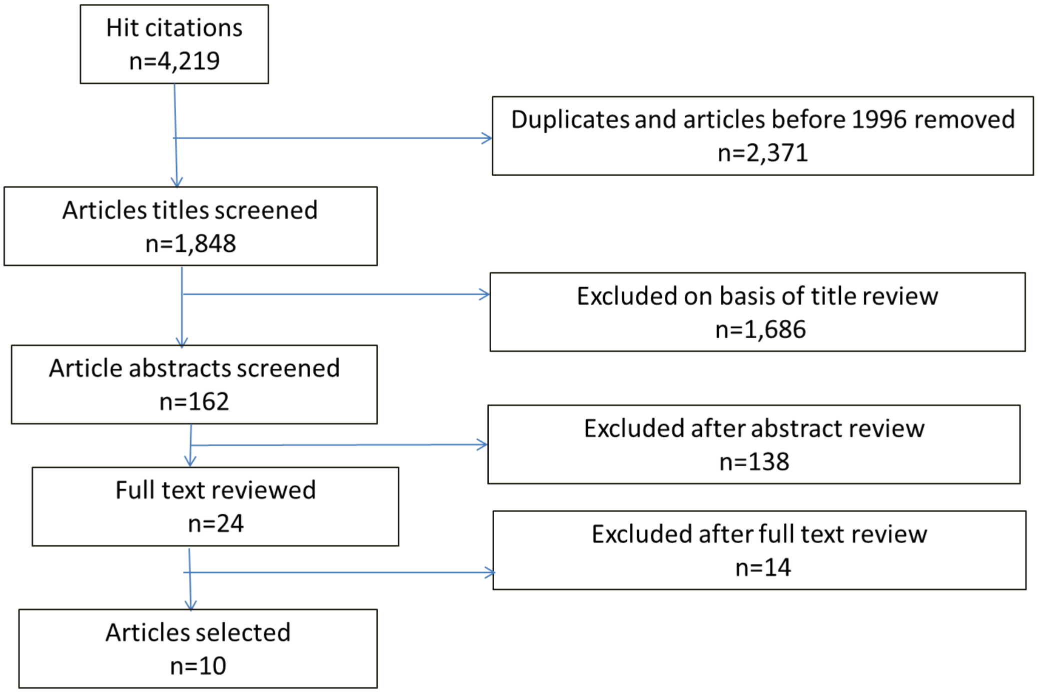
Objectives of literature review

This literature review aims to inform the evaluation of SEWA's CHW-led group health education intervention amongst adult women. While the reviews summarised above provide a wide range of evidence on CHW interventions, none focused on, or differentiated the effect of, CHW-led group health education. The objective of this literature review is to evaluate whether, and in what circumstances, CHW-led group health education interventions affect knowledge, behaviour and health outcomes. In light of SEWA's history as a membership-based organisation that works towards women's empowerment, this chapter also summarises findings on interventions that provide insight into evaluating SEWA's approach to CHW-led health education.

Methods

Search terms for (i) *health education* (health education, behavio* change, group education, health behaviour, health promotion) and (ii) *health worker* (health worker, health aide, health auxiliary, medical auxiliary) were combined and searched for in title, abstract and keyword fields. MeSH terms were utilised where available, such as for health auxiliaries, health education and behaviour, and the remaining terms were entered as free text. Searches conducted in November 2014 in seven databases – PubMed, Global Health, Embase, Popline, Web of Science, Scopus and IMSEAR– yielded an initial 4,219 hits (Figure 2.1). Inclusion criteria were: randomised evaluations; interventions led by CHWs that included group health education as a major component; and studies published after 1995, in any language or geographic region. Many of the 162 abstracts reviewed did not include sufficient description of the CHW intervention; 24 articles underwent full text review in order to differentiate group based interventions from other CHW-led health education activities. Of these, 14 were excluded for the following reasons: (i) the health education intervention was not implemented by a CHW (ii) CHWs only implemented another form of education such as one-to-one visits or community media, without a group education component or (iii) the intervention did not recruit participants through community-based outreach. Thus, school-based or facility-level health education interventions were excluded. Evaluations that did not employ a randomised design were excluded. Where available, I read published literature that described the interventions evaluated in the selected papers.

Figure 2.1 Search results



In addition to this systematic search, I present findings from two recently published reviews on alternatives to CHW-led health education relevant to SEWA, specifically interventions with women's groups and microfinance programs aimed at improving health outcomes [67, 68] . I also searched for non-randomised studies conducted in India on CHW-led group health education amongst women. Search terms included a combination of MeSH terms for health education (health promotion, health education, behaviour) and health worker, as above, with India, and I searched reference lists of identified papers. Three published studies that reported on CHW-led group education with women were identified.

Findings

Systematic literature review

After excluding articles according to criteria described above, the search retrieved ten studies, five of which were conducted in low-income countries (Annex 2). The remaining five were implemented amongst ethnic minority women in the United States. The selected articles are categorised into three groups below: (i) improved knowledge and uptake of preventive health screening and behaviour amongst adult women (ii) education to improve knowledge and treatment behaviour regarding malaria; and (iii) complex interventions that included a CHW-led group education component to improve maternal and child health outcomes.

CHW education and outreach to improve preventive health behaviour amongst adult women

Three trials were conducted in the United States to improve screening rates for cervical and breast cancer amongst women in ethnic minority communities. One study that aimed to improve cervical cancer screening amongst Vietnamese-American women evaluated the introduction of group education sessions conducted by CHWs into an ongoing media education program. The CHWs followed education sessions with one-to-one encouragement and support in scheduling pap tests[69, 70]. The intervention group reported greater increases in pap tests than the group exposed to media alone (15.3 percentage points increase vs. 5.4 percent, p=.001). Receipt of a pap test was associated with improved knowledge about cervical cancer. Although the intervention group reported a higher rate of pap tests, screening rates also improved in the control (media-only) group; findings suggested that targeted media was also an effective intervention to improve knowledge and behaviour in this setting[71]. An intervention to improve knowledge, pap test screening and self-efficacy amongst Hispanic women in the United States involved the delivery of two education sessions conducted by local CHWs, known as *promotoras* [72]. Reported pap test rates were higher in the intervention group (71% vs. 22%; p=0.004), a difference observed to be mediated by increased knowledge about cervical cancer. Findings supported the benefits of integrating a group education component into health worker activities to improve both knowledge and preventive health behaviour amongst women.

In an intervention to improve breast cancer screening amongst Vietnamese-American women, Nguyen and colleagues evaluated the effect of adding two CHW-led educational sessions and telephone calls to a media education program on mammography and clinical breast exam rates[73]. The addition of the CHW education component improved breast cancer screening on four outcomes, including self-reported ever mammography (OR=3.62, 95%CI 1.98,5.01; p<.001) and receipt of clinical breast exam within two years (OR=3.04, 95% CI(2.11,4.37, p<0.001). However, unlike the group's earlier findings regarding cervical cancer[69], reported screening was not associated with improved knowledge in this study. Authors suggested that the addition of CHW outreach to the media program was effective due to their common cultural background and social relationship with participants, and called for further research into how the position of CHWs within social networks can mediate behaviour change.

A CHW-led intervention to reduce cardiovascular disease risk amongst a Hispanic population in the United States implemented two months of weekly educational sessions, followed by telephone calls and a clinic-based group session to encourage behaviour change[74]. The control group was only provided with educational materials once, with no CHW follow-up or education. Adjusted findings detected lower diastolic blood pressure (75.5 vs. 79.8 mmHg; p<.001) and improvements in self-reported behaviours related to cardiovascular risk, such as salt intake and weight control practices, amongst the intervention group. There was no evidence of a difference in other clinical indicators related to cholesterol or systolic blood pressure. Changes in behaviour and awareness were observed in both experimental and control groups, suggesting print materials alone may have had an effect. Limitations due to self-reporting of behaviour and accuracy of measurement methods were also noted.

A similar, more intensive intervention was implemented amongst Hispanic women for six months, through both CHW-led group education and individual follow-up sessions[75]. Outcome measures included dietary habits, measures of physical activity, clinical measurements related to cardiovascular risk (such as blood pressure and weight), and knowledge. The evaluation indicated evidence of improved knowledge scores (p<0.001) and dietary habit scores (p=0.009) for women in the intervention group, as well as smaller, yet statistically significant improvements in waist circumference and physical activity. There was no evidence of any differences in other cardiometabolic outcomes between intervention and control groups nine months after baseline measurements. Findings were consistent with short-term improvements in behaviour and weight loss, which could translate into improved health outcomes with longer term intervention and follow-up.

In Sri Lanka, a community randomised trial aimed to improve knowledge and attitudes on family planning through CHW-led education. The intervention involved four community-based education sessions that utilised flip charts and other printed educational materials[76]. A six-month follow-up indicated strong evidence for higher utilisation of modern family planning method amongst women in the intervention areas (OR=8.25, 95% CI: 5.44,12.54; p<0.001), as well as improvements in knowledge and attitudes. Reported results did not take into account the cluster randomised design, however, which would have affected the precision of effect estimates.

Community-based malaria control

Two trials evaluated the effect of CHW-led education on knowledge and behaviour related to malaria. In rural Tanzania, health workers were trained to teach community-based women leaders to recognise symptoms of malaria and treat uncomplicated cases amongst children under five in their community [77]. Although the intervention description referred to women's groups, it was unclear if the CHWs facilitated groups of women leaders, or if women leaders trained in malaria case management organised group sessions in the community. Prevalence of anaemia, the primary outcome, decreased slightly more in the intervention group (43.1 percentage points compared to 36.5; $p=0.038$), but there was no evidence of effect on secondary outcomes on prevalence of fever and mean body weight. A government intervention implemented at the same time as the intervention subsidised mosquito nets and improved first line antimalarial treatment, which may have reduced malaria incidence in both treatment and control areas. While the authors concluded that the evaluation demonstrated the feasibility of a CHW-led intervention to reach mothers through women's groups, the lack of clarity in the description of the intervention limits conclusions on the role of CHW-led group education.

A 1996 study described an intervention implemented in Colombia, Ecuador and Nicaragua that trained village health workers to conduct community-based education workshops, home visits and community meetings to raise awareness on malaria control[78]. The intervention approach and educational tools were designed after formative research was conducted on local awareness of malaria. Health workers randomised to the intervention utilised a locally produced film, print materials such as flip charts and cards, games and discussions in group meetings. Assessment of the implementation process indicated that CHW were actively involved in the participatory sprit of the intervention, despite some difficulties with new visual aids that were introduced. Knowledge about malaria and drug-taking behaviour improved amongst participants in two of three sites, in a comparison of post-intervention knowledge of symptoms and treatment of malaria between intervention and control areas ($p<0.05$). Findings did not report estimates of precision or adjust for clustering, however. The findings highlighted the feasibility of CHW-led, locally tailored health education programs, the importance of support for health workers in providing health education as part of regular activities and of community participation in the development and implementation of an intervention.

Complex interventions that included CHW-led group education

Two South Asian trials evaluated the effect of CHW-led interventions that included, but were not limited to, group education to decrease neonatal mortality. A three-armed trial in Bangladesh compared home visits or group education with no intervention[79]. In the home visit arm, CHWs were trained to promote antenatal and birth preparedness, conduct postnatal home visits and provide basic treatment to neonates. In both the home visit and group education arm, community mobilisers disseminated maternal and child health messages in a group setting. The community education arm had higher intensity of meetings and additional resources to support education efforts. Home visits resulted in a 34% reduction in neonatal mortality in the last six months compared to the control arm (RR=0.66, 95%CI (0.47-0.93, p=0.011), while there was no evidence of a reduction in the group education arm. There was evidence of improvement in care practices such as clean cord-cutting and breastfeeding initiation in both arms. While the findings support home visits as an effective strategy but not group education sessions, the authors also suggested that a community care strategy may require a longer implementation period and greater coverage to achieve an effect.

In Pakistan, a community-based intervention to improve perinatal and neonatal outcomes included health education through group sessions by government CHWs, home visits, linkages between CHWs and traditional midwives and establishment of community health committees[47]. Control area government CHWs continued with regular activities primarily through home visits. The evaluation detected a 15% reduction in neonatal mortality (RR 0.85, 95% CI 0.76-0.96; p=0.02) compared to areas without the intervention, as well as improvements in delivery and newborn care practices. Findings are consistent with health benefits of CHW-led intervention, wherein group education was one component of a multi-faceted health promotion effort.

Alternatives to CHW-led education

A meta-analysis and review of research on interventions with women's groups provided insight into the effect of participatory group learning processes [67]. Seven trials in Bangladesh, Malawi, Nepal and India involved the establishment of women's groups to design and implement community-based strategies to improve neonatal and maternal health outcomes. The participatory model marks a departure from CHW-led group education through the use of an action research-facilitated learning cycle, interactive tools and joint action to address both demand for and supply of health services. Groups were facilitated by local women who were not previously health workers. The meta-analysis reported that implementation of participatory women's groups was associated with a reduction in neonatal mortality (OR 0.80; CI: 0.67,0.96) and a non-significant reduction in maternal mortality (OR 0.77; 95% CI: 0.48-1.23), with statistical heterogeneity across trials. The proportion of pregnant women who participated in the intervention was linearly associated with reductions in both outcomes. Hypothesised mechanisms for improvements in health outcomes were based in the principle that organising women into facilitated groups through a participatory learning cycle led to individual, community and social action to change behaviour and determinants of health, such as improved antenatal care uptake and increased access to services through organising funds and transport. A common factor across trials appeared to be collective action towards supply-side interventions. Specific behavioural change varied across settings: in Nepal, for example, improvements in health-seeking behaviour related to delivery were noted as the most likely explanation for a reduction in neonatal mortality while the India trial suggested that improved home practices by birth attendants and use of delivery kits – with no major change in health-seeking behaviour of women – may have been responsible [80, 81].

Another variation of CHW-led health education is interventions that integrate health education with microfinance groups, which is particularly relevant as most of SEWA's members also participate in its microfinance activities. A recent review of studies that utilised a variety of evaluation designs suggested a generally positive effect of health education on knowledge, and some improvement in service utilisation and health outcomes, amongst microfinance clients. The authors also note the need for more rigorous research on how health education can be integrated into microfinance groups[82]. In South Africa, a randomised trial of a microfinance and group health education intervention reported a 55% reduction in reported intimate partner violence, with no effect on the two other primary outcomes, unprotected sexual intercourse or HIV incidence[83]. A subsequent analysis of the specific contribution of group education suggested that microfinance clients exposed to health education were more likely to report behaviour consistent with women's empowerment and reduction of intimate partner violence and HIV risk than women who only participated in financial services[84]. Another experiment to provide education on child health to female microfinance loan groups in Peru reported increased knowledge amongst recipients, but no overall effect on the primary outcome of child health and nutrition status[85]. Notably, the effect on child health outcomes appeared to vary with the skill level of the trainer: women who interacted with a skilled educator reported reduced levels of bloody diarrhoea in their children.

Non-randomised studies in India

Three non-randomised studies were identified that evaluated the effect of group education on women's health knowledge or treatment-seeking behaviour in India. In rural Haryana, a pre-post intervention study reported that knowledge about reproductive tract and sexually transmitted infections improved after participation in a health education program led by health workers, through individual visits and group sessions. The introduction of group health education in particular was cited as reason for an eight-fold increase in attendance at a government health clinic, although detailed attendance data were not reported[86]. In another rural setting, rural adolescent girls participated in facilitated monthly group education sessions on menstrual hygiene. A pre-post intervention study in 23 villages found that the proportion of adolescent girls who reported using sanitary napkins increased from 5% to 25% after three years. Other factors that may have influenced the increase in use of sanitary napkins were not discussed, however [87]. A separate process evaluation indicated that, given the sensitive nature of discussing menstruation openly, health workers were instrumental in countering resistance amongst families and promoting attendance. Further, it noted that knowledge was not sufficient to influence behaviour change, and that community-based distribution of subsidised sanitary napkins facilitated increased use[88]. In a third study, also in a rural area, village-level nurses conducted group education with small group of women on breast cancer prevention, using teaching aides and practical demonstrations[89]. A post-intervention survey reported improved knowledge and use of breast self-exam. A lower proportion of older women reported use of self-exam, citing that it was not important at their age.

Discussion

This literature review identified only ten studies that evaluated the effect of CHW-led group education sessions, despite the widespread use of CHWs in health systems[48]. The limited number of papers may reflect the overall lack of rigorous evaluations of CHW programs, as noted in several literature reviews[42, 48, 51, 90], or low utilisation of group education sessions as an intervention strategy. For example, evaluations of health education interventions based in India included either home visits or peer education; none included CHW-led health education in a group setting. Nine of the ten studies reported positive outcomes, which may suggest publication bias – another possible reason for the low number of studies identified. While three observational studies in rural India, in settings similar to the SEWA intervention, reported positive outcomes related to behaviour change, none employed a concurrent control group or described the intervention processes in detail.

In the reviewed studies, CHW-led group education sessions were reported to improve knowledge and influence care-seeking behaviour across a range of settings. In addition, CHW-led group education may also contribute to improving health outcomes, when part of a multi-faceted intervention [91]. While studies reviewed provided fairly detailed descriptions of the intervention mechanics, they provided minimal analysis of why or how the interventions had an effect – likely due to a lack of process-oriented research as well as limitations on the length of publications. Factors considered to contribute to positive effects were CHW's ability to communicate with participants; use of local knowledge to share information; interactive communication tools and follow-up by CHWs[69, 72-75]. Several of the interventions noted the contribution and perceived effectiveness of print-based educational materials and teaching aides, such as flip charts and games.

While the evaluations concurred on the feasibility of CHW-led group education, several characteristics of the interventions varied across settings. This suggests that group education may be effective in a range of circumstances, as well as highlights the need to understand the processes associated with CHW-led group education further. All programs defined CHWs as local women recruited from the community they served, but with different service, implementation and payment structures. Most interventions recruited CHWs or partnered with non-governmental or community programs for the intervention, while only one trained government CHWs [47]. The duration and design of group sessions also varied, which may be linked to the intended behavioural change. For example, attempts to change embedded care-seeking practices, such as diet or delivery care, were implemented through intensive health education interventions, such as eight focused educational sessions followed by individual follow-up and additional activities [47, 75]. In contrast, changes in behaviour marked by a single, discrete activity such as undergoing a pap smear test or administering malaria treatment were associated with a lower number of education sessions. Notably, the relatively shorter breast screening and pap test interventions were add-ons to existing media campaigns [69, 73].

Accordingly, CHW-led group education may add value to wider health promotion activities, such as media education. It is possible that the ongoing media campaign served as the primary source of information, while CHWs facilitated the use of health services. Although not discussed in-depth, access or availability of services did not emerge as a barrier to behaviour change in these settings. Further, several of the interventions involved follow-up home visits or individual counselling sessions, which may have further supported improved preventive health practices through increased comfort, consistent contact and tailored messages. The multifaceted intervention in Pakistan demonstrated that education sessions, implemented along with home visits and community interventions, may capitalise on CHW's strengths as educators *and* service providers to improve neonatal outcomes [47]. Evidence suggests that the mechanisms by which CHWs affect health behaviour may involve their position as a community role models or support provided through informal interactions[73]. While improved knowledge in women exposed to group education was associated with increased uptake of pap smear tests, for example, women who underwent mammography did not report changes in knowledge. Similarly, although in a different approach, women's groups interventions suggest that behaviour changes may be facilitated by dynamics that emerge in a group setting, such as joint identification of problems and solutions, without the structured transfer of knowledge[67].

Although there is some evidence that CHW-led group education can improve knowledge and health-related behaviour, there is limited evidence for its role in improving health outcomes. Despite improvements in knowledge, lifestyle interventions aimed at reducing cardiovascular risk did not detect changes in most clinical outcomes [74, 75]. Similarly, the comparison of group education with home visits in Bangladesh, the only 'head-to-head' evaluation of its kind identified, did not detect evidence of an effect of group education on neonatal mortality in the time frame studied[79]. The only intervention to detect an effect on a health outcome (neonatal mortality) included a combination of group education with home visits and community-based health promotion, implemented by CHWs linked to the government health system; the effect of group education could not be differentiated from other activities [91]. Microfinance interventions that include a group health education component have reported changes in knowledge and behaviour, but no effects on health outcomes. Most studies noted the longer period of time required to measure an effect of community-based interventions on health outcomes.

The limited evidence available suggests that CHWs can play a unique role in disseminating information to improve knowledge and in facilitating service utilisation. Given the continued support for CHW programs in health systems around the world, more analysis of whether, how and the health system environment in which CHW-led group education can affect knowledge and behaviour is a critical need for interventions research [43, 48]. Further, although most interventions reviewed did not explicitly discuss the theoretical model for behaviour change, application of such frameworks in both intervention and evaluation design will provide more insight on the potential role of CHWs. Similarly, investigation is required into the processes by which CHWs can mediate improvements in health outcomes. More research in low-income settings, as well as comparison of CHW-led group education with other approaches, will enhance the evidence base as well as contribute to strategies to strengthen the role of CHWs in health systems and communities.

II. Literature Review: Hysterectomy in low and middle income countries, with a focus on India

Introduction

Hysterectomy, the removal of the uterus, is the leading reason for non-obstetric surgery amongst adult women in many high-income countries[92]. Common indications for hysterectomy include fibroids, dysfunctional uterine bleeding, uterine prolapse and chronic pelvic pain[93]. Reviews of clinical guidelines in the United States have advised hysterectomy as appropriate only if major impairment and symptoms are present, and after conservative surgery and/or hormonal treatment has been attempted[93, 94]. There is no established benchmark rate for hysterectomy; incidence varies widely between and within countries. An estimated 5.1 women per 1,000 women above age 15 underwent the procedure in 2004 in the United States, while incidence in Australia is estimated to be 3.1 per 1,000 women[33, 95]. Within Germany, age-standardized rates vary across federal republics, ranging between 2.1 to to 3.6 per 1,000 adult women [96]. In these settings, hysterectomy is most commonly conducted in women over the age of 45 [97, 98].

While there has been no cross-country analysis of the frequency of hysterectomy, available research points to several factors that contribute to the wide variation in incidence of hysterectomy within and across countries. Hysterectomy rates have been associated with women's social, economic and educational background, physician characteristics and health insurance coverage [99-105]. Further, there is a lack of established indications for hysterectomy for benign conditions and limited data on the long-term outcomes of hysterectomy, leading to variation in clinical practice [93, 106-108]. Qualitative studies have reflected wide diversity in gynaecologists' assessment of the indications for and necessity of hysterectomies: one study points to differences in advising hysterectomy based on physician sex, training and geography [108-110]. High lifetime risk in some settings–one in three in the United States, for example–has suggested that the procedure may be subject to misuse and has resulted in calls for medical audits and surveys of clinical practice[111]. For example, an analysis of 497 hysterectomies conducted in the United States reported that at least 70% were recommended inappropriately, primarily due to lack of diagnostic evaluation or failure to try alternative procedures[112]. Research, popular media reports and women's health activists have also suggested that attitudes towards intervention in women's bodies are a factor in medically unindicated hysterectomy[113-115].

Research on hysterectomy has primarily been conducted in high-income settings, using hospitals' administrative databases, national population surveys and community-based research. Studies based in low and middle-income countries have focused on obstetric emergencies and clinical reviews, with limited analyses of population-level data. The lack of research outside of high-income settings may reflect lower rates, or limited interest in the subject. However, in India, numerous recent media reports (2012-13) have suggested that hysterectomy is increasingly used as routine treatment for gynaecological ailments, presumably influenced by profit considerations and incentives under Rasthriya Swasthya Bima Yojana (RSBY), the national health insurance scheme[116-118]. With limited research available on the epidemiology of hysterectomy outside of high-income countries, it is difficult to evaluate these observations in India.

Objectives

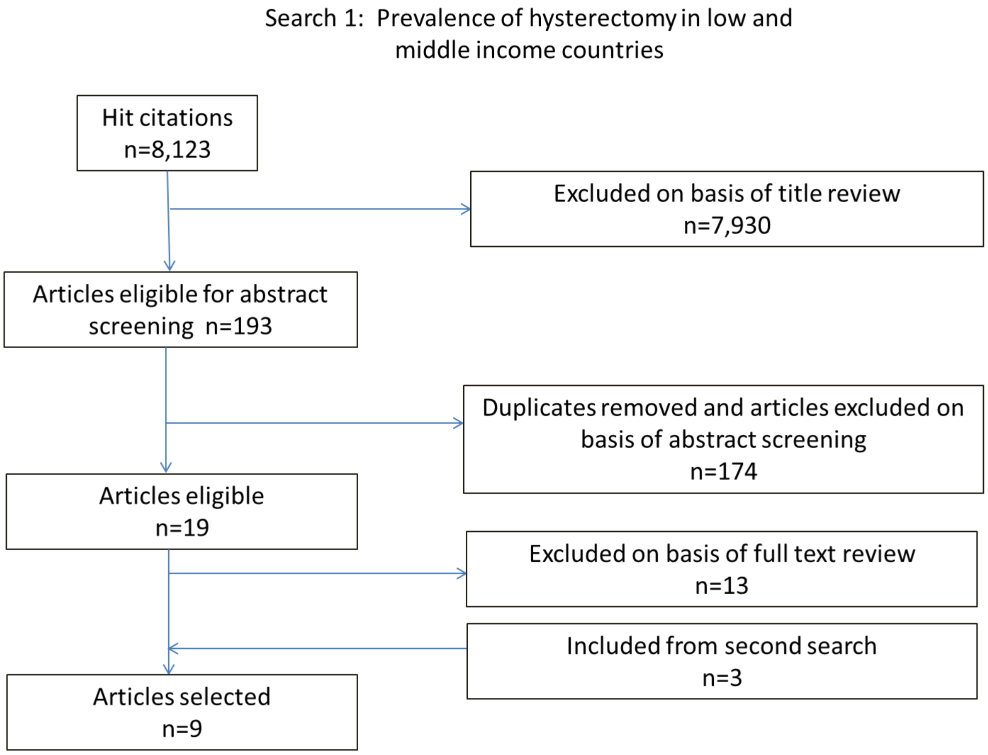
To contextualise my research on hysterectomy amongst low-income women in Gujarat, this chapter reviews literature on i) measures of the frequency of hysterectomy (prevalence and incidence) in low and middle income countries and ii) medical audits, treatment-seeking behaviour and health systems research on hysterectomy specific to India. In addition, I present an overview of the sociocultural context in which women in India seek treatment for gynaecological ailments.

Methods

A systematic literature search was conducted on the prevalence of hysterectomy in low and middle income countries. The search term hysterectom* was combined in separate searches with prevalence, rate, risk, incidence, epidemiolog* and surveillance, using MeSH terms and the adjacent (adj3) or near function where available, in the title, keywords and abstract fields. Searches were conducted in September 2014 in seven databases: PubMed, EMBASE, Scopus, Web of Science, Popline, IMSEAR and Global Health and yielded 8,123 initial hits (Figure 2.2).

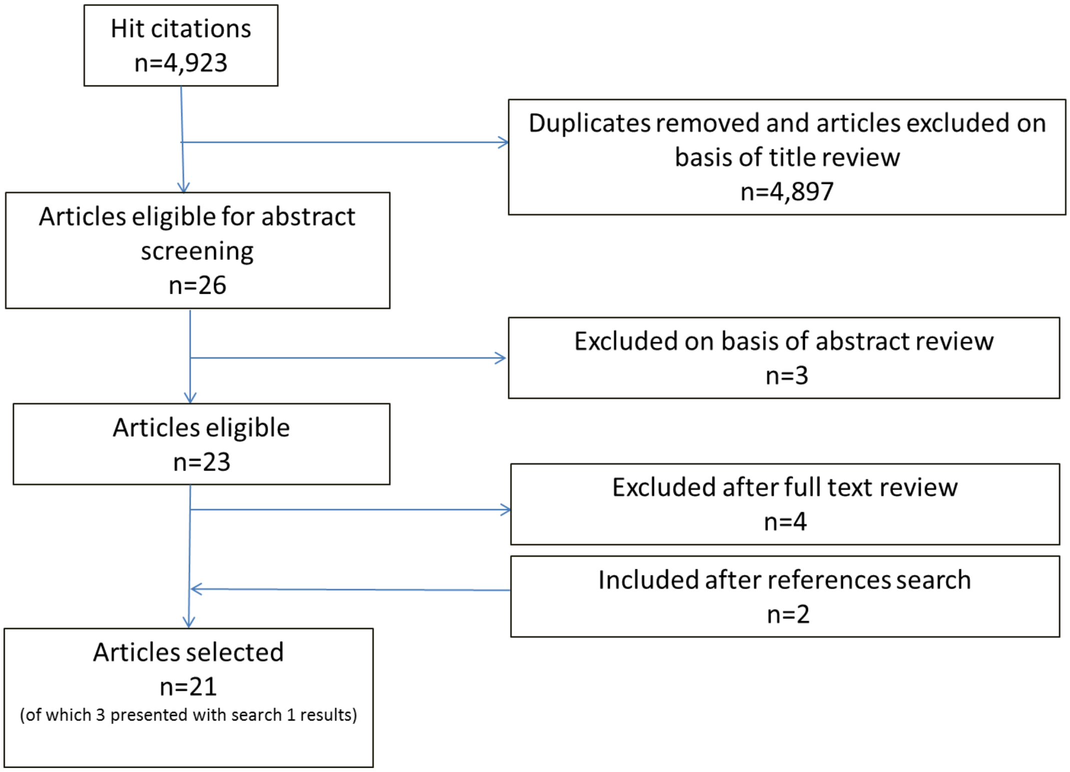
Inclusion and exclusion criteria were as follows. Papers were included if they were (i) population-based research studies that reported measures of hysterectomy frequency, including studies that reported on hysterectomy while focussing on a different condition such as urinary incontinence and (ii) published since 2000 in any language. A 15 year cut-off was chosen to focus on more recent estimates of hysterectomy. Studies were excluded if they: (i) did not include denominator information on the population at risk of hysterectomy (ii) limited research to obstetric hysterectomy or (iii) were conducted in countries classified as high income by the World Bank in 2014[119]. Of the initially identified articles, 193 were retained based on a review of titles. A review of abstracts resulted in full paper review of 19 studies, of which six articles met the inclusion criteria. Two of these six studies (one in Jordan and one in El Salvador) utilised women attending a primary health care clinic as the denominator, and hence technically did not meet inclusion criteria. They were included, however, for two reasons: (i) the authors represented the findings as prevalence estimates representative of the population at risk and (ii) excluding these two would have resulted in a review of only four studies, three of which were conducted in India.

Figure 2.2 Search 1: Prevalence of hysterectomy in low and middle income countries



For India-specific research on hysterectomy, searches were repeated in each database using only hysterectom* and India, yielding 4,923 initial hits (Figure 2.3). Papers were included if they were published since 2000 and reported on hysterectomy at the population level, including studies in a facility or insurance scheme setting in which the denominator was hospitalised women or enrolled beneficiaries . Studies on side effects or longterm outcomes related to hysterectomy, clinical reviews of surgical methods or individual case reports were excluded. Three studies [120-122]had already been identified and reviewed in the previous search and are not included in the search results below. Twenty-six abstracts that related to hysterectomy in India were reviewed, of which 23 met the inclusion criteria and underwent full-text review. Four studies were excluded after full text review because they did not report measures of the frequency of hysterectomy. References were searched and identified two additional studies, resulting in a total of 21 studies. Three of these studies reported on prevalence of hysterectomy in sub-groups of women as part of research on hospitalisation, sex workers and gynaecological morbidity. They did not include measures of hysterectomy frequency in the key words or abstracts, and were thus not identified in the previous search. These three studies were included in the review of results of the first search on measures of frequency of hysterectomy, while the remaining 18 which were included addressed risk factors, health services utilisation or medical necessity related to non-obstetric hysterectomies. As there were no studies on the sociocultural context of hysterectomy in India identified in the above searches, thirty-two studies on gynaecological morbidity or reproductive health were identified from a previous search on women's morbidity (Annex 1). A full text review of these identified twelve studies that provided relevant context on social and cultural influences on women's treatment-seeking decisions.

Figure 2.3 Search 2: Hysterectomy in India



Findings

The literature search identified very limited research on the prevalence of hysterectomy in low and middle-income countries and no studies that reported on incidence. Two studies in Jordan [123, 124] and one study in El Salvador[125] reported on hysterectomy as part of research on the prevalence of urinary incontinence. In a 2005 population-based study to investigate urinary incontinence amongst rural Jordanian women between the ages 50 and 65 years (n=182), 8.4 percent of women reported previous hysterectomy[123]. Age at the procedure was not reported. A 2013 study of 1,001 women above age 30 attending a primary health clinic in urban Amman estimated hysterectomy prevalence of 7.3 percent, again with no age at hysterectomy reported [124]. This may be an underestimate of the prevalence of hysterectomy in the population, as the study excluded women previously diagnosed with urinary incontinence, which may be associated with hysterectomy. Further, the study was conducted in health clinics amongst women seeking treatment for other ailments; although the authors suggested the population was representative, it may have excluded women who did not seek primary health services. Of 236 women aged 31 to 75 who were interviewed in health clinics in a 2007 study in rural El Salvador, 4.2 percent reported having undergone a hysterectomy[125]. Age at the procedure was not reported. Part of a study on women's attitudes toward reproductive health and menopause, the population was limited to women seeking treatment in clinics, who may not represent the entire population of women at risk of hysterectomy.

Prevalence in India

Six studies conducted in India provided estimates of the prevalence of hysterectomy in different populations (Table 2.1). One study reported standard errors, while the remaining five did not provide estimates of precision (and the reported information was not sufficient for calculations). A 2008 survey conducted to describe hysterectomy amongst 1,000 women (> 15 years of age) in rural Haryana estimated that 7.0 percent of adult women had undergone the procedure [120]. Age-specific prevalence was highest amongst women aged 45-54 (15.1%) at the time of survey, and lower (8.7%) amongst women in both the 35-44 and >55 year age groups. Age at the time of the procedure was not reported. The leading indication for surgery reported by women was excessive menstrual bleeding. Close to half (47%) of women reported using a government hospital for hysterectomy. A large majority (89%) of women reported seeking medical advice from three or more health care providers, the first source of care most commonly a local or traditional practitioner. Two-thirds of women waited at least one month to have the procedure after being advised to have it, due to fear of surgery or financial concerns. Almost half also spoke to another woman who had undergone hysterectomy before their own procedure. Four percent of women reported regretting having a hysterectomy.

Table 2.1 Estimates of hysterectomy prevalence in low and middle income countries

Study location	**Year**	**Rural/Urban setting**	**Age in years**	**Population surveyed**	**Sample size**	**Prevalence estimate**
El Salvador[125]	2007	Rural	31-75	Health clinic attendees	236	4.1
Jordan [123]	2005	Rural	50-65	Community-based study	182	8.4
Jordan [124]	2013	Urban	>30	Health clinic attendees	1,001	7.3
India						
Andhra Pradesh[126]	2013	Rural	18-45	Sex worker population	529	7.8
Chandigarh [127]	2004	Urban	40-60	Community-based study	725	5.9
Delhi[121]	2011	Urban	>15	Community-based study	1,271	2.5
Gujarat [122]	2011	Both	>15	Insured and uninsured women	3,855	5.3-9.8
Goa [128]	2004	Both	18-45	Community-based study	2,262	1.7
Haryana[120]	2008	Rural	>15	Community-based study	1,000	7.0

A 2011 study of 3,855 urban and rural women in Gujarat estimated hysterectomy prevalence amongst women covered by a microinsurance scheme operated by SEWA and women without insurance[122]. Amongst currently insured women (standard errors reported in parentheses), 9.8 percent (0.2) of rural and 5.3 percent (0.2) of urban women had had a hysterectomy while amongst currently uninsured women, 7.2 percent (0.2) rural and 4.0 percent (0.1) urban women reported having had the procedure. Mean age at hysterectomy was 36 years for rural women and 39 years for urban women. One-third of rural women and over one-half of urban women utilised a public facility for the procedure. Univariate analyses did not detect evidence of a difference in risk of hysterectomy by present insurance status, although insurance status at the time of procedure was unknown. A 2011 study to describe surgical patterns in an affluent urban colony in East Delhi (n=1,271 adult women) estimated that 2.5 percent of women over the age of 15 had undergone hysterectomy[121]. In a 2004 study of the effect of menopause in urban Chandigarh, 5.9 percent of women aged 40-60 years old reported having had a hysterectomy[127]. A 2006 study of dysmenorrhea amongst 2,262 women aged 18-45 in Goa reported that 1.7 percent had undergone hysterectomy [128]. The mean current age of women who reported hysterectomy was 42.9 years, but age at the procedure was not reported. Lastly, in a 2013 screening study for microbicide feasibility amongst female sex workers aged 18-45 in rural Nellore, Andhra Pradesh, 7.8 percent reported having had a hysterectomy[126]. No further information was reported.

Medical audits in India

In addition to population-based research, facility-based histopathological analyses have provided insight into causes of hysterectomy. All eight of the identified audit reports were conducted in large, government hospitals, primarily in rural areas (Table 2.2). The majority of women studied underwent the procedure between the ages of 40 and 50. Variations by age, location and religion were observed in the identified reasons for hysterectomy. Leiomyoma (fibroids), adenomyosis and cervical cancer were the leading reasons for hysterectomy, with variation by setting. In a histopathological analysis of hysterectomy cases in women under the age of 35, ovarian and cervical malignancy comprised 14 percent of cases[129], compared to less than five percent in examinations of all women above the age of 18 in all other settings[130-134].

Table 2.2 Summary of histopathological studies of hysterectomy cases in India

Setting	Sample size	Age of women	Leading causes of hysterectomy*	Audit of medical necessity
Rural Himachal Pradesh[133]	922	Majority aged 40-49	Prolapse (32%) Leiomyoma (29%)	10% of cases had no definite pathology
Rural Jammu Kashmir[132]	698	Majority aged 41-50	Leiomyoma (30%) Prolapse (24%)	Pre-operative diagnosis matched histopathology in at least 2/3 cases
Rural Karnataka[129]	84	Women <35	Malignant cases only Ovarian cancer (71%)	Not evaluated
Rural Karnataka[131]	527	Mean age 48±10 years	Fibroids (40%)	99% of cases considered justified 76 cases amenable to conservative treatment
Rural Karnataka[135]	293	Majority aged35-45	Prolapse (36%) Leiomyoma (12%)	Not evaluated
Rural Punjab[134]	373	Mean age 45 ±9 years	Benign cases only Leiomyoma (44%) Adenomyosis (19%)	Leiomyoma diagnosed correctly in 50% of cases; adenomyosis incorrect in all cases
Rural Uttar Pradesh[130]	870	Majority aged40-49	Leiomyoma (22%) Adenomyosis (22%)	98% had clear pathology
Urban Uttar Pradesh[136]	1000	Majority aged 41-50	Cervical cancer (57%) Benign conditions (43%)	Not evaluated

**Reported as categorised by authors*

A comparison of Hindu and Muslim women who underwent hysterectomy in Noida, an urban area outside of New Delhi, reported that a lower proportion of Muslim women underwent hysterectomy for cervical malignancies compared to Hindu women [136]. Studies conducted in rural Karnataka, Jammu and Himachal Pradesh observed uterine prolapse as a leading cause of hysterectomy, compared to a higher proportion for fibroids and almost no prolapse in urban areas[131, 133-135]. In all settings, the large majority of procedures were conducted through abdominal hysterectomy, with the exception of those done for uterine prolapse where vaginal hysterectomy was used.

Authors evaluated the medical necessity of hysterectomies conducted by comparing clinical diagnoses and histopathological results. Findings varied by study setting. In an audit based at a large teaching hospital in Karnataka, the authors concluded that 76 of 527 (14%) hysterectomies performed were amenable to more conservative medical management[131]. Researchers in a government hospital in rural Uttar Pradesh found no pathology in two percent of 870 cases[130], while 10 percent of 922 specimens in a rural Himachal Pradesh hospital had no clear pathology[133]. In rural Punjab, 11 of 18 cases performed in women under 30 years old were deemed medically unnecessary[134].

Health systems research

Several Indian studies provided perspective on health services utilisation and health systems concerns raised by hysterectomy patterns. A costing of hysterectomy for facilities, rather than cost incurred by patients, reported the mean cost (in Indian rupees, 1 GBP=94 rupees) to be Rs. 4,124 to government facilities; Rs. 10,081 to private for-profit hospitals and Rs. 57,622 to a private charity hospital, the high amount at the latter due to a low case load[137]. In a review of 63 hysterectomies conducted on insured women in rural Gujarat, Ranson and John reported an average cost of Rs. 5,010 incurred by women, of which a mean amount of Rs. 1,277 was reimbursed [138]. The majority of 728 cases reviewed in rural Andhra Pradesh incurred a cost between Rs. 7,500 and Rs. 10,000[139].

A study of providers who conducted hysterectomies on SEWA-insured women in Kheda, Gujarat reported widely varying quality of care[138]. Authors documented practices that included providers performing hysterectomy on demand, conducting oophorectomy without consultation or consent, and working in non-hygienic conditions in operating theatres. Histopathology of specimens was not conducted by any of the 12 providers interviewed. A focus group discussion with ten women who had not undergone hysterectomy revealed that they perceived advice regarding hysterectomies to be better in government facilities compared to private doctors, although the majority of procedures were conducted by the latter. In rural Andhra Pradesh, where 97% of cases were conducted in the private sector, women were not informed of their options or potential side effects of hysterectomy and oophorectomy at a young age. The mean age at hysterectomy in the 132 cases reviewed in this setting was 28.5 years[140].

Hysterectomy has been reported as the leading reason for use of health insurance by adult women in several schemes [138, 139, 141, 142]. Documentation of surgeries conducted under Arogya Shri, a government insurance program in the state of Andhra Pradesh, amongst young women has led to hysterectomy's removal from the coverage package due to suggestions of medically un-indicated hysterectomy[139, 140, 143]. Hysterectomy was reported as the leading reason for admission amongst women insured by RSBY in Gujarat [142]. Studies have also noted differences in treatment-seeking behaviour based on insurance status. In rural Karnataka, a descriptive review of 776 cases, 176 of whom were insured, observed that insured women were older, waited for a shorter period of time and were more likely to have fibroids, compared to uninsured women who waited up to two years to seek treatment, with higher prevalence of indications of carcinoma [144]. VimoSEWA, a scheme in Gujarat, reported hysterectomy as the highest reason for claims amongst adult women. A comparison of women insured by VimoSEWA with uninsured women, however, did not detect evidence of a difference in the odds of undergoing hysterectomy in the past six months, based on a cross-sectional analysis of 1,934 women in rural and urban Gujarat [145].

Women's perspectives on hysterectomy also varied across study settings. In Gujarat, women felt that menstrual taboos and restrictions could be sufficient reason to justify or demand hysterectomy, although provider opinions were deemed paramount in the decision-making process[138]. In Andhra Pradesh, however, hysterectomy was reported as a cause of considerable debt and physical suffering due to side effects. In a study of 50 women who had undergone hysterectomy in New Delhi, most (92%) did not know what type of hysterectomy was conducted or what alternative treatment was available[146]. A large majority requested more information on hysterectomy through pamphlets and from their providers.

Sociocultural factors related to hysterectomy

While there has been very limited research on hysterectomy in India, studies on gynaecological morbidity, particularly related to menstrual disorders, provide context on the influences on women's perceptions and decisions related to treatment. Several studies have suggested that Indian women live in a 'culture of silence[147]' – fuelled by gender inequality and social norms – that proscribes women from communicating an illness or using household resources for treatment related to reproductive and sexual health[148-152]. Accordingly, cultural expectations that women will demonstrate resilience in the face of hardship, and not prioritise their needs over others, may translate into low treatment-seeking rates[153]. For example, less than half of women studied in rural Rajasthan, Maharashtra and Tamil Nadu and in urban Mumbai sought treatment for vaginal discharge, menstrual disorders or abdominal pain[149, 153-156]. Reasons for not seeking care were related to normalisation of gynaecological ailments, fear or embarrassment, financial constraints and lack of decision-making power over health care. However, two studies amongst low-income women in rural Gujarat and rural Karnataka reported that the majority of women sought multiple sources of treatment for similar ailments as reported in other studies[157, 158]. Suggesting that the 'culture of silence' is not universal, these findings also underscore regional diversity regarding perceptions and treatment of gynaecological ailments.

In the two ethnographic studies identified that explored perceptions of gynaecological morbidity, women's attitudes towards gynaecological symptoms and ailments reflect the role of cultural norms in defining and treating illness[154, 158]. The most common gynaecological complaints involved vaginal discharge, menstrual disorders and uterine prolapse. Attitudes towards menstruation and menstrual disorders, given their relevance to research on hysterectomy, are summarised here. Menstruating women are considered 'polluting': particularly in rural India, they cannot enter the kitchen, temples or sacred places, with more stringent rules in some communities[14, 158, 159]. Women in rural Rajasthan linked menstruation and their gynaecological problems with *kamjori,* bodily weakness[154]. Women who suffer from weakness are more prone to excessive menstrual bleeding, which was a symptom of a defect in the uterus or cervical cancer. In a state of *kamjori/*weakness, factors such as sterilisation, pregnancy, eating hot foods, and mental tension are more likely to cause menstrual problems. In this setting, most women did not seek treatment for gynaecological ailments unless they became severe.

Women in rural Gujarat, on the other hand, attributed reproductive ailments to excessive *garmi* – heat in the body[158]. Based in the ayurvedic concept of humoral balance, *garmi* suggests that illness originates from an imbalance of hot and cold. *Garmi* was linked to ingestion of hot food, allopathic medicines, alcohol consumption and sexual intercourse. Sterilisation was linked to manifestations of *garmi*, as a result of the heat that resulted from an invasive tubal ligation. Most women sought private care for ailments, as locally available government health services only provided family planning or immunisation. Women who reported excessive menstrual bleeding frequently inquired about the possibility of hysterectomy as a permanent solution to menstrual problems. They also avoided treatment that involved allopathic oral medicines, due to fear of excessive heat production.

Discussion

This review highlights the very limited research available on measures of the frequency of hysterectomy in low and middle-income countries. A search that included all countries yielded an initial 18,465 hits; almost all studies that reported incidence and prevalence were based in high-income settings. Case-control studies conducted in Nepal, Brazil and China and facility-based studies in Egypt, Ethiopia, Malaysia, Pakistan and Nigeria that studied hysterectomy were excluded from this review because they did not provide denominator information about the population at risk. In North America and Europe, nationally representative surveys and databases of medical admissions and insurance utilisation provide population data for epidemiological analyses. In India and other low-income settings, community-based estimates of hysterectomy have been based on small samples, in specific sub-populations, with limited population data and measures of precision presented. Variation in time periods, population characteristics and age structure limits comparisons between the available data, while lack of incidence or age-standardised data prevents assessment of trends over time or with rates estimated in other countries.

While noting the limitations of comparing prevalence data in different populations, estimates in India, El Salvador and Jordan are similar or slightly lower than those in Asian high-income settings –8.8% in Taiwan and 7.5% in Singapore – and one high-income Eastern European country, Estonia (11.7%) [160] [161, 162]. However, the mean age of hysterectomy in India (where reported) is approximately ten years younger than that reported in the high-income settings [97, 98, 163]. Prevalence also appears to vary by geographic setting, health systems environment and socioeconomic status within India. While only 2.5 percent of women in an affluent colony in Delhi reported hysterectomy, the procedure was reported as more prevalent amongst low-income women in rural areas. Comparisons of insured and uninsured women in a community-based scheme do not suggest differences in hysterectomy patterns based on insurance coverage, but there has been no comparison of women insured by higher coverage government schemes with uninsured women. Further, available population-based estimates of hysterectomy present very limited analysis of risk factors or health care utilisation patterns associated with the procedure.

The primary medical indications in India – fibroids, adenomyosis and prolapse – suggest that a proportion of cases are amenable to initial medical management or less invasive treatment. However, histopathological reports suggested that the large majority of procedures conducted in government hospitals were appropriately recommended, compared to 20% to 70% found inappropriate in Taiwan and the United States, respectively[112, 164]. Audits also indicated a higher mean age of women that reported in community-based studies, although the study settings may not be comparable. Medical audits were conducted in large government teaching hospitals, while community-based studies reported high proportions of procedures conducted by private providers. Accordingly, these assessments of medical necessity may not be representative of wider patterns in India. Further, facility-based research has raised concerns about the quality of gynaecological care and cost incurred by women, as well as women's limited knowledge of hysterectomy before undergoing the procedure.

There is limited research on the social and cultural context of treatment-seeking behaviour for gynaecological morbidity, both in India and globally[165]. Available research in India suggests that sociocultural perceptions vary by setting – underscoring the importance of localised, context-specific research. The lack of available or effective services for gynaecological ailments, however, was common across settings[149, 153-155, 158, 166]. Several studies also noted women's perceptions of the iatrogenic roots of gynaecological problems: sterilisation, intra-uterine device insertion and abortion are perceived as causes of subsequent infections or disorders[154, 155, 158, 165].

This review underscores the type of research required to evaluate hysterectomy levels and trends in India. Analyses of population-based data and estimates of incidence are required to establish national patterns and make meaningful comparisons within and between settings. Given the regional diversity suggested by available studies, more community-based research is required to document and identify local risk factors. Medical audits conducted in a range of health facilities, particularly private hospitals where the majority of procedures is conducted, would provide insight into clinical practice as well as identify medically unindicated procedures. Age-specific data are required, as well as estimates of incidence, are required to evaluate trends in India. Longterm research on side effects of hysterectomy is also needed, along with consideration of the health implications of a relatively younger age at hysterectomy in India. Examination of the role of health insurance and health systems environments requires more research based on population-level data, rather than analyses of enrolled beneficiaries alone. Encouragingly, the next round of the NFHS in India will include hysterectomy in its 2014-15 survey of a nationally representative sample of households [167]. Combined with medical audits and perspectives of providers and women, regular analysis of national data will provide insight into why hysterectomy has emerged as a public health concern in India. Lastly, research on the social and cultural determinants of hysterectomy will provide critical insight into: women's perspectives on the procedure; facilitating factors and barriers; the implication of the procedure on women's role in the family and on gender norms; and on potential areas for intervention.

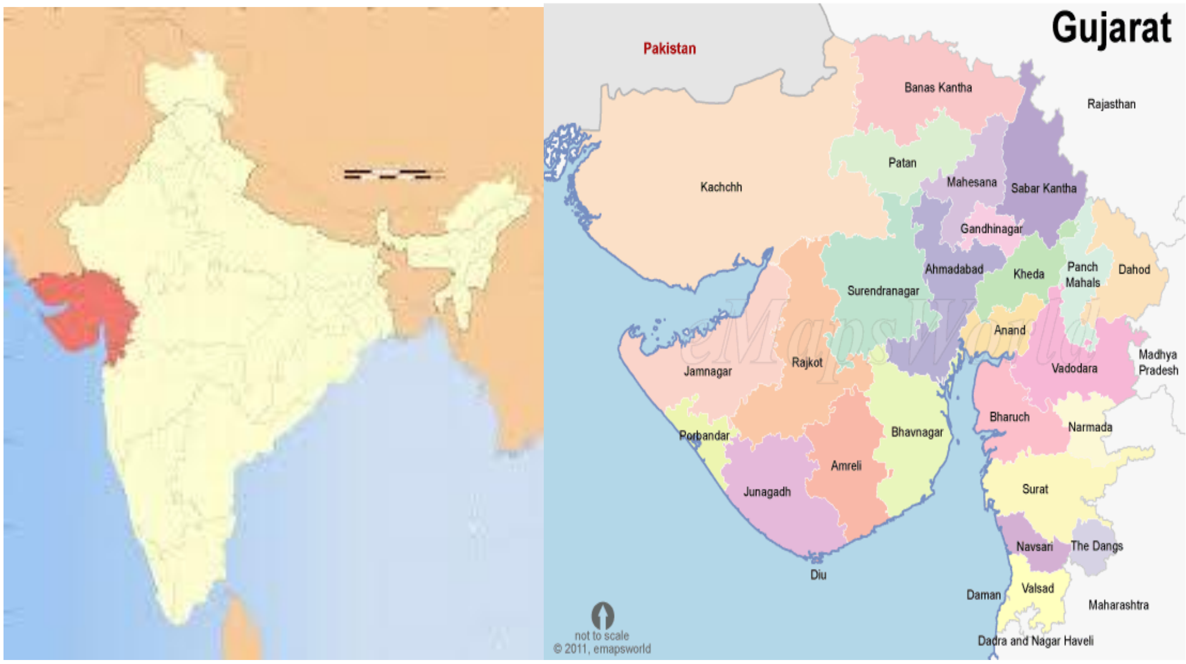
Chapter III. Study Background

I. Setting

Gujarat

The intervention, evaluation and qualitative research were conducted in Ahmedabad district and Ahmedabad city in Gujarat, India (Figure 3.1). With a population of 60 million people on India's Western border, Gujarat is amongst the top five contributors to India's economic growth, with the third highest per capita income [168]. The infant mortality rate and maternal mortality ratio, while steadily decreasing, remain considerably higher than targets set by the state[169]. At the time of the intervention, the maternal mortality ratio was estimated to be 160 per 100,000 live births, considerably lower than the national ratio of 254 per 100,000 live births[170]. The sex ratio was 918 females per 1,000 males, compared to the national ratio of 940 per 1,000[171]. Malnutrition in both children and adult women has remained a concern, alongside an increase in obesity (Table 3.1).

Figure 3.1 Gujarat State, Western India and detailed map of Gujarat



Source: www.emapsworld.com

Table 3.1 Selected health indicators for Gujarat

Indicator	Gujarat (1998-99)	Gujarat (2004-05)	All India (2004-05)
Infant mortality rate (per 1,000 live births)	62.6	49.7	57.0
% anaemic children (6-35 months)	74.5	80.1	78.9
% underweight children (<3 years)	41.6	41.1	40.4
% anaemic married women (15-49 years)	46.3	55.5	56.2
% married women with below normal BMI	37.0	32.3	33.0
% women who are overweight or obese	15.8	20.3	14.8

Source: National Family Health Surveys 2 and 3[4]

Gujarat's public health system faces a shortfall in human resources, particularly specialists. The state employs six gynaecologists, with 267 unfilled posts[172]. The National Rural Health Mission (NRHM), initiated in 2005, is India's flagship health programme to improve rural infrastructure and human resources. Accordingly, the state has recruited close to 30,000 village health workers (known as Accredited Social Health Activists, or ASHA workers) to cover its 18,539 villages[169]. In addition to implementing the centrally sponsored Janani Suraskha Yojana (JSY) scheme for institutional delivery, Gujarat provides free delivery and postnatal care in private facilities for women who hold below poverty line (BPL) cards.

Utilisation of health services in Gujarat, as in most of India, is largely financed by individual households. Outpatient and inpatient care are predominantly sought in the private sector (Table 3.2)[2]. Household OOP health expenditure accounts for 78% of total health spending in the state[173]. In 2009, Gujarat initiated roll-out of RSBY, a health insurance scheme that provides hospitalisation coverage up to Rs.30,000 in public and private hospitals for BPL card holders[174].

Table 3.2 Proportion of treatment in private sector (2004), Gujarat (%)

Treatment type	**Rural**	**Urban**
Outpatient	79	82
Inpatient	69	74

Source: National Sample Survey Organisation, 2004[2]

SEWA

The intervention was designed and implemented by SEWA, a trade union for women workers in India's informal economy founded in 1972 in the state of Gujarat. SEWA members are agricultural workers, manual labourers, street vendors and home-based workers – workers without regular wages, employment protection or maternity benefits. SEWA's twin goals are full employment and self-reliance for women workers, pursued through activities that include labour organising, livelihoods generation, financial protection and capacity building. It established the first microfinance bank for low-income women in India, SEWA Bank in 1974, followed by a series of women-owned enterprises and capacity building institutions. It identifies itself at the confluence of the trade union, co-operative and women's movements, with an aim to influence both local action and national policy[175]. In 2014, the union reported a membership of over 1.9 million women in nine states[176].

A 2009 study of SEWA members in Gujarat reported that illness expenditure was the leading cause of indebtedness amongst its members [177]. SEWA has long perceived health to be a pressing concern for its members, as a critical component of labour security [175]. Accordingly, in 1984 it established SEWA Health, a community health program run by health workers and Lok Swasthya Mandali, a women-owned cooperative of health workers and midwives. Eight years later, SEWA developed a low-cost life, hospitalisation and asset insurance service, VimoSEWA, to protect members from indebtedness (described below). In addition, SEWA has actively lobbied for policy changes to improve women's health and health security: it was instrumental in the introduction a Social Security Act for Unorganised Workers, in the design of the RSBY and the inclusion of traditional midwives in maternal health policy in Gujarat [178] [177]. This intervention was implemented by SEWA Health, in partnership with VimoSEWA.

SEWA Health

SEWA's health program is implemented by health workers, locally known as *arogya sevikas,* who fit the widely accepted definition of a CHW: women who reside in the community, are selected locally, and trained to provide basic education and primary health services[179]. They are chosen either through SEWA community meetings, where they are identified as bright, outspoken women or through recommendation by another health worker. Initial training consists of classroom and practical sessions over three months. They are supervised by a SEWA health organiser working at the urban ward or rural block level. They report monthly outreach data and undergo six-monthly reviews.

CHWs are paid monthly stipends of Rs. 3,500 to Rs. 5,000, slightly higher than the minimum wage for skilled manual workers in Gujarat[180]. There is no minimum educational requirement, although most have attended primary school or SEWA literacy training. They conduct home visits in the entire community, provide basic health information, and sell low-cost allopathic and *ayurvedic* medicine (produced by the health co-operative) for which they receive a commission. *Arogya sevikas* are closely linked to public providers, and support women in negotiating the public health system through accompanied referrals and advocacy for lower costs in government hospitals. While the longstanding focus of the program has been primary health care, it has expanded and changed organically over 25 years. Recent donor-supported initiatives include provision of maternal and child health services, HIV/AIDS prevention and adolescent reproductive and sexual health education.

VimoSEWA

VimoSEWA is a voluntary, community-based insurance scheme initiated in 1992. In partnership with insurance companies who bear risk, VimoSEWA provides a range of insurance products to women (Table 3.3) through its non-profit cooperative. VimoSEWA insures adult women as the primary insured, who have the option to purchase additional coverage for spouses and children.

Table 3.3 VimoSEWA Health Products in 2009 (Indian Rupees, 1 GBP=INR 94.4 on 14.1.2015)

	Member	**Spouse**	**Children**	**Total**
Scheme 1				
Annual premium	175	125	100	400
Hospitalisation coverage	2,000	2,000	2,000	6,000
Scheme 2				
Annual premium	375	350	100	825
Hospitalisation coverage	6,000	6,000	2,500	14,500

Like most Indian CBHI schemes[181], VimoSEWA provides hospitalisation coverage that includes hospital and provider charges, medicines, transportation and other expenditure incurred while admitted in an inpatient facility. For a claim to be admissible under the scheme, the member must be hospitalised for a minimum of 24 hours. VimoSEWA does not cover expenditure on outpatient treatment or childbirth. In 2012, the health scheme insured approximately 80,000 policies, about 6 percent of SEWA's membership[182]. RSBY began roll-out in SEWA's rural focus areas in 2011[183]. No other community-based health insurance schemes operated in VimoSEWA's coverage areas at the time of the intervention, and very few (0.6%) households in lower income groups in Gujarat reported coverage by a health insurance scheme in 2006 [184].

Payment for hospitalisation costs by VimoSEWA members is made in two ways. In Ahmedabad city and parts of rural Gujarat, members can obtain 'cashless' treatment if they are admitted in empanelled public, private for profit and private non-profit hospitals (the latter are locally known as trust hospitals). Admitted members inform VimoSEWA as soon as they are admitted and VimoSEWA pays the hospitals directly. In other areas, members pay out-of-pocket and are reimbursed for expenses on submission of hospital bills. Previous research at VimoSEWA has found that the scheme provides members with a degree of financial protection, but the coverage is not comprehensive[29]. The scheme has also been examined from an equity perspective. Research findings indicated that the scheme was successful in enrolling the poor, and utilisation patterns were broadly comparable among urban members of different socioeconomic groups. Among rural members however, the better off were more likely to submit claims. Barriers to utilisation included distance to hospitals, difficulty with claims paperwork and lack of awareness about insurance coverage[185]. Child care, household responsibilities and opportunity costs such as lost wages were also identified as obstacles to treatment-seeking, for women in particular[186]. A survey conducted by Ranson in 2000 amongst 242 VimoSEWA-insured and 381 uninsured households did not find evidence of increased hospitalisation amongst insured women[187]. Since then, VimoSEWA has not assessed hospitalisation rates or treatment-seeking of insured members compared with uninsured women.

Claims analysis

From 2007-2009, VimoSEWA received a total of 12,027 hospitalisation claims, or 35 claims per 1,000 insured, similar to NSS hospitalisation estimates for Gujarat of 29 and 36 per 1,000 persons, (rural and urban, respectively)[2]. Health claims comprised approximately 90% of all claims submitted to VimoSEWA during this period. Table 3.4 presents the distribution of causes of common claims and cost per claim for adult women. A high proportion of hysterectomies were found to be conducted in women younger than 45 years (Figure 3.2). VimoSEWA was surprised by the high proportion of hospitalisation for seemingly common, preventable ailments and the frequency of hysterectomy. They sought to understand whether the scheme served as an incentive for unnecessary hospitalisation or medically unindicated procedures. SEWAs CHWs, who conducted health education and facilitated use of primary health care, believed their job was to prevent hospitalisation for such conditions before it occurred.

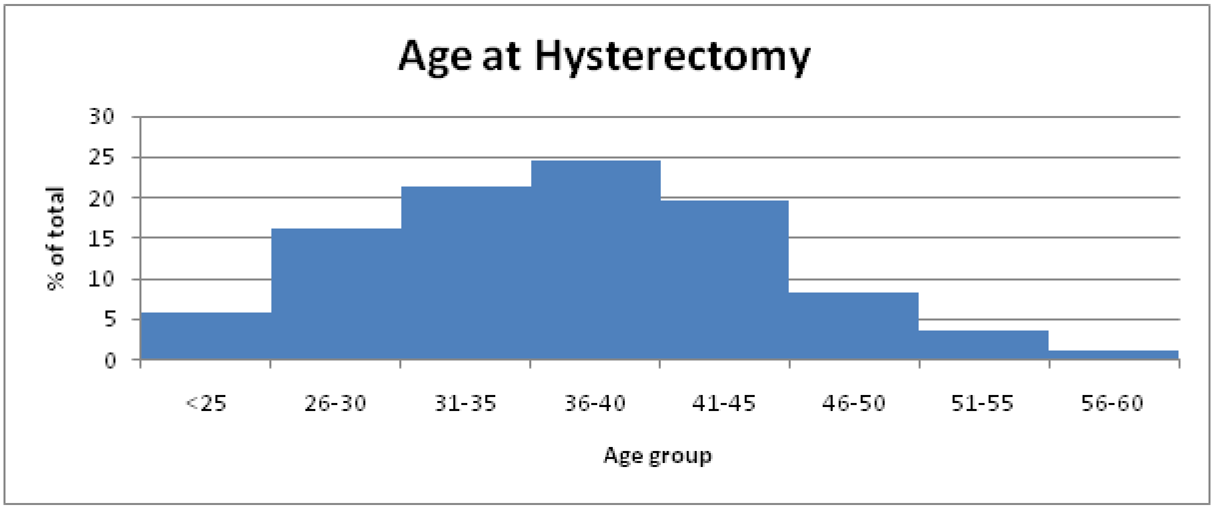
Thus, further discussion led to the design of a community-based intervention to address these three conditions, described in detail below.

Table 3.4 VimoSEWA leading claims in adult women, 2007-2009 (n=6,680)

Condition	**Claims (n)**	**% claims by all women**	**Claimant mean age (SD)**	**Mean claim cost (INR)**
Fever/Malaria	972	14.5	36.3 (9.0)	1,391
Diarrhoea/Gastroenteritis	933	14.0	36.9 (9.5)	1,639
Hysterectomy	524	7.8	37.6 (7.3)	5,091
Respiratory infection	348	5.2	40.0 (9.6)	1,809

Source: VimoSEWA Claims Data, 2007-2009

Figure 3.2 Age at hysterectomy amongst VimoSEWA claimants, 2007-2009 **(n=524)**



II. Intervention description

Preliminary discussions with CHWs based on the claims analysis indicated that diarrhoea and fevers are indeed common, for which women typically sought facility-based treatment after trying home remedies, self-treatment through chemists or local practitioners. Conversations with hysterectomy claimants revealed that they were unaware of what the operation entailed. Accordingly, SEWA Health hypothesised that some of this hospitalisation could be prevented through a community health program targeted at raising awareness on prevention and immediate treatment for diarrhoea and fevers and improving knowledge of hysterectomy.

Design process

SEWA submitted a proposal to the Microinsurance Innovation Facility of the International Labour Organization (ILO) to design, implement and evaluate an intervention to reduce VimoSEWA claims for diarrhoea, fever and hysterectomy. ILO committed to providing financial resources that covered 70 percent of total costs, with a 30 percent contribution from SEWA. SEWA decided that the donor resources – USD 165,000 – would be directed towards the evaluation study, while SEWA's contribution would include its community health team, local travel and project coordinator costs. Both SEWA Health and VimoSEWA, as non-profit cooperatives, were committed to financial sustainability without external support. Given the relatively low project budget and the limited resources of both cooperatives, the most economical approach was to utilise the existing CHW team to design and implement the intervention. The approach to intervention design, therefore, was largely heuristic, as detailed in the next section. The evaluation, by necessity, would assess effectiveness within SEWA's existing human resources, rather than efficacy of an intervention implemented with additional team members. If the intervention were effective in reducing claims, VimoSEWA planned to invest its own financial resources to sustain health education for the three conditions after the project period. The implications of this arrangement on the intervention's minimum detectable effect size are detailed in Chapter 4.

The intervention design process, conducted in detail after the proposal was accepted, was guided by SEWA Health's basic principles for programs: community participation, women-led and women-focused inputs, and strengthening the existing public health system, rather than developing parallel health services[178]. The study location, chosen before initiating further design, required areas where both CHWs and VimoSEWA were active. A mapping exercise indicated that CHWs and insurance services overlap in Ahmedabad city, but only in some rural areas of Ahmedabad district. Accordingly, Ahmedabad city and two rural sub-district blocks,[c] Sanand and Dholka, each with insurance coverage in at least 30 households (HH) per CHW, were chosen for the intervention. These areas were covered by 28 CHWs (16 rural, 12 urban). As described in Table 3.5, one urban CHW covers an area with 4,000-7,000 persons, while her rural counterpart covers 5,000-8,000 persons each. Each covers approximately 1,100 households.

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[c] Ahmedabad district is divided into 11 blocks, of which SEWA is active in five.

Table 3.5 Population covered by CHWs (28) and VimoSEWA in study area, 2009

Area	CHWs included in study	CHW coverage (population)	Insurance membership (individuals)
Ahmedabad city (12 CHWs)	16	81,535	35,802 (27,627 policies)
Ahmedabad district (16 CHWs)	12	104,615	11,716 (9,399 policies)

VimoSEWA and SEWA Health had decided that the intervention would focus on three of the leading reasons for hospitalisation claims by women: diarrhoea, fever and hysterectomy. It aimed to reduce hospitalisation for conditions amenable to prevention or outpatient treatment, or in the case of hysterectomy, only that which is not medically required. The category of fever, however, was unclear, as it could include malaria, respiratory infection or other bacterial or viral causes. Gujarat is classified as one of India's eight high malaria endemic states, within which Ahmedabad is categorised as a high-risk city[188]. An epidemiological study of malaria in Ahmedabad estimated an annual incidence of 12 cases per 1000 persons – nine times higher than government estimates – of which one-third is *p.falciparum*[189]. Since VimoSEWA only classifies a claim as malaria if a laboratory diagnosis is submitted, it is likely that a proportion of fever claims, particularly those from institutions without laboratory facilities, were indeed malaria. Although a medical review of fever and malaria claims was not conducted, it seemed logical to focus on malaria-related fevers, as well as general preventative behaviour to prevent infections or other causes of fever.

CHWs randomised to intervention areas (randomisation procedures are described in the following chapter) spent two days in a design workshop, followed by two one-day meetings, to discuss potential intervention content, relevant evidence and feasibility. CHWs first identified and assessed existing interventions for the target conditions by SEWA and the government (Table 3.6). Overall, SEWA did not address any of the target conditions with an evidence-based strategy or in an in-depth manner. The focus of its primary health services, outside of health education, was to promote the SEWA health co-operative's *ayurvedic* and herbal medicine products—which provided a financial incentive to CHWs and supported sustainability of the co-operative–but had not been evaluated for effectiveness. Most government interventions were perceived to be of limited effectiveness due to limited outreach and availability of human resources. The design went through several iterations, pilot testing and feasibility analyses between February 2009 and March 2010. SEWA viewed this process as a practical, grassroots method of ensuring ownership by health workers and communities.

Table 3.6 Existing interventions in Ahmedabad city and district

Health Issue	**SEWA services**	**Government programs**	**Limitations (as perceived by CHWs)**
Diarrhoea	Sale of ayurvedic medicines Previous toilet and sewage intervention in Ahmedabad city	Provision of ORS (ASHA) Chlorination of water tanks Antibiotic treatment at primary health centres	ASHA does not carry ORS Medicine not free at primary health centre
Malaria	Sale of herbal repellent cream	Indoor residual spraying Insecticide treatment for bed-nets Malaria workers conduct blood tests Free diagnosis & treatment	Spraying sporadic Bed-nets not used Malaria workers unreliable – limited community outreach
Hysterectomy /gynaecological morbidity	Sale of ayurvedic medicine for white discharge	Pap tests at mobile camps Free cancer treatment	No gynaecologist or exams available at primary health centre

CHWs then identified possible causes of hospitalisation for diarrhoea, fever and hysterectomy in conceptual frameworks, to identify the factors amenable to intervention by CHWs. Conceptual frameworks for diarrhoea and hysterectomy are below (Figures 3.3a and 3.3b).

Figure 3.3a Conceptual framework: causes of hospitalisation for diarrhoea

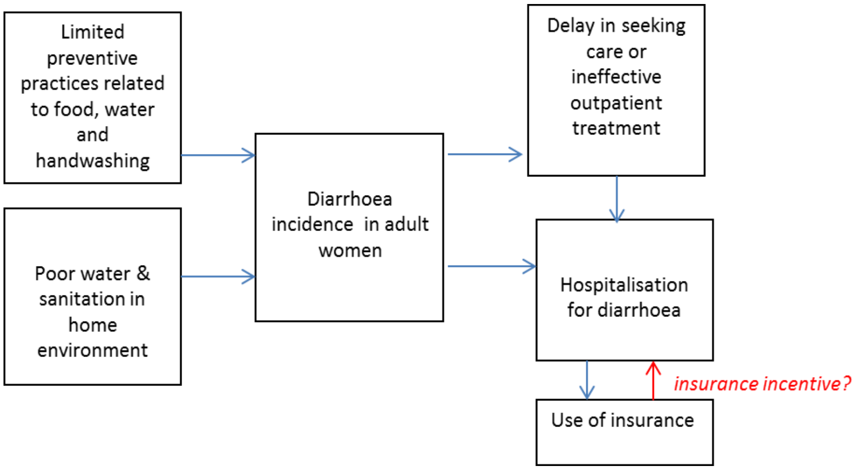
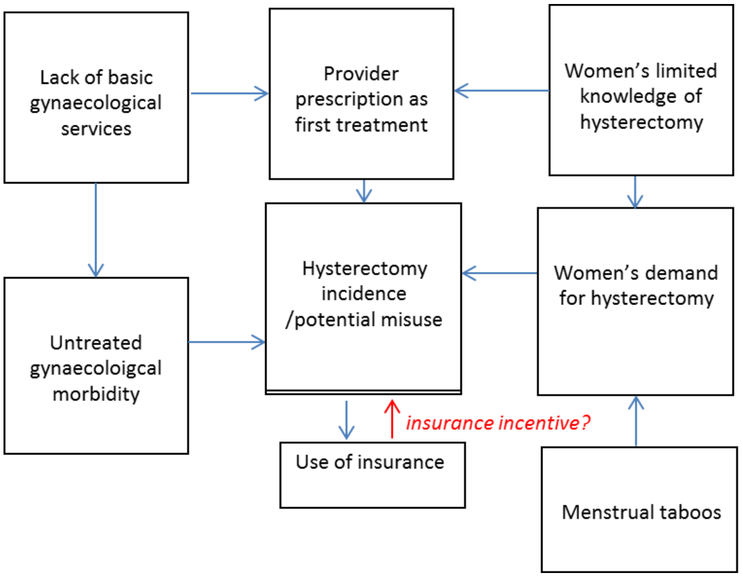


Figure 3.3b Conceptual framework: causes of hysterectomy



CHWs suggested potential intervention options (Table 3.7) for each condition through small group exercises. The interventions were each discussed in turn, assessed for feasibility and appropriateness in the local context with external experts, who included a preventive medicine specialist from a local medical college, a health communication expert from Mudra Institute of Communication Design in Ahmedabad and two gynaecologists, along with a research intern who conducted a review of evidence on interventions related to diarrhoea and malaria. Several intervention options were considered but rejected either due to poor feasibility, lack of evidence or existing government efforts, as detailed below.

For diarrhoea, CHWs were keen to distribute soap to households to support education efforts. Since the budget did not include resources to purchase soap, Hindustan Lever, a company that produces handsoap and promotes handwashing in rural India, was approached as a sponsor, but the relationship did not materialise. Instead, it was recommended that CHWs promote handwashing with soap through education, without distribution. CHWs also discussed promotion of oral rehydration solution (ORS) as immediate treatment for diarrhoea. Although ORS packets are widely available in urban areas, government health workers do not uniformly distribute packets in rural areas due to limited supply or lack of outreach. Thus, the group weighed promoting ORS versus a home-based fluid therapy of sugar, salt and water. They decided to promote ORS packets in both urban and rural areas as the first treatment of choice and also demonstrate the right proportions for home-based solution to women in person. Further, although standard guidelines for ORS indicate use of boiled water, health workers felt unsure about promoting extra use of fuel or firewood for already poor households. This idea was discussed with SEWA members in pilot health education sessions, who felt that messages should be shared, as people tend to act within their own means. Sanitation interventions were deemed important, but not feasible in this current project due to resource limitations. Mahila SEWA Housing Trust, a sister agency that specialises in sanitation for low-income families, was invited to provide design input into interventions for diarrhoea.

For malaria, CHWs rejected promotion of mosquito bednets, citing that nets are cumbersome, rarely used, and had long been promoted by the government, with little success. CHWs' suggestion to promote natural repellents such as neem was vetoed by experts due to lack of scientific evidence of effectiveness; chemical, DEET-based repellents were suggested as a more effective alternative. Of the mosquito repellents, both rural and urban workers felt education on plug-in formulations would be more acceptable. This came as a surprise, given the affordability of soap cited as an obstacle to handwashing. Yet perceptions of the effectiveness and value of a plug-in mosquito repellent by women seem to outweigh cost concerns. Health workers also expressed concern over viable repellents for very poor households, who could afford neither creams nor electronic repellent. They felt traditional methods should also continue to be promoted, such as burning neem, onion or garlic peels to repel mosquitoes from the home. The health communication consultant expressed concern over the promotion of traditional methods that lacked an scientific evidence base, but health workers suggested they remain in messaging so that women understand such methods were a last resort or to be used in conjunction with other repellents. Lastly, health workers felt that messaging on basic sanitation, cleanliness, removal of stagnant water and prevention of water-logging would be important, both for household level change and to provide women with information to hold the local government accountable for structural changes. In particular, the government had recently established Health and Sanitation Committees, which were identified as a potential place for advocacy for interventions such as improved drainage and regular anti-mosquito spraying.

When the group discussed potential interventions for hysterectomy, they felt women should be made aware of the procedure, its side effects and alternatives as a method to stem demand. SEWA's team then compiled a list of key facts about hysterectomy, common myths, and additional information that should be conveyed to women through education with gynaecologist resource persons. Advocacy with providers, a longterm effort, was deemed too premature since there was little understanding of the determinants of hysterectomy. Instead, they decided that women would be advised to seek a second opinion before undergoing a hysterectomy, preferably from a free government provider, and that monitoring and advocacy efforts could be considered as a future intervention.

Table 3.7 Suggested interventions and feasibility filter

Issue	Hypothesised causes	Suggested interventions	Barriers	Feasibility
Hospitalisation for diarrhoea	Contaminated drinking water and food	Promote boiling water and food storage practices	Expensive to boil water	No
	Living environment	Improve piping, toilets and water	Requires difficult govt advocacy	Yes; through advocacy
	Limited handwashing with soap	Health education and soap promotion	Affordability of soap	Yes
	Delay in treatment	Promote ORS and government outpatient care	ASHA may not carry ORS packs; Poor quality govt services	Yes
Hospitalisation for malaria and related fevers	Mosquito bites	Bed nets Mosquito repellent	Low utilisation Irregular govt insectiside treatment	No
	Delay in treatment	Ensure malaria worker performs tests and provides treatment	Sustained advocacy required	To some extent
	Living environment	Activate Village Health and Sanitation Committee	Already in process; longterm goal	To some extent
Hysterectomy	Untreated gynaecological morbidity	Advocacy for gynaec services	No availability of doctors; longterm advocacy required	In longer term
	Provider inducement	Monitor and audit providers	Difficult in practice	No
	Women's demand	Information on hysterectomy and side effects	Knowledge may not change demand	Yes

Intervention approach and delivery

Although the broad goal of the intervention was to change women's behaviour regarding prevention and treatment of the three conditions, a theoretical model for behaviour change was not developed. While a wide range of literature examines the role of behavioural change theory in intervention design, SEWA had neither sufficient internal technical human resources nor funds to hire external experts to design a theory-based intervention. Thus an individual-focused, relatively narrow approach to behaviour change through health education was chosen for three practical reasons. One, CHW home visits were ongoing, but CHWs and supervisors perceived they had limited impact on women's knowledge. Group sessions, on the other hand, were perceived to be more effective in reaching and retaining women for longer periods. An earlier evaluation of a one-year SEWA HIV/AIDS health education program that used multiple media tools indicated that message recall was highest amongst women through attending group education sessions, followed by film screenings and wall paintings. Second, SEWA, as well as its donors and government partners, had long debated the effectiveness of group health education: although it was commonly used, there was limited evidence on the effectiveness of the approach. This study provided an opportunity to conduct an evaluation of a specific, CHW-led health education method. Third, and most importantly, SEWA had a limited budget within which to implement an intervention and conduct an evaluation. CHWs would not be able to devote full-time efforts to this particular intervention; it would have to be an add-on to existing activities. Thus, group health education sessions were deemed a feasible intervention with respect to financial and human resources – and easily scalable through CHWs if proven effective.

Operationally, health education was defined as a tool to improve knowledge and change women's attitudes through information dissemination and discussion in a group setting. Further, SEWA's CHWs were seasoned local leaders – activism-oriented women who have mobilised their communities on a range of issues through the trade union. Hence the sessions, in addition to reaching individual women, could potentially affect social norms and engage women in community action. Since education would be conducted in groups, the intervention could not be restricted to insured women; CHWs aimed to reach all women in their area. Restricting sessions only to insured women who may live far apart also would not have been practical. Moreover, the intervention could benefit uninsured women as well. Actions amenable to health education were then selected from Table 3.7 and converted into the 'key messages' of the intervention:

Diarrhoea prevention and immediate treatment

(i) Handwashing with soap after defecation and cleaning children's stools, before eating and before cooking

(ii) Immediate treatment of diarrhoea with ORS, using boiled water

(iii) Utilise government services for first point of care

Fever/malaria

(i) Use mosquito repellent, preferably with DEET

(ii) Utilise government diagnostic and treatment services rather than private services

(iii) Prevent mosquito breeding through removing stagnant water around dwellings and in the community

Hysterectomy

(i) Understand indications, side effects, options and key questions to ask health providers

(ii) Seek a second medical opinion before undergoing hysterectomy

The intervention was implemented through:

(i) Group education sessions on diarrhoea, malaria and hysterectomy, with groups of 10-15 women conducted three to five times per month by each CHW in her work area. Each session was an hour long and held in a member's home or public area at a time convenient to women workers. Women were invited to participate in education sessions in advance by CHWs during their daily rounds and house visits, and reminded again on the day of the session. CHWs recorded attendance at each session and aimed to ensure women attended at least two different sessions. Women who did not attend sessions were reminded on home visits and before the next session, with attempts to schedule the next session at a convenient time. Follow-ups, however, were not tracked.

Sessions consisted of teaching, discussion and practical demonstrations, using film, print media and participatory games. Each session usually focused on a single topic (diarrhoea, fever/malaria or hysterectomy) with the key messages reinforced throughout the session. CHWs were experienced in conducting group education sessions, but not in a focused manner or with communication aides. This intervention built on their communication experience and aimed to strengthen quality through interactive tools and a focus on three topics through key messages. In addition, Mahila SEWA Housing Trust conducted group sessions, in conjunction with CHWs, on how to improve sanitation infrastructure in intervention areas, focusing on advocacy through local government Health and Sanitation Committees.

(ii) Communication aides for sessions were developed in partnership with an advertising agency that focuses on rural health issues. The communication expert who designed the materials had over twenty years' experience in both rural marketing for Ogilvy and Mathur (a leading advertising agency in India) and in designing public health tools for the Government of India. SEWA provided the list of key messages to the social marketing and health communication firm, contracted to develop innovative, participatory games and tools to supplement group education. The tools underwent extensive review and revision by health workers and through pilot testing, a process which took over six months. Since hysterectomy was a new topic for health workers, a film was produced as a tool to support education sessions. The film script was written by a small production house based in Mumbai who had experience with women's health issues. CHWs and health team management reviewed the script and provided input into film content, including through the production phase.

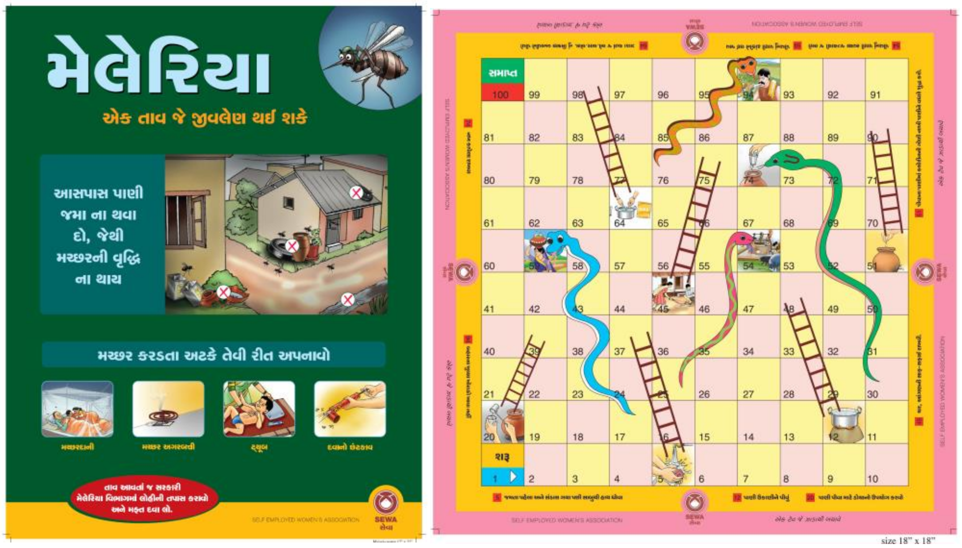
Four sets of products were developed:

(a) Posters and flip charts with illustrated diagrams to serve as communication aides during sessions. These were developed by the advertising agency, piloted by CHWs and then revised accordingly (Figure 3.4).

(b) Two tailor-made 'snakes and ladders' participatory games on diarrhoea (Figure 3.4) and malaria in which health-promoting behaviour takes a player up a ladder, while illness-causing actions take her down the snake. Winners were given a 'health' kit that contained a nail cutter, SEWA-produced ayurvedic mosquito repellent and soap, to reinforce the key messages.

(c) Take-home illustrated pamphlets for participants that detailed the key messages. The pamphlet on hysterectomy was developed in-house in consultation with SEWA's gynaecologist.

Figure 3.4 Malaria poster and snakes and ladder game



(d) 15-minute film on hysterectomy with case studies from SEWA members, visual illustrations of the procedure, interviews with local gynaecologists and information on potential side effects.

(iii) Community media: Community wall paintings on prevention and treatment of diarrhoea and malaria were designed and placed in prominent, central locations in each intervention area (Figure 3.5). They contained key messages as well as topics not covered in sessions, such as boiling water.

Figure 3.5 Wall painting on diarrhoea, promoting handwashing, boiling water and ORS

(iv) CHW training, support and monitoring

After the design workshops, a formal training session on the intervention content was conducted over two days by SEWA Health's training team and SEWA's in-house gynaecologist. This training was followed by five sessions, spread out over three months, conducted by external resource persons who had participated in the design process. They included: two sessions on hysterectomy and its side effects, two sessions on diarrhoea management and malaria prevention, and one session on participatory communication. In addition, a SEWA Health manager conducted monthly refresher trainings and discussions on progress, held in conjunction with monthly reporting meetings. The project manager attended education sessions to provide hands-on support when requested and as a part of monitoring; she typically visited four sessions per month. CHWs submitted weekly reports with a summary of trainings held and topics covered. Detailed reports were submitted monthly, including attendance sheets from each session. Intervention CHWs continued with their regular activities, as implemented by 14 control CHWs (Table 3.8).

Table 3.8 CHW activities in control and intervention areas

Activity	**Control**	**Interv-ention**
Home visits and group education on common illnesses (excluding diarrhoea, malaria and hysterectomy)	X	X
Accompanied referral to health services	X	X
Medicine sales and insurance promotion	X	X
Linkages with government providers	X	X
Activate Village Health Committees	X	X
Group education sessions on hysterectomy with film viewings		X
Communication tools/handouts on hysterectomy		X
Group education on diarrhoea with ORS demonstrations		X
Group education on fever/malaria with interactive games		X
Wall paintings on diarrhoea and malaria		X
Education sessions conducted by Mahila Housing Trust		X
Monthly refresher training for CHWs		X

Timeline

The intervention was piloted in April 2010, after completion of the baseline survey, and fully implemented by October 2010. It continued until June 2012, with extension into control areas through dissemination of materials (Figure 3.6).

Figure 3.6 Implementation timeline

2009				2010				2011				2012			
Jan-Mar	Apr-June	Jul-Aug	Sept-Dec	Jan-Mar	Apr-June	Jul-Aug	Sept-Dec	Jan-Mar	Apr-June	Jul-Aug	Sept-Dec	Jan-Mar	Apr-June	Jul-Aug	Sept-Dec
Design Phase					Pilot		Implementation							Extend to control	

Chapter IV. Research Methods

This chapter details the methodological approaches utilised for each study. Section I details the design of the trial and methods used for the trial analysis, which follows the CONSORT guidelines for reporting on cluster randomised trials[190]. Section II describes the methods utilised for an in-depth investigation of hysterectomy, which included qualitative exploration of influences on women's decisions and a mixed-methods analysis of predictors of hysterectomy. Section III describes the methods employed for the intervention process evaluation, followed by reporting of procedures followed regarding ethics and informed consent.

I. Intervention evaluation

Overview of trial design

The evaluation utilised a cluster randomised design to assess the effect of the health education intervention. The intervention was implemented by CHWs in their communities through primarily group outreach activities; contamination would likely have resulted if the intervention had been randomised to individual women in the same CHW catchment area. Further, some components of the education intervention, such as wall paintings and posters, were implemented at the community level and could not be randomised to individuals. Accordingly, the chosen unit of randomisation was the CHW. Clusters were defined as each CHW's discrete geographical outreach area. CHWs serve three to five villages in rural areas and two to five slum pockets in urban Ahmedabad. Catchment areas did not overlap between CHWs. The evaluation utilised a cohort design to measure the impact of the intervention.

Eligibility of clusters

Clusters were considered for inclusion in the trial if a SEWA CHW already served the area and VimoSEWA's insurance programme had insured at least 30 women in the past year. All 28 CHWs who work in Ahmedabad city (12) and two rural blocks of Ahmedabad district (16) were included in the trial. Although an additional ten rural SEWA CHWs were available, they were excluded due to limited VimoSEWA coverage in their areas.

Interventions

As detailed in Chapter III, the interventions consisted of health education sessions on fever, diarrhoea and hysterectomy delivered by CHWs to insured and uninsured women in a group setting, use of community media tools, education on government sanitation programs and training sessions for CHWs. CHWs in control areas continued with ongoing activities, which included home visits, referral services and linkages with government health services.

Outcome measures

(i) The primary outcome – claims submission for diarrhoea, fever and hysterectomy – was measured by the claim rate for the three conditions using SEWA's claim database (see below): *n claims/person time insured.*

(ii) Reported hospitalisation amongst insured and uninsured women for the three conditions was measured through four rounds of a household survey (see below): *n hospitalisations/person-time.*

(iii) Reported morbidity related to fever, diarrhoea and gynaecological ailments amongst insured and uninsured women was measured through four rounds of a household survey (see below): *n episodes/person-time.*

(iv) Out-of-pocket expenditure related to hospitalisation and morbidity episodes for the three conditions was measured through four rounds of a household survey (see below): *n rupees/episode*.

Sample size and study power

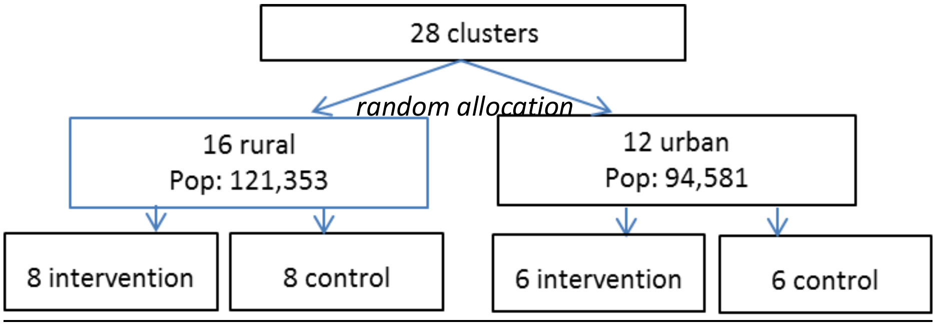
The number of clusters included in the trial, 28 in total, was determined by the number of CHWs available in areas where VimoSEWA operates. For the study's primary outcome, claims submissions, all claims submitted in the study area would be utilised. To determine the minimum effect size that the study would be able to detect, VimoSEWA's CEO and the study advisor, a health economist, considered the financial implications of a potential reduction in claims on the claims ratio and operating budget. A non-profit organisation, VimoSEWA was committed to financial sustainability without donor support. Thus if there were evidence of an intervention effect, VimoSEWA would have to invest the resources to sustain the health education intervention as part of its operations. Taking into account its financial constraints, VimoSEWA defined a minimum intervention effect of 30-40% reduction in claims for the three conditions. A lower reduction would not have generated sufficient resources to sustain or justify the operational costs of a health intervention aimed at reducing claims.

The between-cluster coefficient of variation *k* was estimated using data on claims submission rates in 2008-2009. The empirical variance, which incorporates a random sampling error that follows the Poisson distribution, was first calculated using 28 observed cluster rates[191]. Using the harmonic mean of observed person-time to account for unequal cluster sizes and a pooled estimate across rural-urban strata, the between cluster coefficient of variation *k* was estimated to be 0.28[191]. The study was estimated to have 77% power ($p<.05$, 2-sided test) to detect a 40% reduction in insurance claims for diarrhoea, fever and hysterectomy.

Randomisation procedures

Randomisation was stratified by urban and rural location to help achieve overall balance, as urban rates of claim submission had been observed to be higher than in rural areas in two previous studies at VimoSEWA [141, 185]. Restricted randomisation was not possible because baseline demographic data were not available for the study population[192]. From a list of 28 CHWs, an external statistician assigned rural CHWs a number from 1 to 16, and urban CHWs from 1 to 12 and used computer generated random numbers to assign each number to one of two treatment categories (Figure 4.1). The project team held a meeting of all CHWs to match the pre-assigned numbers to CHW names and to announce treatment allocation. Cluster allocation was blinded to surveyors.

Figure 4.1 CHW Allocation



Data sources and data collection methods

The evaluation utilised two data sources: a VimoSEWA database on routinely collected membership and claims in the study area and repeated cross-sectional household surveys in a randomly selected cohort of insured and uninsured women (Table 4.1).

Table 4.1 Evaluation outcomes and data sources

Outcome of interest	**Expected effect: Insured**	**Expected effect: Uninsured**	**Data source**
Insurance claims for diarrhoea, fever or hysterectomy	Decrease	Not applicable	Claims database
Reported hospitalisation for diarrhoea , fever or hysterectomy	Decrease	Decrease	Household survey
Reported morbidity for diarrhoea, fever and gynaecological ailments	Decrease	Decrease	Household survey
Reported out of pocket expenditure	Decrease	Decrease	Household survey

Claims database

VimoSEWA collects membership and claims information in two databases, linked by a unique SEWA social security number for each member. The membership database includes information on age, sex, occupation and marital status for all women who pay a membership premium. The claims database records the name, age and sex, reason for claim, place of treatment, length of stay and reported expenditure related to every submitted claim. Information is submitted by VimoSEWA sales and claims servicing agents and entered into the database on a rolling basis.

Since trial clusters were defined by CHW work areas, VimoSEWA members in the database had to be mapped to clusters. Rural members were mapped in a straightforward manner, as both CHWs and VimoSEWA utilise the same village names, with the exception of spelling differences due to data entry in English from Gujarati documents. Linking VimoSEWA members to clusters in urban areas was more challenging. Most SEWA members reside in informal settlements that have not been granted formal planning permission or access to water or electricity, for example. Since municipal records do not document informal or unregistered colonies, a surveyor from SEWA Academy followed each CHW on her daily rounds to list households in each slum settlement that she covered. VimoSEWA lists addresses and area names based on premium collection receipts written in Gujarati, which are then entered into the VimoSEWA database in English. Since most areas do not have street names or house numbers, addresses are typically individual descriptions of the area and nearby landmarks.

To capture subtle differences in transliteration, spelling and addresses, the VimoSEWA database was mapped to clusters manually, rather than depending solely on search functions in Microsoft Excel and

Stata. This was not always straightforward. For example, Ayesha, an urban CHW, was listed by a surveyor as covering parts of Rahikyal, a large area which includes dozens of slum settlements, one of which is Nura Ni Chali (Nura street). A VimoSEWA member was listed in the VimoSEWA database with the address Nurani Chowk (Nura intersection/square) in Rakhial (spelled without a y). Nurani Chowk is at the end of the street by the same name, and women who live there were also part of Ayesha's cluster, despite not being listed as residents of Nura Ni Chali. To limit such errors, I involved VimoSEWA workers and CHWs in the matching process and relied on my own previous knowledge from having implemented community health programs in Ahmedabad City.

The baseline analysis utilised all membership data and submitted claims for a pre-intervention period from January 2009 to May 2010. All claims submitted from September 2010 till February 2012 were included in the intervention analysis, allowing for a three month start-up period after the intervention began in June 2010.

Household surveys

Household surveys were conducted to i) collect information on demographic characteristics of the study population ii) include uninsured women in the intervention evaluation and iii) collect information from women on morbidity and treatment-seeking behaviour in the past month, and hospitalisations in the past six months. A baseline survey was conducted from January to March 2010, followed by three survey rounds at six-month intervals following implementation of the intervention. The survey instrument can be found in Annex 3.

For the household survey, sample size of the study cohort was determined based on the coefficient of between cluster variation estimated using claims data and budgetary considerations. A sample size of 35 uninsured and 35 insured households per each cluster was chosen – a total of 1,960 households across 28 clusters. Insured and uninsured women were included in the household survey to enable the investigation of predictors of insurance coverage and to investigate for evidence of effect modification by insurance status. The study was estimated to have 74% power ($p<.05$, 2 sided test) to detect a 40% reduction in hospitalisation for diarrhoea, fever and hysterectomy.

Table 4.2 Household survey sample size 1 cluster=70 households

	Clusters	**Insured HH**	**Uninsured HH**	**Total HH**
Rural	16	560	560	1,120
Urban	12	420	420	840
Total	28	980	980	1,960

Household selection

The sample of 70 households per cluster was selected randomly, separately for insured and uninsured households. Women were excluded from the survey if they were no longer present at the listed address, and replaced by another eligible woman in the cluster when possible. For insured households, a list was compiled from the VimoSEWA database. Thirty-five households were randomly selected from each cluster by an external statistician using computer-generated random numbers. A total of 969, rather than 980, insured women were selected because two clusters had fewer than 35 insured women in the cluster at the time of selection. Twenty-three women (2%) who were initially selected were not found in their cluster. Of these, eight women were from a village that was mistakenly matched to a cluster due to a spelling inconsistency – Siyawada was confused with Shiyavada – and were replaced with women from the correct village. The remaining 15 women who were not found in their cluster had no replacement available. For uninsured households, a list of households was compiled by a researcher who followed each CHW on her daily rounds, from which 35 were randomly selected in a process similar to that described above.

Data collection and management

Each insurance claim was verified by a VimoSEWA visit at the time of hospitalisation, as per the organisation's normal procedures. The claims database was accessed at the end of the study period by the research team. The Indian Academy of Self-Employed Women (SEWA Academy), an independent but SEWA-affiliated research agency, conducted the household surveys. A team of 10 local women familiar with SEWA, either through membership or previous participation in its activities, was trained as survey fieldworkers. They were informed that an intervention was underway, but were blinded to allocation. While they may have seen wall paintings in intervention areas, these areas are typically full of communication materials by SEWA, the government and other organisations; wall paintings alone were unlikely to have been indication of a specific intervention.

An adult woman was selected for interview in each household. In insured households, the respondent was the primary VimoSEWA policy holder. In uninsured households, the primary SEWA union member or spouse of the male head of household was selected. Consent procedures are described in the next section. Survey data were double-entered into a Microsoft Access database by SEWA Academy. A supervisor observed a random sub-set of interviews and checked each survey form manually before data entry. I performed internal consistency checks after each round using Stata 11, and sent queries to the research agency for clarification/correction. Monitoring data was submitted monthly by CHWs; reports included the number and topic of trainings conducted, with names of women who attended. Summary data, excluding names, were entered in a database by SEWA's health team. The project managers attended a sub-set of intervention sessions and reviewed CHW reports monthly.

Statistical methods

Methods used are described separately for the baseline analysis and the analysis of the trial outcomes – rates of claims, hospitalisation and morbidity – and the analysis of out of pocket expenditure. Statistical analyses were performed using Stata 11.

(i) Baseline data

Data collected at baseline were first analysed to describe the study population. As this study was the first time VimoSEWA had collected data on uninsured women in Ahmedabad city and district, insured and uninsured women were compared to identify: (i) predictors of insurance coverage (ii) differences in recent (30-day) morbidity and outpatient treatment-seeking behaviour and (iii) the association between insurance coverage and hospitalisation. The svyset command was utilised to take into account the cluster sampling and sampling weights for insured and uninsured households. Sampling weights were calculated at cluster-level, as both the population size and insurance coverage varied by CHW work area.

Demographic and socioeconomic characteristics of insured and uninsured households were examined to identify predictors of insurance coverage and factors that may be associated with differences in treatment-seeking behaviour. Socioeconomic indicators (income, education, dwelling type, toilet, drinking water access) were analysed separately rather than as a score derived using principal components analysis, as some of these variables could be independently associated with morbidity or hospitalisation. Although women workers in the informal economy typically engage in multiple income-earning activities[175], only the respondent's stated primary occupation was included in the analysis. After examining unadjusted odds ratios calculated using logistic regression, multivariable logistic regression was used to identify predictors of insurance status. Variables associated with ($p \leq .05$) or those that could be theoretically associated with, insurance coverage were included. Results are presented as adjusted odds ratios with 95% confidence intervals. Overall p-values for variables with more than two levels were obtained using Wald tests. Urban and rural data were analysed separately in the initial, crude analyses and then combined in multivariable analyses, with urban/rural location formally tested for effect modification.

Data on recent morbidity and treatment-seeking were then compared between insured and uninsured women. Recent morbidity was defined as any illness in the past month, to limit recall bias and to capture home-based treatment or care sought in ambulatory facilities as accurately as possible. Self-reported reasons for morbidity were categorised to the extent possible in the absence of clinical reports. Given the large variety of illnesses and hence small category sizes, morbidity-related data are presented as descriptive proportions. The association between current insurance coverage and hospitalisation, defined as an inpatient admission for 24 hours or more in the past six months, was examined through logistic regression. Multivariable logistic regression included variables associated with insurance coverage and those considered to be associated with hospitalisation, both theoretically and through examining crude odds ratios. The role of urban/rural location was examined through inspecting stratum-specific odds ratios and formally tested for effect modification. Lastly, reasons for hospitalisation, type of hospital and length of stay were presented to identify any differences between insured and uninsured women.

(ii) Trial analysis

a) Baseline analysis

Analysis of the intervention effect on the primary outcome, claims rates for diarrhoea, fever and hysterectomy, utilised the VimoSEWA membership and claims databases. Demographic characteristics of members during a 17-month pre-intervention period were compared between the intervention and control arms to identify imbalanced variables to include in the trial analysis. Claims for the three conditions were tabulated by cluster, and claims rates per person year were calculated and compared using both individual data and cluster-level means[193]. Unadjusted cluster level summary rates were compared in urban and rural strata using an unpaired *t-test*, to assess if rates differed by location as in previous analyses of VimoSEWA data. The distribution of baseline claims rates across 28 clusters was examined for normality. As the claims rates were only slightly skewed, and three clusters had zero claims, a log transformation was not applied. The coefficient of variation *k* was estimated using the empirical variance of observed baseline claims rates and adjusting for random sampling error, for both rural and urban strata[191].

Similar baseline analyses as described above were conducted using the household survey data. Since women were selected into the survey sample based on insurance status, data are presented separately for insured and uninsured women. Overall balance of the treatment arms was examined across a wider range of demographic variables, as well hospitalisation and morbidity rates, amongst insured and uninsured women. Baseline hospitalisation and morbidity rates were calculated using both overall data and cluster summaries. Although neither hospitalisation nor morbidity rates were normally distributed, the log transformation was not applied in either case due to clusters with no events. The coefficient of variation *k* was estimated for both hospitalisation and morbidity rates, separately for rural and urban location.

b) Intervention effect on claims, hospitalisation and morbidity

With 14 clusters in each treatment arm, the trial was at the borderline size for which individual-level regression methods can provide reliable estimates[191]. Analyses of intervention effect were conducted using individual regression methods for correlated data first, followed by estimates based on cluster-level summaries to confirm the robustness of the analysis based on individual values. Analysis was by intention to treat. In the initial analysis, women's insurance status at baseline was used to define the insured and uninsured groups.

A Poisson regression random effects model was fitted to estimate the effect of the intervention on claims rates for the three conditions[194]. The unadjusted rate ratio and 95% confidence intervals were first estimated, followed by an effect estimate adjusted for rural-urban location and cluster-level baseline claims rates. The latter was included to control for baseline imbalance in claims rates and to reduce between-cluster variation, in order to increase the power and precision of endline point estimates[191]. Likelihood ratio tests of models with and without the intervention effect were performed to obtain p values.

Using cluster-level rates post-intervention, a crude rate difference was estimated and an unpaired *t-test* was applied to compare rates across treatment arms. An unadjusted rate ratio was also computed to facilitate comparison with the crude rate ratio derived from individual level data. A 95% confidence interval for the rate ratio was estimated by dividing and multiplying the estimated RR by an error factor, and the p value obtained using the *t* distribution[191]. Analysis of co-variance, adjusting for rural-urban location and cluster-level baseline claims rates, was performed on cluster summary rates to obtain an adjusted estimate of the rate difference.

Analyses of the effect of the intervention on hospitalisation and morbidity rates for the three conditions were conducted using similar methods to those described above. Overall post-intervention hospitalisation and morbidity rates were calculated, and presented separately for insured and uninsured women. A Poisson regression random effects model was fitted to individual data to obtain unadjusted rate ratios first, followed by estimates adjusted for rural-urban location, cluster level baseline rates, insurance status and survey round. Survey round was included to adjust for any seasonal effects. Insurance status was formally tested for effect modification by incorporating an interaction term, while noting that such analysis would have low power[194]. Likelihood ratio tests were performed to obtain p values for all analyses. Additional analyses were performed to adjust for imbalanced baseline variables.

To check the robustness of analyses using individual-level data, crude rate ratios were estimated using cluster level data and compared to estimates derived from the random effects model. An unpaired *t-test* was applied to compare unadjusted cluster level hospitalisation and morbidity rates. While noting that the *t-test* has been demonstrated to be robust to departures from normality, particularly when the number of clusters in each arm is equal, nonparametric Wilcoxon rank-sum tests were also performed to compare p values to those obtained using the *t* test[195]. Analysis of covariance was performed on cluster summary rates, adjusting for insurance status, rural-urban location, survey round and cluster level baseline rate, to obtain adjusted estimates of the rate difference. For hospitalisation data, sensitivity analyses were performed using reported insurance status at subsequent rounds, rather than insurance status at baseline.

<u>(iii) Out-of -pocket expenditure</u>

If the intervention had an effect on rates of claims, hospitalisation or morbidity, an effect on mean out of pocket expenditure at the cluster level would have been expected. Mixed effects linear regression models would have been fitted to individual data to estimate difference in mean expenditure, and then adjusted for rural-urban location, insurance status, survey round and mean cluster-level baseline expenditure to obtain an adjusted estimate[191].

As there was no evidence of a treatment effect on any of the above-mentioned outcomes, out-of-pocket expenditure was not expected to have changed due to the intervention. Instead, a separate chapter presents descriptive statistics on expenditure to provide more insight into treatment-seeking patterns and their associated costs in the study population. Mean, median and range of expenditure are presented by arm, rural-urban location, type of facility and insurance status. Box whisker plots are used to display the distribution of expenditure for two focus conditions. Linear regression, using robust standard errors to account for non-normality of the expenditure data, was performed to compare expenditure patterns across rural-urban location and insurance status.

II. In-depth examination of hysterectomy

Qualitative study

A qualitative study was designed after analysis of the baseline data on prevalence of hysterectomy. The primary objective was to explore the socioeconomic, cultural, individual and household factors that influenced women's decisions to undergo hysterectomy, with a sub-objective to examine whether VimoSEWA coverage influenced women's decisions.

Field approach

The fieldwork employed an ethnographic approach to qualitative data collection, drawing on ten years' previous experience working as a health program director and researcher with SEWA in the study areas and six months of fieldwork focussed on investigating hysterectomy, to situate accounts within women's lived experiences. I was already familiar with modes of daily living, village dynamics, health services and local terminology in the study setting. Further, affiliation with SEWA allowed me to interact casually with women and their families and observe how health care decisions were embedded in the local context[196]. I utilised a combination of participant observation, in-depth interviews and case studies to observe and analyse the complex phenomena that influenced women's decisions[197]. In the initial phases of research, I interacted and observed women and their families in daily life, particularly health-related activities, and I accompanied community health workers on home visits, health care referrals and group meetings. I also reviewed quantitative data from the baseline household survey and discussed findings with women and their families, grassroots SEWA health and health insurance workers and government heath staff. Through this process, I identified seven provisional themes to explore through in-depth interviews: women's experiences with gynaecological morbidity; drivers of women's demand; socioeconomic/occupation-related determinants; family/household and intergenerational dynamics; health insurance status; health provider practices; physical, emotional and economic consequences of hysterectomy.

Interview guides (Annex 4) were utilised to cover these *a priori themes*, but were modified to explore new themes as they emerged, such as fear of cancer or experience with menstrual difficulties. Women who had undergone hysterectomy were identified through SEWA's CHWs, referrals from interviewees and key informants. I conducted interviews until (i) the group represented both variation in insurance status and length of time elapsed since the procedure and (ii) no new analytical themes emerged. Thirty-five women were interviewed, eleven of whom were insured by SEWA and/or the government. Nineteen women had undergone the procedure in the past five years (seven in the past year) and could provide specific details of the treatment-seeking process. The remainder offered perspective on longer term effects of hysterectomy.

I also interviewed five local gynaecologists, who had conducted 20 of the 35 hysterectomy cases conducted in the area. It was not logistically feasible to link a specific woman's case history with her provider to develop case studies, although I was able to conduct analysis linking women's cases with the viewpoints of the identified provider. Where possible, I also read women's medical case histories and test results if they agreed. Interviews were conducted individually with thirteen key informants and three women with gynaecological ailments who did not proceed with the operation, as well as in groups with three sets of younger women who have not had a hysterectomy. These were all identified during the course of research. Young women were identified in three villages, where groups were readily formed through connections I had made on earlier visits. I kept extensive field notes throughout this process, to describe each setting and experience, document my own reflections and identify new ideas.

During the design and research process, I read qualitative studies focused on women's bodies, health and their interactions with medical intervention, such as Kielmann's analysis of women's perceptions of morbidity[20], ethnographies contained in Lock and Kaufert's volume *Pragmatic Women and Body Politics*[198] and Behague's study of caesarean sections in Brazil[199], in order to familiarise myself with methods of understanding women's narratives and perspectives. Analyses of biomedicine such as Lock and Nguyen's *An Anthropology of Biomedicine*[200] and sociological analyses of medicalisation[201-203] provided theoretical frameworks to contextualise my observations.

Analysis

The objective of this research was to understand the multiple influences on women's decisions to undergo hysterectomy, with an aim to inform future interventions and policy related to women's health. Accordingly, a framework method was applied to conduct thematic analysis, in which I aimed to understand hysterectomy by exploring the findings through an inductive approach, rather than test specific hypotheses[196]. Although I sought to contextualise the findings within, and contribute to, theoretical frameworks that address women's health care decisions, it was not an explicit research aim to develop theory; hence a grounded theory approach was not pursued.

The analysis was conducted through several steps consistent with framework analysis. I consulted qualitative research guides for analytical tools [204, 205], as well as textbooks on anthropological methods for broader frameworks[197, 206]. As a first step, interviews were transcribed in Gujarati, after which I checked transcripts through re-listening to each audio recording. Open coding was utilised to categorise content by different influences on hysterectomy, such as individual characteristics, social determinants and modes of decision-making. An analytical framework that identified codes, thematic groupings and broad causal pathways was developed after analysis of several transcripts, and discussed with an anthropologist on my advisory committee (Dominique Behague). As I was the only person with access to the data, I chose not to use a software package for analysis. Next, I developed a matrix of cases and themes, in which each interview was structured in rows and thematic areas/coding groups were presented across columns. Each cell contained information that detailed how a woman's experience fitted (or did not apply to) a specific theme. Women were compared across individual sub-themes and demographic variables to identify heterogeneity, as well as to generate new themes. After this first round of analysis, I drafted a preliminary note that identified analytical themes and further questions to explore.

At this point, I returned to theoretical work on medicalisation and ethnographies that focused on women's bodies and reproductive health. While I found that many analytical concepts were no longer relevant to my findings, such as the view of medicalisation as provider-driven intervention or somatisation, specific works resonated and contributed to generating analytical themes. In particular, the idea of women's pragmatic agency (Lock and Kaufert), as illustrated through case studies on sterilisation, childbirth and reproductive technology, provided the primary theoretical lens for further analysis[198]. The matrix was thus further developed and utilised to analyse sub-groups of women and across themes. For example, women were analysed across sterilisation status and the thematic idea of hysterectomy as freedom from risk, compared to the view of hysterectomy as pragmatic treatment. The matrix also allowed for identification of specific case studies that would be utilised to represent thematic areas. I aimed to integrate reflexivity throughout the process by: keeping and reviewing field notes regularly; comparing my findings with the quantitative study and other research on hysterectomy and medical interventions; and by discussing case study choices and the theoretical framework with Dr. Behague and two former SEWA colleagues who engage in qualitative research[196, 206].

Quantitative analysis of survey data

Analysis of the trial indicated no evidence of an effect of the intervention on rates of claim submission, hospitalisation or morbidity. Accordingly, a cohort analysis to estimate incidence and identify predictors of hysterectomy, including data from both treatment and control areas over four rounds of the household survey, was performed. Data were entered into a Microsoft Access database and analysed using Stata 11. The svyset command was utilised to take into account the cluster sampling and sampling weights for insured and uninsured households. The stset command was utilised to define person-time at risk. Women who reported past hysterectomy prior to the period covered by the baseline survey were excluded. The incidence of hysterectomy, based on cases reported by the primary adult respondent over the two-year survey period, was estimated using the exponent of the Poisson regression coefficient. Crude rate ratios for a range of demographic characteristics such as income, location, education, insurance status, number of living children and sterilisation history, were estimated using Poisson regression. Wald tests were utilised to obtain p values for variables with more than one level. A multivariable Poisson regression model was fitted with variables with crude rate ratios observed to be associated with ($p \leq 0.05$), or those that could be theoretically associated with, hysterectomy. Effect modification was investigated for sterilisation history, education, insurance status and rural/urban location.

Mixed methods approach

While incidence and some individual-level predictors of hysterectomy could be estimated from the cohort study, the complexity of the social, structural and behavioural factors that influence why women undergo hysterectomy called for integration of a qualitative approach to identify the determinants and pathways associated with hysterectomy[207]. Further, given the lack of previous research in low-income settings, a mix of quantitative and qualitative data allowed for triangulation of findings and more extensive exploration of determinants in this setting[207]. The mixed methods examination of hysterectomy utilised two data sources, detailed above: (i) a quantitative, population-based cohort study amongst adult women and (ii) in-depth ethnographic research amongst women, health care providers and key informants. All participants reviewed a study information form with researchers and provided consent to participation and sharing of findings, as detailed above. Identities of all sources have been anonymised.

Quantitative and qualitative methods were combined sequentially in the design and analysis phases. The quantitative survey was designed first, and included basic questions to estimate prevalence of hysterectomy in the study population. After analysing the baseline data, the need to examine both proximate and distal, as well as individual and social, factors was identified as important to understanding identify the determinants of hysterectomy. Two steps were taken: (i) survey questions pertinent to hysterectomy and reproductive health history were added to subsequent survey rounds and (ii) a qualitative study to explore individual, social and health systems determinants of hysterectomy was designed, as described above. The mix of providers and average age reported in the baseline led to inclusion of in-depth interviews with government health providers and younger women.

The mixed methods analysis was both inductive and deductive, in an iterative approach that combined data through triangulation and by 'following a thread'[208]. The quantitative cohort data were analysed first to estimate incidence and identify predictors of hysterectomy. A thematic analysis of qualitative data was conducted next to examine processes and determinants. Next, findings from both sets of data were triangulated to identify convergence, dissonance and gaps[207]. New analytical themes in either set of data also led to further analysis in the other. For example, in-depth interviews with women suggested that views on hysterectomy varied by sterilisation history (a 'thread'), which prompted quantitative analysis of effect modification by sterilisation status. Finally, predictors and underlying determinants were examined together to identify their intersections and comparisons with other settings.

III. Process evaluation

The intervention process evaluation presented in this thesis focusses only on hysterectomy for two reasons. One, the findings on hysterectomy provided an opportunity to contextualise the intervention with insight into individual, social and structural factors that may have influenced both the implementation and results. Two, it was not logistically feasible for me to conduct qualitative research and analyse process data for all three conditions. I chose to focus on hysterectomy in an in-depth process evaluation while a colleague at SEWA examined the intervention processes related to diarrhoea and fever.

The process evaluation was based on the principles of theory-based impact evaluation, components of which were identified by White (2009) as:

> *(1) map out the causal chain (program theory); (2) understand context; (3) anticipate heterogeneity; (4) rigorous evaluation of impact using a credible counterfactual; (5) rigorous factual analysis; and (6) use mixed methods [209].*

The intervention evaluation, described in Section 1, addresses points (4) and (5) above. Based on the conceptual framework initially designed with CHWs, I developed an intervention causal chain (Figure 4. 2) after reviewing baseline findings and relevant literature. Quantitative and qualitative data were collected and analysed along the intervention pathway, to examine each step or assumption between inputs and outcomes, such as: who actually participated in the intervention, whether implementation differed from the intended plan, and changes in intermediate outcomes that may have affected the final outcomes. Findings from the in-depth qualitative study on hysterectomy provided context on the social, economic and health systems for the intervention, as well as insight into barriers and facilitators related to treatment-seeking for hysterectomy. Heterogeneity was examined in the trial analysis through investigation of effect modification related to insurance status and rural/urban location, while the process evaluation further examined how the intervention may have been implemented (or received) differently amongst insured and uninsured women and by rural/urban location.

Data sources included: (i) CHW registers and monitoring data (ii) short interviews with 379 participants to test message recall, conducted by the same external research agency that conducted the evaluation. Interviewees were randomly selected from participant lists submitted by CHWs and asked questions based on the key messages (iii) qualitative, in-depth interviews with ten participants, 14 CHWs and 2 program managers (iv) household surveys utilised for the evaluation and (v) observation of intervention sessions. Guides are found in Annex 5. For the latter, at least two sessions were observed for all 14 CHWs, and two CHWs were followed over six months, during which I observed a series of health education sessions and interacted with participants. Interviews with CHWs and program managers were transcribed, and session observations recorded in notes.   Household survey data were analysed using Stata 11, and process monitoring data were analysed in Microsoft Excel. Qualitative interviews were conducted and transcribed in Gujarati. Notes were organised using open coding and analysed thematically.

Data were: (i) assessed along the causal chain to identify achievements and breakdowns (ii) contextualised with findings from qualitative research and (iii) interpreted with a view towards improving practice. The different data sources were triangulated at specific points in the causal chain, such as using both process and survey data to estimate outreach, or by combining qualitative interviews and session observations to understand effectiveness. My approach to the process evaluation was necessarily participatory to some extent, as I had a central role in its design and early implementation. I aimed to achieve a balance between participation and observation by employing reflexivity–being aware of and documenting my position throughout the research period and analysis–as well as utilising multiple forms of data to triangulate findings[206].

Figure 4.2 Intervention causal pathway

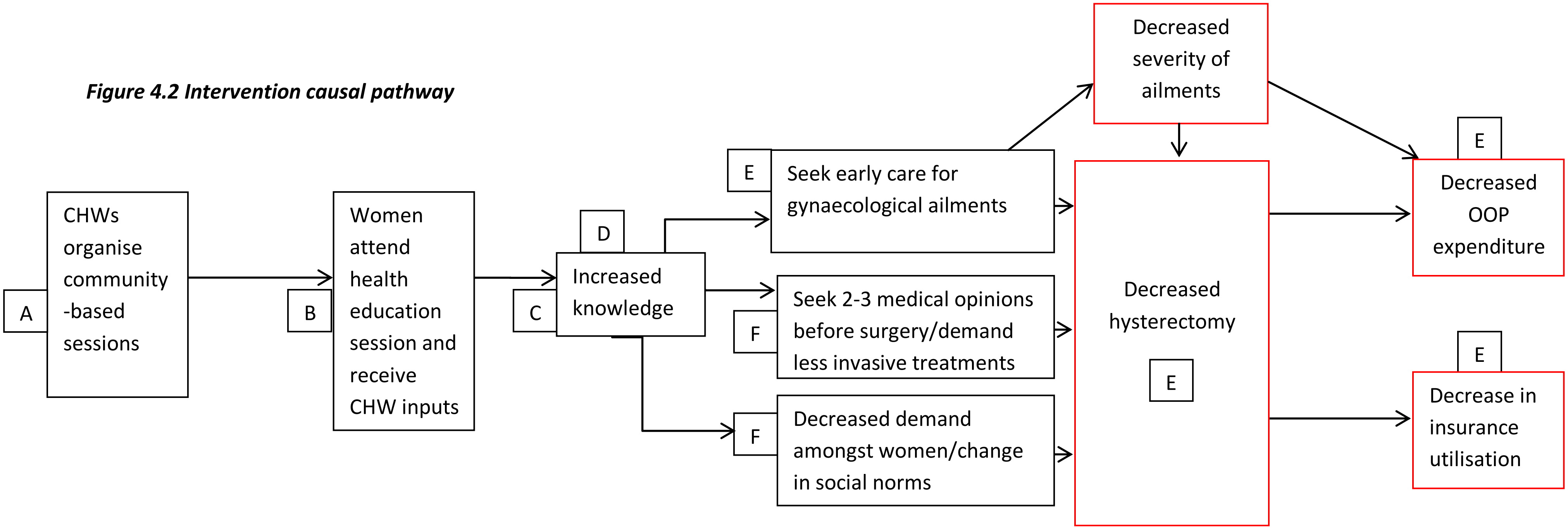


Diagram key	**Data sources**
A. Session implementation	Monitoring data, CHW/manager interviews
B. Session attendance	CHW registers and HH survey
C. Session effectiveness	Participant observation
D. Participant knowledge of key messages	Health education spot checks
E. Reported treatment-seeking behaviour	HH survey
F. Attitudes towards hysterectomy	In-depth interviews with women and CHWs

IV. Ethical considerations

Intervention evaluation

Ethical approval for randomisation was sought locally before the study began, to ensure that only CHWs allocated to the intervention participated in its design. The intervention was first discussed in June 2010 at the Annual Meeting of the Executive Committee of SEWA's Health Cooperative, where SEWA health activities are regularly discussed. The Health Cooperative consists of 500 health workers and midwives, including all CHWs who participated in the intervention, and elected leaders that represent the SEWA membership. After reviewing the intervention goals and implementation plan, the cooperative passed a resolution approving a randomised intervention implemented by its member CHWs. Since cooperative members included elected SEWA representatives from the 28 clusters, cluster members were not approached individually for consent to randomisation.

Individual data were protected both through restricting access and removal of identifying information. Individual consent was not sought for use of claims data, as claims analysis formed a part of routine monitoring and evaluation at VimoSEWA. Insurance data were accessed before the intervention began and three months after it concluded. Surveyed households were identified by a unique id that concealed identifying information. All survey participants provided oral informed consent, after researchers reviewed a study information form with the interviewee and, if necessary or appropriate, additional household members. Both the local ethics committee and CHWs considered oral consent the most appropriate convention for the survey, rather than written consent, as most women in the area had not attended formal schooling. As no adverse consequences of the intervention were anticipated at the cluster or individual level, a data safety and monitoring board was not constituted. The participant information forms and study protocol can be found in Annex 6.

Qualitative research

For the qualitative research, all interviewees provided written consent after reviewing a study information form with the author that included a description of the objectives and how provided information would be utilised and shared. The information forms can be found in Annex 7. All interviewees were asked for consent for anonymous inclusion in publication.

Process evaluation

CHW reports and monitoring data that were entered into a database did not include names of participants. Participants in education sessions who were later interviewed provided informed consent after reviewing a study information form, as above, and were included in the application for ethics approval for the qualitative research. As Project Director of the study, I had access to all project documents and meeting records. All findings were shared and discussed with SEWA management, CHWs and representatives of the membership.

Ethical approvals

Ethical approval for the intervention, evaluation and qualitative research was granted by a board constituted by SEWA's Health Cooperative Executive Committee and external experts, as per Indian Council of Medical Research guidelines, and by the Ethics Committee of the London School of Hygiene and Tropical Medicine (Annex 8). The study was registered as ISRCTN21290274.

Role of the funder

The study was funded by International Labour Organization, Microinsurance Innovation Facility Grant R2-189. The funder had no role in the design, implementation or analysis of the study.

SECTION TWO

Chapter V. Baseline findings: description of study population and comparison of insured and uninsured women

This chapter describes the study population and compares the demographic characteristics and treatment-seeking behaviour of VimoSEWA-insured with uninsured women. As described in Chapter III, VimoSEWA questioned whether the scheme promoted hospitalisation for conditions potentially amenable to outpatient care or for unnecessary procedures. Analysis of the baseline household survey amongst insured and uninsured women provided some insight into this question as well as provided a picture of overall hospitalisation patterns in the population before the start of the intervention. Cluster-level baseline claims and hospitalisation rates in the intervention and control arms are further compared in Chapter VI. This chapter is a paper that was published in BMC Health Services Research in 2014[145]. The text is exactly as published, except for numbering of tables and figures.

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Student Sapna Desai

Principal Supervisor Simon Cousens

Thesis Title

Community health worker-led education to change women's treatment-seeking behaviour: A cluster randomised trial and qualitative investigation in Gujarat, India

If the Research Paper has previously been published please complete Section B, if not please move to Section C

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Where was the work published?

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I performed all statistical analyses, drafted the manuscript, incorporated comments from co-authors and submitted the article for publication.

Student Signature: Date: 6.2.2015

Sapna Desai

Supervisor Signature: Date: 6.2.2015

Understanding CBHI hospitalisation patterns: A comparison of insured and uninsured women in Gujarat, India

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Abstract

Background

Community-based health insurance has been associated with increased hospitalisation in low-income settings, but with limited analysis of the illnesses for which claims are submitted. A review of claims submitted to VimoSEWA, an inpatient insurance scheme in Gujarat, India, found that fever, diarrhoea and hysterectomy, the latter at a mean age of 36 years, were the leading reasons for claims by adult women. To understand this pattern, we compare the morbidity, outpatient treatment-seeking and hospitalisation patterns of VimoSEWA-insured women with uninsured women.

Methods

We utilise data from a cross-sectional survey of 1,934 insured and uninsured women in urban and rural Gujarat, India. Multivariable logistic regression was utilised to identify predictors of insurance coverage and the association of insurance with hospitalisation. Self-reported data on morbidity, outpatient care, hospitalisation and length of stay are compared between insured and uninsured women.

Results

Age, marital status and employment category of adult women were associated with insurance status. Reported prevalence of recent morbidity, type of illness, outpatient treatment and outcomes were similar among insured and uninsured women. Multivariable analysis reveals strong evidence of a higher odds of hospitalisation amongst the insured (OR = 2.7; 95% ci. 1.6, 4.7). The leading reason for hospitalisation for uninsured and insured women was hysterectomy, at a similar mean age of 36, followed by common ailments such as fever and diarrhoea. Insured women appear to have a higher probability of being hospitalised for all causes than uninsured women, rather than specifically for fever, diarrhoea or hysterectomy. Length of stay was similar; the insured were not more likely to be admitted for only one day, the minimum required for reimbursement. The insured utilised a mix of trust, public and private hospitals, while two-thirds uninsured women utilised private hospitals.

Conclusions

Despite similar reported morbidity patterns and initial treatment-seeking behaviour, VimoSEWA members were more likely to be hospitalised. The data do not provide strong evidence that the differential is explained by inpatient hospitalisation replacing outpatient treatment for common illnesses or that insurance is the primary inducement for hysterectomy in the population. Rather, it appears that VimoSEWA members behave differently in deciding if, and where, to be hospitalised for any condition. Further research is required to explore this decision-making process, the roles, if any, played by adverse selection and moral hazard. Lastly, these hospitalisation patterns raise concerns regarding population health needs and access to quality preventive and outpatient services.

Keywords
Community-based health insurance, treatment-seeking behaviour
(MESH): Health insurance, India, hysterectomy, female, hospitalization

Background

Community based health insurance (CBHI) is a health financing arrangement that aims to reduce risk of catastrophic health expenditure and improve access to health care in low-income settings. Most CBHI schemes are rooted, to varying degrees, in principles of risk-sharing, community solidarity, participatory decision-making and voluntary affiliation[210]. According to findings from a systematic review in 2009 that covered 31 studies and 118 schemes, and an earlier review of 12 schemes in Asia and Africa, there is strong evidence that CBHI schemes can decrease out of pocket spending on health care [211] [28]. A large proportion of schemes in low-income settings cover only inpatient hospitalisation expenses, and CBHI coverage has been associated with increased hospitalisation in a number of studies [212-217]. However, health systems issues such as poor quality of services and lack of patient empowerment remain barriers to increased treatment-seeking [218, 219], while low enrolment limits coverage of CBHIs and similar voluntary schemes[220]. Despite these weaknesses, CBHIs continue to be implemented in many low-income countries, as a potential tool to improve access and financial security [210].

Much of the existing research on CBHIs and hospitalisation in low-income settings has focused on the association with increased hospitalisation, with limited analysis of the underlying health conditions that drive utilisation. In fact, careful analysis of morbidity profiles in combination with treatment-seeking behaviour by (CBHI) insurance status can shed light on the role of insurance in increasing use of both outpatient and inpatient health services, including the risk of inefficient provider-induced or patient overutilization of services (moral hazard). Analysis of data on morbidity and treatment patterns can also be useful for exploring whether there is a higher likelihood of enrolment by persons more prone to seeking care (adverse selection).

To our knowledge, only three CBHI studies have integrated an epidemiological analysis to compare hospitalisation amongst the insured and uninsured in low-income settings. Devadasan et al compared reported illness – categorised as minor, major or chronic – amongst matched insured and uninsured households in rural India [221]. Despite similar levels of minor and chronic illness, the insured were 2.5 times more likely to present with a major ailment and almost twice as likely to be hospitalised as the uninsured. However, the insurance scheme covered only hospitalisation and all hospitalisations were automatically categorised as major illness – which may account for the difference in reported morbidity patterns between the insured and uninsured. In contrast, an evaluation of Filipino micro-insurance units that cover inpatient care reported similar incidence of recent morbidity amongst the insured and uninsured. Yet the insured had a 50% higher risk of hospitalisation for both communicable and non-communicable illnesses, as well as more physician encounters and institutional deliveries[222]. Similarly, a detailed study of the impact of the Bwamanda hospital scheme in Zaire reported a 2.9-fold higher admission rate for the insured[223]. The authors analysed care for two 'justified high priority' conditions – caesarean sections and strangulated hernias – and found significantly lower rates amongst the uninsured.

In our own experience at VimoSEWA, a CBHI in India that covers only 24-hour or longer hospitalisation, a recent analysis of claims indicated that close to forty percent of adult hospitalisation was for common, typically mild illnesses such as fever and diarrhoea, as well as hysterectomy amongst women in their mid-thirties[141]. This pattern surprised VimoSEWA's management and SEWA's community health team, who questioned if: (i) the scheme's inpatient-only design effectively serves to replace outpatient treatment for common illnesses such as diarrhoea and fever with reimbursable, inpatient hospitalisation (ii) the scheme and/or providers promote unnecessary procedures, particularly hysterectomy at a young age and (iii) some of the burden of illness and hospitalisation was preventable through community intervention. As a first step in exploring the first two questions, we conducted a household survey to compare morbidity, outpatient treatment-seeking and hospitalisation patterns of women insured by VimoSEWA with uninsured women in the same geographical areas. A health education intervention was designed to test (iii), along with qualitative research on the three questions. This paper reports the findings from the household survey.

VimoSEWA

VimoSEWA is a voluntary, community-based insurance scheme initiated in 1992 by the Self-Employed Women's Association (SEWA), a women's trade union with 1.3 million members in nine states of India [224]. The majority of VimoSEWA's members are women workers in the informal sector in the state of Gujarat. In partnership with insurance companies, VimoSEWA promotes a range of voluntary insurance products to women workers through its non-profit cooperative. VimoSEWA insures adult women as the primary insured, who have the option to purchase additional coverage for spouses and children (Table 5.1).

Table 5.1 VimoSEWA Health Products (Indian Rupees. 1 USD = INR 54.5)

	Member	**Spouse**	**Children**	**Total**
	Scheme 1			
Annual premium	175	125	100	400
Annual total hospitalisation coverage	2,000	2,000	2,000	6,000
	Scheme 2			
Annual premium	375	350	100	825
Annual total hospitalisation coverage	6,000	6,000	2,500	14,500

Like most Indian CBHI schemes[181], VimoSEWA provides hospitalisation coverage that includes hospital and provider charges, medicines, transportation and other expenditure incurred while admitted in an inpatient facility. For a claim to be admissible under the scheme, the member must be hospitalised for a minimum of 24 hours. VimoSEWA does not cover expenditure on outpatient treatment or childbirth. In 2012, the health scheme insured approximately 80,000 policies, about 6 percent of SEWA's membership[182]. No other micro- or community-based health insurance schemes operated in VimoSEWA's coverage areas at the time of this survey and very few informal sector households (in Gujarat and India) hold any other voluntary private health insurance policies. A subsidized government health insurance scheme, the Rashtriya Swasthya Bima Yojana (RSBY), began roll-out in SEWA's focus rural areas in 2011[183].

Payment for hospitalisation costs is made in two ways. In Ahmedabad city and parts of rural Gujarat, members can obtain 'cashless' treatment if they are admitted in empanelled public, private for profit and private non-profit hospitals (the latter are locally known as trust hospitals). Admitted members inform VimoSEWA as soon as they are admitted and VimoSEWA pays the hospitals directly. In other areas, members pay out-of-pocket and are reimbursed for expenses on submission of hospital bills.

Previous research at VimoSEWA has found that the scheme provides members with a degree of financial protection, but the coverage is not comprehensive[29]. Twenty-three percent of VimoSEWA members hospitalised in 2003 experienced catastrophic health expenditure, defined as annual hospital expenditure greater than 10% of annual income, after reimbursement[34]. The scheme has also been examined from an equity perspective. Research findings indicated that the scheme was successful in enrolling the poor, and utilisation patterns were broadly comparable among urban members of different socioeconomic groups. Among rural members however, the better off were more likely to submit claims. Barriers to utilisation included distance to hospitals, difficulty with claims paperwork and lack of awareness about insurance coverage [185]. Child care, household responsibilities and opportunity costs such as lost wages were also identified as obstacles to treatment-seeking, for women in particular[186].

A review of VimoSEWA health claims in 2001 indicated that the most common reasons for adult hospitalisation were accidents, malaria, gastroenteritis and hysterectomy[29]. A follow-up review in 2009 revealed that the leading reasons for adult hospitalisation claims were for illnesses such as fever, diarrhoea/gastroenteritis and respiratory infection – which are considered common illnesses amenable to prevention or outpatient treatment if diagnosed early. Hysterectomy was the primary reason for claims amongst rural women, at an average age of 37 years, considerably younger than in countries where data are available[30-33]. A survey conducted by Ranson in 2000 amongst 242 VimoSEWA-insured and 381 uninsured households did not find evidence of increased hospitalisation amongst insured women[187]. Since then, VimoSEWA has not assessed hospitalisation rates or treatment-seeking of insured members with the uninsured.

Study Objectives

This analysis is one of a set of studies at SEWA to explore treatment-seeking behaviour amongst low-income women in Ahmedabad city and district in Gujarat. It builds on previous research at VimoSEWA by comparing insured women to the uninsured, and contributes to the literature on CBHI by integrating an epidemiological approach to the analysis of healthcare utilisation patterns. We examine three issues. First, we examine demographic characteristics of VimoSEWA and uninsured women to identify factors associated with insurance coverage, particularly those which could potentially affect treatment-seeking. Second, we compare insured and uninsured women with respect to the prevalence of morbidity in the past month and place where treatment was sought (self/outpatient clinic/hospital/none), in order to examine treatment choices that are not covered by VimoSEWA's inpatient-only scheme. Third, we compare insured and uninsured women with respect to hospitalisation in the past six months, comparing type of illness, length of stay and place of hospitalisation.

Methods

This study utilises data from a cross-sectional baseline household survey conducted from January to March 2010 amongst a sample of insured and uninsured households in Ahmedabad district and Ahmedabad city, Gujarat. The survey was designed to provide baseline information for a subsequent evaluation of a health education intervention amongst insured and uninsured women. We compare demographic, morbidity and treatment-seeking patterns across 28 clusters where the intervention was to be implemented. The survey was conducted in 16 rural and 12 urban clusters, with clusters defined as discrete geographical units serviced by a single SEWA community health worker (CHW). CHWs serve both insured and uninsured households: approximately eight to ten percent of the 200-500 households in each cluster are insured by VimoSEWA. The sample was stratified by urban and rural location, as urban rates of claim submission have been established to be higher than in rural areas in two previous analyses[141, 185].

Household selection

For insured households, 35 households from each cluster were randomly selected from the VimoSEWA database. A researcher followed each CHW on her daily rounds to list uninsured households, from which 35 were also randomly selected. Thus, 70 households were selected per cluster to give a total of 1,960 households.

Data collection

The survey collected information for all family members on demographic and socioeconomic characteristics, morbidity and all treatment-seeking behaviour in the past 30 days and hospitalisation and associated expenditure in the past six months. In each household, an adult woman was selected for interview. In insured households, the respondent was the primary VimoSEWA policy holder. In uninsured households, the primary SEWA union member or spouse of the male head of household was selected. All respondents provided oral informed consent. Both the local ethics committee and CHWs considered this the most appropriate convention, rather than written consent, as most women in the area have not attended formal schooling. Ethics approval was granted by the Executive Committee of the SEWA Health Cooperative.

Data analysis

Data were entered into a Microsoft Access database and analysed using Stata 11. The svyset command was utilised to take into account the cluster sampling, sampling weights for insured and uninsured households, and the rural/urban stratification. Sampling weights were defined by cluster, as both the population size and penetration of insurance vary by CHW work area. All tables present weighted proportions.

We conducted three analyses to compare insured and uninsured women. In the first analysis, we examined demographic and socioeconomic characteristics of insured and uninsured households and women in order to identify any factors that may later be associated with differences in treatment-seeking behaviour. Socioeconomic indicators (income, education, dwelling type, toilet, drinking water access) are presented and analysed separately rather than as a score derived using principal component analysis, as we believed that some of these variables could be independently associated with morbidity or hospitalisation. Although women workers in the informal economy typically engage in multiple income-earning activities[175], only the respondent's stated primary occupation was included in the analysis. After examining unadjusted odds ratios calculated using logistic regression, multivariable logistic regression was used to identify predictors of insurance status. We included variables with crude odds ratios observed to be associated with ($p \leq .05$) or those that could be theoretically associated with, insurance coverage. Results are presented as adjusted odds ratios with 95% confidence intervals. Overall p-values for variables with more than two levels were obtained using Wald tests. Urban and rural data were stratified in crude analyses and then combined in multivariable analyses, with location formally tested for effect modification.

In the second set of analyses, data on recent morbidity and treatment-seeking were compared between insured and uninsured women. Recent morbidity was defined as any illness episode in the past month, to limit recall bias and to capture outpatient treatment-seeking behaviour as accurately as possible. Morbidity in the past 30 days included chronic illness, as we did not inquire about chronic illness separately at the individual level.

In the third analysis, the association between current insurance coverage and hospitalisation, defined as an inpatient admission for 24 hours or more in the past six months, was examined through logistic regression. Multivariable logistic regression included variables associated with insurance coverage and those considered to be associated with hospitalisation, both theoretically and through examining crude odds ratios. The role of urban/rural location was examined through stratified odds ratios and formally tested for effect modification. Lastly, reasons for hospitalisation, type of hospital and length of stay were compared to identify any differences between insured and uninsured women. Throughout, self-reported reasons for recent morbidity and hospitalisation were categorised into illness or symptom groups to the extent possible without clinical reports. Given the large variety of illnesses and hence small category sizes, we present morbidity-related data with descriptive proportions rather than formal statistical tests.

Results

A total of 1,934 adult female respondents (980 uninsured/954 insured) from the selected sample of 1,960 households were interviewed in the baseline survey. Twenty-six insured women were unavailable, mostly in Ahmedabad city, with no replacement available in the same cluster. Demographic and socioeconomic characteristics are presented in Tables 5.2 and 5.3.

Insurance coverage

Unadjusted odds ratios indicate no major differences in demographic or socioeconomic characteristics at the household level between insured and uninsured respondents, examined separately within rural (n=1,118) and urban (n=816) strata (Table 5.2). Living conditions appeared to vary across location: more rural households lived in precarious mud houses rather than brick or cement dwellings, and urban households were more likely to have a toilet. With respect to individual-level characteristics (Table 5.3), insured women were older, more likely to be employed, and, in rural areas, less educated than their uninsured counterparts. Also, a higher proportion of insured women were widows. Although insured and uninsured women reported similar levels of morbidity in the past 30 days, insured women were more likely to perceive their own health as average, compared to uninsured women who reported higher levels of very good health.

Table 5.2 Household level characteristics of insured and uninsured women in Gujarat (n=1,934)

	Rural					**Urban**				
	Uninsured		**Insured**			**Uninsured**		**Insured**		
	n	**%**	**n**	**%**	**p value**	**n**	**%**	**n**	**%**	**p value**
Household structure										
Extended family	248	44.2	237	44.9	0.76	152	35.3	157	39.6	0.32
Nuclear	312	55.8	321	55.1		268	64.7	239	60.4	
Mean annual income(INR)										
0-60,000	258	45.7	273	47.9	0.48	178	39.6	144	34.6	0.16
60,001-120,000	227	40.9	218	39.6		185	43.3	199	54	
120,001-180,000	43	7.5	44	8.5		40	11.8	31	7.6	
180,000+	32	5.9	23	4		17	5.2	22	3.8	
Dwelling type										
Mud house	110	21.1	107	23.2	0.70	26	4.8	16	3.0	0.46
Semi	336	57.3	330	55.9		258	54.6	218	52.9	
Solid	114	21.6	121	21		136	40.6	162	44.0	
Toilet										
Yes	251	48.6	223	44.7	0.45	297	79.7	299	78.5	0.82
No	309	51.4	335	55.3		123	20.3	97	21.5	
Religion										
Hindu	519	89.4	523	92.0	0.70	347	83.3	333	84.6	0.87
Muslim	41	10.6	34	7.8		71	16.2	60	15.0	
Drinking water										
Individual tap	415	71.9	406	74.4	0.76	331	85.1	310	82.2	0.64
Shared tap	38	5.7	35	7.0		52	7.8	46	8.7	
Other	107	22.4	117	18.6		37	7.1	40	9.1	

Table 5.3 Individual characteristics of respondents *(female respondents ≥15 yrs) n=1,934*

	Rural					**Urban**				
Respondent characteristics	**Uninsured**		**Insured**		**p value**	**Uninsured**		**Insured**		**p value**
	n = 560		**n = 558**			**n = 420**		**n = 396**		
	n	**%**	**n**	**%**		**n**	**%**	**n**	**%**	
Age group										
Age 15-24	102	17.3	48	8	<0.001	63	14.7	31	8.5	<0.01
Age 25-34	215	38.7	200	35.8		153	33.7	99	24.3	
Age 35-44	166	28.5	208	37.3		117	27.7	152	38.4	
Age 45-54	60	11.9	83	14.6		64	14.8	85	21.7	
Age 55+	17	3.6	19	4.3		23	9.0	29	7.0	
Education										
Never studied	308	51.5	353	62.7	0.02	202	43	184	44.3	0.79
Primary (1–5)	99	18.3	92	18.2		82	18.3	76	20.6	
Secondary +	153	30.2	113	19.1		136	38.6	136	35.2	
Marital status										
Married	530	94.4	495	88.2	<0.01	366	86	311	79.5	0.03
Unmarried/divorced	5	0.8	1	0.3		16	4.2	19	4.6	
Widowed	25	4.8	62	11.5		38	9.8	66	15.8	
Primary occupation										
Agriculture/Livestock	384	64.4	416	75.9	0.15	11	1.7	8	1.7	0.001
Self-employed/service	71	14.7	74	13.6		201	52.1	255	68.5	
Salaried worker	11	2.4	4	0.7		8	1.8	26	5	
Unemployed	94	18.5	64	9.8		200	44.5	107	24.8	
Reported 30 day morbidity										
No	508	89.6	477	85.6		347	83.6	310	79.6	
Yes	52	10.4	81	14.4	0.17	73	16.4	86	20.4	0.36
Own health perception										
Poor	10	1.6	12	2.3	<0.01	11	3.1	8	2.4	0.04
Average	413	71.3	434	77.2		264	62.8	288	71.2	
Very good	137	27.1	112	20.5		145	34.1	100	26.5	

Multivariable regression (Table 5.4) indicated similar patterns of demographical characteristics to those observed in the preliminary analysis above. There was no evidence of an association between insurance coverage and reported 30-day morbidity, and the adjusted analysis indicates that average (compared to very good) health status was associated with insurance coverage. There was little evidence that urban/rural location modified the effects of age (p=0.38) or marital status (p=0.20) on insurance coverage. There was some evidence that that the association between employment and insurance coverage (p=0.05) varied with location, with occupation group associated with insurance coverage amongst urban, but not rural, women.

Table 5.4 Factors associated with insurance status among adult women (n=1,934)

Variable	**n**	**OR adjusted**	**95% CI**		**p value**
			LB	**UB**	
Age					<.001
Age 15-24	244	(b)			
Age 25-34	667	1.4	1.0	1.9	
Age 35-44	644	2.2	1.5	3.1	
Age 45-54	292	2.0	1.3	3.2	
Age 55+	88	1.2	0.4	3.3	
Marital Status					<.001
Married	1,703	(b)			
Unmarried/Divorced	41	1.4	0.5	3.7	
Widowed	191	2.0	1.5	2.6	
Education					0.52
Never educated	1048	(b)			
Primary level	349	1.0	0.7	1.2	
Secondary level	538	0.8	0.6	1.2	
Occupation group					<.001
Agriculture	805	(b)			
Self employed	615	0.9	0.6	1.4	
Salaried	49	1.2	0.6	2.6	
Unemployed	465	0.5	0.3	0.7	
Reported 30 day morbidity					0.23
No	1,647	(b)			
Yes	287	1.2	0.9	1.7	
Own health perception					
Poor	41	(b)			
Average	1,399	1.1	0.6	1.9	0.04
Very good	44	0.8	0.5	1.5	

(b): Baseline group

Morbidity and treatment-seeking

Insured women reported slightly higher prevalence of morbidity in the past 30 days than uninsured women (adjusted OR = 1.2), although this difference may be due to chance (p=0.23). Fever and other common illnesses comprise the majority of cases of morbidity experienced in the past thirty days, followed by symptoms related to hypertension and asthma. There is some variation in symptoms reported by insured and uninsured women in rural areas, although overall the pattern is similar across insurance status (Table 5.5).

Table 5.5 Type of morbidity experienced in past 30 days (n=287)

Illness type	**Uninsured**		**Insured**		**Total**	
	n = 123		**n = 164**		**n = 287**	
	n	**%**	**n**	**%**	**n**	**%**
Accident/injury	4	3.8	6	3.4	10	3.7
Body pain	13	12.7	16	8.4	29	12.2
Cold/cough	17	17.6	11	10.0	28	16.8
Diarrheal	8	6.7	11	5.0	19	6.5
Eye	0	0.0	2	0.7	2	0.1
Fever	43	31.3	55	37.0	98	31.9
Gastric	6	4.6	17	8.5	23	5.0
Gynaecological	5	3.4	7	4.0	12	3.5
Respiratory	2	1.6	5	2.5	7	1.7
Skin	1	0.5	4	4.0	5	0.8
TB	1	0.4	1	0.5	2	0.4
Urinary	0	0.0	5	2.5	5	0.3
Weakness	0	0.0	3	2.0	3	0.2
NCD	23	17.6	21	11.5	44	17.0

The majority of women sought treatment in an outpatient clinic setting, with no notable differences in place of first treatment by insurance status (Figure 5.1). A similar proportion of women sought no treatment or chose to treat themselves with home remedies, with a slightly higher proportion amongst the insured in rural areas. Reported treatment outcomes for recent morbidity were similar for insured and uninsured women (Table 5.6).

Figure 5.1 First place of treatment for reported morbidity in past 30 days

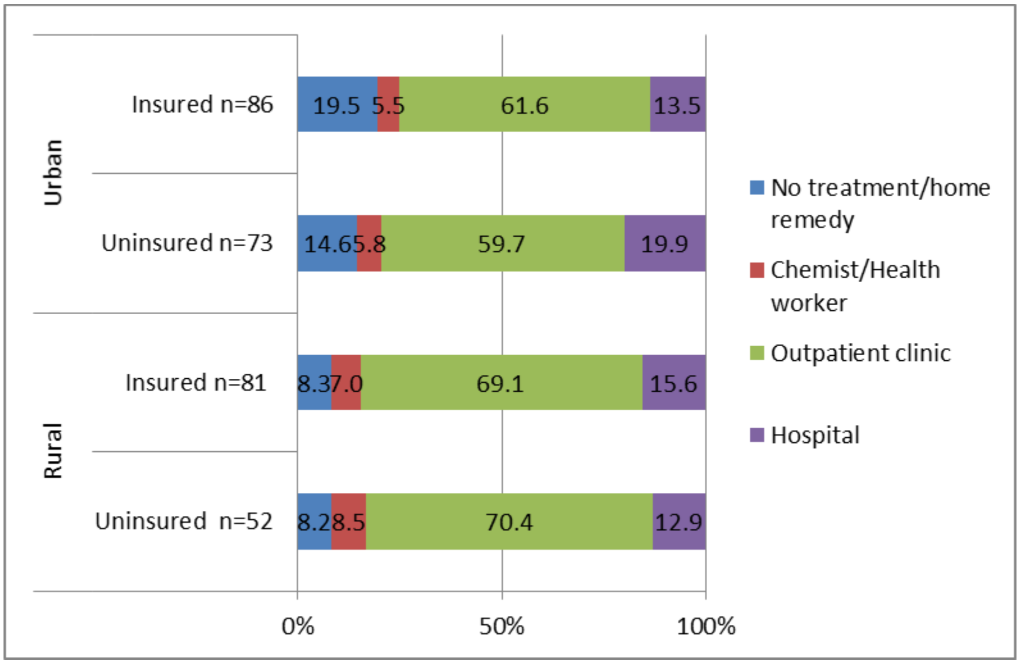

Table 5.6 Treatment result for reported morbidity (n=287)

	Rural n = 130				**Urban n = 157**			
	Uninsured		**Insured**		**Uninsured**		**Insured**	
Treatment result	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
Cured	23	45.3	33	45.7	36	52.9	39	44.4
Not cured*	8	18.4	14	19.5	19	25.1	21	27.4
Treatment continued	21	36.3	31	34.8	16	22.0	26	28.2

*Not cured but treatment discontinued.

Hospitalisation and insurance coverage

In an unadjusted analysis of women who reported hospitalisation in the past six months (n=99) (Table 5.7), insurance coverage was associated with higher odds of hospitalisation in both rural (OR=2.76, p=0.001) and urban (OR=2.45, p=0.04) women. Amongst the rural insured, average perceived health status (rather than poor or very good) was associated with hospitalisation.

Table 5.7 Hospitalisation amongst rural and urban adult respondents (n=1,934)

	Rural						**Urban**					
	Uninsured			**Insured**			**Uninsured**			**Insured**		
	n = 560			**n = 558**			**n = 420**			**n = 396**		
	n	**%**	**P value**	**n**	**%**	**p value**	**n**	**%**	**p value**	**n**	**%**	**p value**
Total hospitalised	18	3.2	(b)	46	8.4	0.001	11	3.0	(b)	24	7.0	0.04
Age group												
Age 15-24	1	1.4	0.46	4	6.9	0.19	3	5.7	0.61	1	2.7	0.85
Age 25-34	9	4.2		22	11.3		4	3.9		5	3.8	
Age 35-44	6	4.2		15	7.9		3	1.9		11	11.6	
Age 45-54	1	0.7		4	4.5		1	2.2		5	4.3	
Age 55+	1	2.5		1	5.5		0	0		2	6.9	
Education												
Never studied	13	3.8	0.78	27	8.1	0.90	3	2	0.30	10	6.2	0.09
Primary (1–5)	2	2.1		9	9.9		2	1.6		7	9.8	
Secondary +	3	3.0		10	8.2		6	4.8		7	6.5	
Marital status												
Married	17	3.3	0.59	43	8.7	0.60	10	3.1	0.32	21	8.2	0.20
Unmarried/divorced	0	0		0	0		1	7.8		1	5	
Widowed	1	1.9		3	6.1		0	0		2	1.8	
Primary occupation												
Self employed	4	6.4	0.69	5	5.8	0.58	8	4.5	0.13	14	6.3	0.30
Agriculture	12	2.9		35	8.8		0	0		0	0	
Salaried worker	0	0		1	20.8		0	0		3	12.3	
Unemployed	2	2.3		5	8.3		3	1.4		7	8.3	
Mean annual income (INR)												
0-60,000	11	3.6	0.72	21	8.3	0.54	4	2.2	0.37	10	5.9	0.76
60,001-120,000	6	3.6		17	7.9		3	1.9		11	7.3	
120,001-180,000	0	0		6	13		3	9.8		1	8.7	
180,000+	1	1.5		2	5.8		1	2.6		2	10.7	
Dwelling type												
Mud house	4	2	0.54	11	9.1	0.96	0	0	0.39	1	6.7	0.47
Semi	10	2.9		25	8.4		9	3.9		11	5.5	
Solid	4	5.3		10	7.9		2	2.2		12	8.9	
Reported 30-day morbidity												
No	18	3.6	0.08	38	8.0	0.42	9	2.9	0.87	19	7.1	0.98
Yes	0	0		8	10.9		2	3.4		5	6.9	
Own health perception												
Poor	0	0	0.69	1	0.22	0.03	1	0.0	0.82	0	0	0.62
Average	15	2.6		43	7.8		6	1.7		20	5.3	
Very good	3	0.67		2	0.35		4	1.2		4	1.8	

In an analysis adjusted for age, education, marital status, occupation, income group, reported 30-day morbidity and perceived health status, (Table 5.8), there was strong evidence of an association of insurance coverage with higher odds of hospitalisation (OR = 2.7; 95% ci. 1.6, 4.7). There was no evidence that the association between insurance and odds of hospitalisation varied between urban and rural populations **(**p=0.86). No other predictors of hospitalisation emerged.

The most common reason for hospitalisation was gynaecological ailments, of which hysterectomy comprised 23 of 31 cases. The mean age of hysterectomy was 36 years. Common ailments such as diarrhoea, fever and vomiting accounted for almost a quarter of cases, followed by non-communicable diseases (Figure 5.2).

Figure 5.2 Causes of hospitalisation **(% of 70 insured and 29 uninsured hospital cases)**

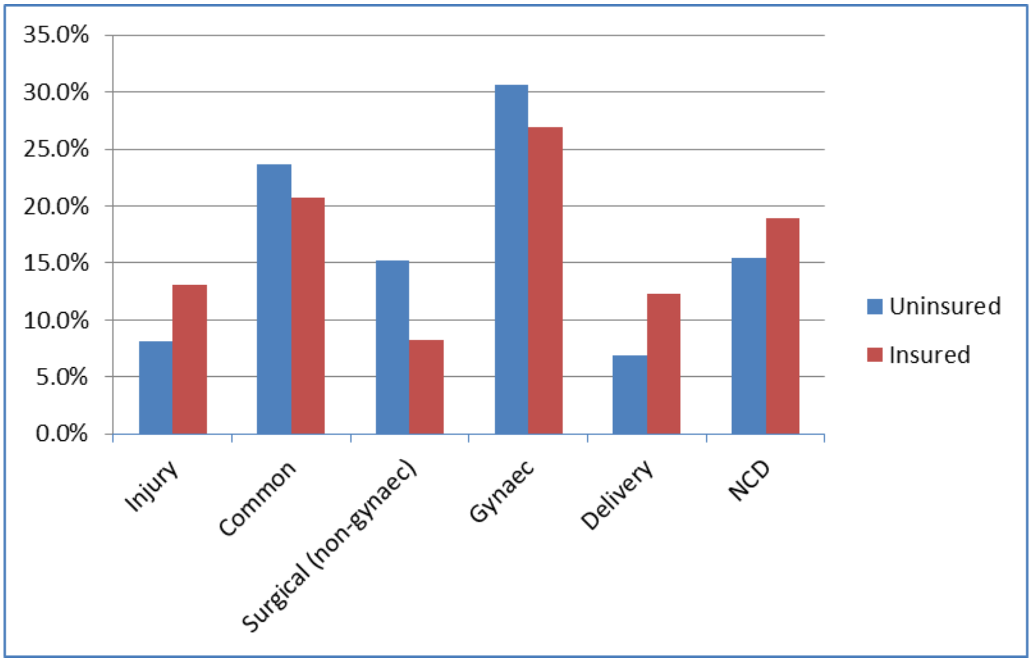

Table 5.8 Association of insurance coverage with hospitalisation (n=1,934)

Adult women ≥15 yrs	**n = 1,934**	**Adjusted OR**	**95% CI**		**p value**
			LB	**UB**	
Insurance status					0.001
Uninsured	980	(b)			
Insured	954	2.7	1.6	4.7	
Age					
Age 15-24	244	(b)			0.62
Age 25-34	667	1.4	0.4	5.3	
Age 35-44	643	1.2	0.4	3.6	
Age 45-54	292	0.6	0.1	2.8	
Age 55+	88	0.4	0.1	2.4	
Education					
Not educated	1047	(b)			0.60
Primary	349	0.6	0.2	1.9	
Secondary	538	1.0	0.5	2.1	
Marital status					
Married	1,702	(b)			0.31
Unmarried/Divorced	41	2.0	0.4	10.8	
Widowed	191	0.4	0.1	1.7	
Occupation					
Self-employed	615	(b)			0.11
Agriculture	805	0.5	0.2	1.3	
Salaried	49	0.3	0.1	1.0	
Unemployed	465	0.4	0.1	1.1	
Mean annual income(INR)		(b)			
0-60,000	853				0.72
60,001-120,000	829	0.9	0.4	1.8	
120,001-180,000	158	1.8	0.5	7.2	
180,000+	94	0.8	0.2	3.0	
Reported 30 day morbidity					
No	1,642	(b)			0.30
Yes	292	0.6	0.2	1.6	
Own health					
Poor	41	(b)			
Average	1,399	2.1	0.3	13.9	0.54
Very good	494	1.4	0.2	9.7	

Table 5.9 presents risk of hospitalisation by cause. The increased level of hospitalisation in insured women was not concentrated in a particular type of ailment or procedure; insured women appeared to have a higher risk of being hospitalised across a wide range of causes, although numbers were small for individual causes. Insured women were also more likely to be hospitalised for institutional delivery, a service not covered by VimoSEWA.

Table 5.9 Risk of hospitalisation by cause (n = 1,934)

Cause of hospitalization	**Uninsured (n = 980)**		**Insured (n = 954)**	
	n	**%**	**n**	**%**
Not hospitalized	951	96.9	884	92.2
Injury/Accident	3	0.3	9	1.1
Gastroenteritis, fever	5	0.7	17	1.7
Surgical (non-gynaecological)	3	0.5	6	0.7
Gynaecological including hysterectomy	12	1.0	19	2.2
Childbirth	3	0.2	6	0.6
Non-communicable	3	0.5	13	1.5

Conditional upon having been hospitalised (n=99), the insured were slightly more likely to stay in the hospital for more than one day, with no difference in length of stay for common illnesses (n=22) such as fever and diarrhoea (p=0.49) or if an additional category of two days is included (Table 5.10). Insurance coverage appeared to affect the choice of where to be hospitalised: the insured used a mix of trust, public and private hospitals, while close to two-thirds of the uninsured used private hospitals, with no use of trust hospitals (Table 5.11).

Table 5.10 Length of stay amongst those hospitalised (n = 99)

	Uninsured (n = 29)		**Insured (n = 70)**	
	n	**%**	**n**	**%**
All illness				
1 day	8	32.6	17	22.4
>1 day	21	67.4	53	77.6
Common illness				
1 day	1	23.8	6	28.7
>1 day	4	76.2	11	71.2

Table 5.11 Place of hospitalisation (n=99)

Type of hospital	**Uninsured**		**Insured**	
	(n = 29)		**(n = 70)**	
	n	**%**	**n**	**%**
Public	11	36.1	17	19.7
Private	18	63.9	39	58.5
Trust	0	0	14	21.8

Discussion

This study contributes to the small but growing literature that incorporates an epidemiological approach into the analysis of insurance schemes that cover hospitalisation. While reported morbidity and outpatient treatment-seeking were similar among the VimoSEWA-insured and uninsured, there was strong evidence of higher hospitalisation rates amongst insured women. We interpret our results below and explore what may explain this differential.

Insurance coverage and treatment-seeking

Demographically, the insured and uninsured were similar in terms of income level, occupation and living standards as indicated by housing/sanitation facilities. The insured comprised slightly older women who were less educated (in rural areas), more likely to be employed, and interestingly, more likely to be widowed than uninsured women. These findings reflect VimoSEWA's stated goals to reach women workers in the informal economy and those who are vulnerable, such as widows. Lower education levels amongst rural VimoSEWA members compared with their uninsured counterparts contrasts with previous research on the scheme as well as other CBHIs in India, wherein the insured are more likely to be literate [187, 225, 226]. This survey inquired about formal education levels, rather than literacy, which is typically defined as the ability to sign one's name. Since SEWA operates literacy programs in rural areas, it is possible that while education is lower, literacy is comparable or higher amongst insured women.

We considered adverse selection – greater likelihood of enrolment by individuals with higher morbidity or proclivity to seek treatment – given previous evidence from voluntary CBHI schemes including VimoSEWA [28, 187, 227, 228]. Although demographic differences in insurance status such as age and marital status may suggest adverse selection, none emerged as independent predictors of hospitalisation in this analysis. The insured and uninsured reported similar recent morbidity rates;

VimoSEWA members were not more likely to report a recent illness than uninsured women. Morbidity profiles were also largely similar: common ailments such as fever and body pain comprised the majority of reported illnesses, along with hypertension and diabetes-related episodes for both groups of women. However, uninsured women reported better perceptions of their overall health and this is suggestive of adverse selection. Unfortunately, the cross-sectional nature of our data makes it difficult to arrive at firm conclusions. One complication is that hospitalisation among the insured may itself influence self-reported health and reflect underlying (supply- or demand-side) moral hazard. Self-reported health status may also reflect unobservable attitudes towards treatment-seeking or omitted variables that differ between the insured and uninsured, differences that could be a reason to enrol in – or be a result of – insurance – coverage [229, 230].

Regarding treatment, insured and uninsured women reported similar first steps after an illness episode in the past month. The majority of women sought care at an outpatient clinic, and the remainder either sought inpatient care or self-treated/did not treat formally in similar proportions. Similar morbidity and outpatient treatment-seeking patterns might lead one to expect that hospitalisation rates would also be comparable amongst the insured and uninsured. Yet we found strong evidence for an association between VimoSEWA coverage and increased odds of hospitalisation amongst adult women in a six-month period. While this finding is consistent with several studies in low-income settings, [221, 222, 231, 232] it provides new insight for VimoSEWA in light of earlier research that found no association between VimoSEWA coverage and increased hospitalisation[187].

Common illnesses

Since VimoSEWA does not cover outpatient care, previous research has suggested that insured women seek hospital-based care in place of outpatient treatment from the outset to avoid out-of-pocket costs[233]. This hypothesis is consistent with a high proportion of claims for common illnesses amenable to outpatient treatment, such as diarrhoea and fever. However, the excess of hospitalisation in insured women was evenly distributed across ailment types. The risk of hospitalisation in the past six months was higher for all causes, not clustered around fever, diarrhoea or other ailments typically treated through outpatient services. Treatment-seeking behaviour for illnesses in the past 30 days did not indicate higher use of hospitals for initial treatment by the insured, including for common illnesses. Reported cure rates were also similar; there was no indication that either group received less effective outpatient care. Further, the length of stay for inpatient hospitalisations – including the proportion of those hospitalised for a 24-hour visit – was similar to that of the uninsured. Insured women were not more likely to be admitted for the minimum one-day period which would qualify for reimbursement. Taken with the opportunity cost associated with hospitalisation for women in the informal sector, this analysis suggests that any substitution of inpatient for outpatient care for common illnesses (a form of moral hazard) by VimoSEWA members may be small.

More insight is provided by recent qualitative research with VimoSEWA-insured urban women who had been hospitalised for fever. Most women indicated that hospitalisation was only sought after outpatient treatment repeatedly failed[234]. Women preferred outpatient care as a first step because it involves lower opportunity costs than hospitalisation – which is consistent with our finding of similar morbidity and outpatient-treatment seeking amongst the insured and uninsured. From insured women's perspectives, hospitalisation was viewed as a last resort to access more potent treatment. The knowledge that partial costs would be covered by VimoSEWA offered security in the decision-making process. Providers indicated that when they suggest hospitalisation for persistent fever or minor ailments that have become more severe, insured women are more likely to agree. Despite VimoSEWA's relatively low coverage amounts, this qualitative research suggests that we cannot rule out either provider-induced or demand-side moral hazard.

Hysterectomy

We examined if the higher hospitalisation rate amongst insured women could be partly explained by higher rates of hysterectomy. Insured women reported slightly higher odds of undergoing a hysterectomy than the uninsured in the past six months, but this difference may be due to chance (p=0.13). The mean ages at which insured and uninsured women underwent hysterectomy were similar – and relatively young by global standards. The reasons reported for hysterectomy, also similar amongst insured and uninsured women, were gynaecological ailments (fibroids, cysts, menstrual difficulty and to a lesser extent, uterine prolapse) – most of which are amenable to non-invasive, first-line treatment. In a separate analysis of our survey data we found that the proportion of women reporting having 'ever undergone hysterectomy' (instead of in a 6-month reference period) was similar between insured and uninsured women, but we did not know their insurance status at the time of the hysterectomy[235].

The data available thus far suggest that having insurance may influence hysterectomy related hospitalisations, possibly as one of a complex set of factors. The coverage provided by VimoSEWA of Rs. 2,000-5,000 covers a significant chunk of the total cost of a hysterectomy (which typically ranges from Rs. 4,000-10,000). Previous qualitative research at SEWA has also identified questionable provider practices, such as conducting hysterectomy on demand or as first-line treatment before less invasive procedures. Provider behaviour is likely to influence the incidence of hysterectomy among women in their mid-thirties – but these practices are likely not limited to insured women or solely in the private sector [235, 236]. We are currently exploring the health system and social determinants of hysterectomy through in-depth qualitative research. Initial findings suggest that a high burden of untreated gynaecological morbidity, the lack of primary gynaecological care, treatment practices in both the government and private sectors, and women's demand for the procedure also contribute to the incidence of hysterectomy in both insured and uninsured women.

Why higher hospitalisation?

In the absence of strong evidence that i) having insurance promotes hospitalisation for common illnesses ii) insurance coverage is the primary driver of unnecessary hysterectomy, we explore other possible explanations for higher inpatient admission amongst the insured. One well-established interpretation in the literature is that CBHI is associated with higher utilisation by removing financial barriers to hospitalisation [221-223, 232]. This could explain why VimoSEWA coverage is associated with higher odds of hospitalisation in this survey, but not previously in the 2001 analysis by Ranson, when cashless admission facilities were not available. Previous research at VimoSEWA indicates that cashless procedures increases claims submissions overall, but does not improve access to hospitalisation for the poorest[237].

A second reason for higher hospitalisation may be that the insured have greater knowledge/confidence in negotiating hospitals, resulting in greater utilisation of inpatient care. Fear of navigating complicated hospital admissions procedures has previously been identified as a barrier to both hospitalisation and claims submission, especially amongst the poorest and those living in rural areas[185]. The greater likelihood of seeking hospitalisation could either be a characteristic of insured women, or a result of being insured.

It is possible that women at ease with health services are more likely to enrol in VimoSEWA in the first place. A higher prevalence of institutional deliveries – a service not covered by VimoSEWA – underscores this possibility. Women insured by a CBHI in South India that covers maternity care were twice as likely to deliver in an institution compared to uninsured women[221], while research in three African countries has found that women CBHI-insured women do not utilise maternal health services at higher rates if they are not included in the scheme coverage[238]. In this context, it is possible that VimoSEWA membership attracts women more likely to use inpatient services, suggesting adverse selection.

Membership in VimoSEWA itself may result in greater negotiating power. Particularly in the surveyed areas, VimoSEWA members are in continued contact with a concentrated force of grassroots SEWA health and insurance workers who live in the community. CHWs regularly accompany SEWA members (not only the insured) to hospitals and facilitate admission when required – ensuring accessibility to hospitalisation and easier navigation of complicated paperwork, even when procedures are not covered by insurance. In addition to CHWs, VimoSEWA members have the added benefit of dedicated insurance workers. Thus it is plausible that insurance coverage results in women being more able, and perhaps more inclined, to seek inpatient care when required.

Apart from the mechanisms above, insurance coverage may trigger a different decision-making process regarding place and type of treatment, both for women and providers. To illustrate, no uninsured women in the survey population reported use of a non-profit trust hospital, compared to 22 percent of the insured, in the past six months.   Since VimoSEWA's cashless procedures are only available at empanelled hospitals, one-third of which are trust hospitals, the insured are encouraged to seek care at specific institutions. If empanelled providers are incentivised by guaranteed revenue from insured patients, they may provide advice that promotes hospitalisation. Further research is required to explore the treatment decision-making process, and the role, if any, played by moral hazard.

Study limitations

The research questions addressed arose directly from our experience working with SEWA Health and VimoSEWA; these findings are likely to resonate with both managers and researchers linked to CBHI schemes in low-income settings.   Because VimoSEWA's primary policyholders are women, we did not assess gender differentials or the effect of a women-centred scheme on rationing of health care within the household. As in most household surveys, our analysis is limited by a reliance on self-reported morbidity [229, 230]. We confirmed that the pattern of hospitalisation reasons reported by insured women matched that of the VimoSEWA claims database. However, if rates of self-reported morbidity were inaccurate, our analysis may have masked an association of recent morbidity with insurance coverage. Accordingly, our understanding of the pathways associated with greater hospitalisation amongst insured women would change.

If insured women had better recall of hospitalisation in the past six months due to interaction with VimoSEWA, we may have underestimated, or inaccurately categorised reasons for, hospitalisation amongst the uninsured. Lastly, this cross-sectional analysis is limited by an inability to capture unobservable characteristics or omitted variables that may differ systematically between the insured and uninsured; our findings may be biased accordingly.

Conclusion

From the perspective of a CBHI, increased hospitalisation across a wide range of conditions may reflect the mission to increase access to care. From a public health perspective, however, our findings are of concern. Why is hospitalisation for fever, diarrhoea and gastroenteritis amongst adult women common in the first place? Poor sanitation and limited preventive health practices result in widespread, persistent waterborne ailments. The failure of outpatient care, as indicated by qualitative findings, eventually leads insured women who can seek hospitalisation to do so, in hopes of more effective treatment. In this scenario, insurance appears to compensate for weaknesses in the health system, albeit at a cost to women. Without preventive health measures and quality outpatient care, these illness patterns are likely to persist – and should be of concern both to health policymakers and CBHIs.

Similarly, hysterectomy amongst insured and uninsured women in their mid-thirties is symptomatic of major gaps in the health system, as well as attitudes towards intervention in women’s bodies. Lack of gynaecological care at the primary level, poor knowledge of side effects, provider attitudes that encourage intervention and sociocultural factors all likely play a role in promoting hysterectomy as a common, first-line gynaecological treatment. While insurance, particularly packages with larger coverage than VimoSEWA may facilitate medically unnecessary hysterectomies, the comparable prevalence in uninsured women calls attention to the lack of reproductive health care and underlying determinants of women's health in general.

Lastly, if the insured indeed enjoy better access to treatment, it is unclear whether they also enjoy higher quality health care or better health outcomes than those without health insurance. Based on our findings, morbidity patterns and outpatient care are similar up until the point of hospitalisation – but there is no indication of whether higher inpatient admission results in better long term health. Thus far, evaluations of CBHI as well as larger social insurance schemes have focused on the quantitative increase in utilisation and financial security afforded by coverage, with limited assessment of the associated effects on health[28, 211, 220]. Encouragingly, a recent study in Burkina Faso has investigated the association of CBHI coverage with mortality outcomes [239]. As publicly-funded health insurance schemes such as Rashtriya Swasthya Bima Yojana (RSBY) expand in India and other developing countries, population health needs, access to quality primary care and longitudinal, health outcomes research deserve consideration in program and evaluation design.

Competing interests

The authors declare that they have no competing interests.

Authors' contributions

SD and AM conceived the study, and participated in its design and implementation. SD performed the statistical analysis and drafted the manuscript. TS participated in the study design and implementation. SC guided the statistical analyses and drafting of the manuscript. All authors read and approved the final manuscript.

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Chapter VI. Intervention Evaluation

I. Effect of the health education intervention on health insurance claims rates

Introduction

This section presents the results of the trial's primary outcome, health insurance claims rates for diarrhoea, fever and hysterectomy. The study hypothesised that a CHW-led health education intervention would decrease rates of claims submission by VimoSEWA-insured adult women for these three conditions.

Methods

This analysis was based on membership and claims information routinely collected by VimoSEWA. Statistical methods accounted for the study's cluster randomised design to examine the effect of the intervention on claims rates for the three conditions. Crude rate differences were calculated using both individual data and cluster level summaries. A random effects regression model was fitted using individual data, adjusted for baseline cluster claims rates, insurance status and urban/rural location. Analysis of variance was conducted on cluster level summaries to check the robustness of effect estimates. The baseline analysis utilised membership and submitted claims for a pre-intervention period from January 2009 to May 2010. Health education sessions were initiated in June 2010, with a three month intervention roll-out phase during the monsoon season. Claims submitted from September 2010 till February 2012 were included in the intervention analysis. A detailed description of data sources and methods is found in Chapter IV.

Results

A total of 3,558 women who were resident in the study area were insured by VimoSEWA at some point in the pre-intervention period (Table 6.1). Based on the demographic characteristics recorded in the VimoSEWA database, intervention and control arms were generally balanced, with the exception of differences in the proportions of agricultural and home-based workers. The majority of women (65% intervention, 71% control) were insured for less than one year of the pre-intervention period, indicating that they did not renew membership for two consecutive years. A higher proportion of urban women (42%) renewed compared to rural members (24%).

***Table 6.1 Overview of pre-intervention VimoSEWA membership and demographic variables* (Jan 2009-May 2010)**

	Intervention	**Control**
Total members	1,839	1,719
Total person-time	1,439	1,255
Mean person-time per woman	0.78	0.73
Demographic variables		
Mean age	37.7	37.1
% married	83.8	85.3
% widowed	10.1	9.4
Occupation		
% agricultural	34.8	44.7
% service	37.3	36.5
% home-based	17.7	10.7
% unemployed	10.1	8.0

There were 389 hospitalisation claims in the pre-intervention period, 37% of which were for diarrhoea, fever/malaria or hysterectomy (Table 6.2). Claims rates based on individual-level data and cluster summaries were similar (5.4 and 5.3 per 100 person-years). Claims rates were slightly higher in the intervention arm compared to the control arm (5.7 vs. 5.0 per 100 person-years). Rural women had a higher rate of claims than urban women, (6.0 versus 4.9), though the difference was not statistically significant (p=0.30). As cluster-level claim rates appeared approximately normally distributed (Figure 6.1) and two clusters had zero claims for the three conditions (Annex 9), the rates were not transformed to a logarithmic scale. The between cluster coefficient of variation *k* in claims rates, estimated using baseline data was 0.46 (urban) and 0.66 (rural).

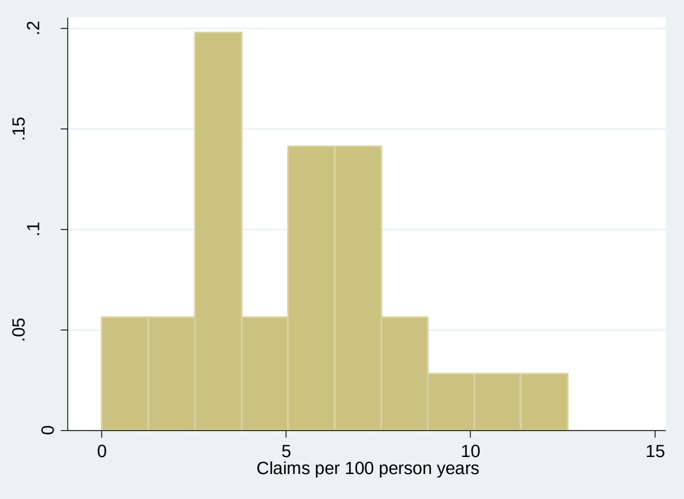
Table 6.2 Summary of baseline claims data, by treatment arm

	Total	**Intervention**	**Control**
Number of clusters	28	14	14
Total claims	375	186	189
Claims - 3 conditions	145	82	63
Total person-years	2,694	1,439	1,255
Individual-level data			
Overall rate/100 p-years	5.38	5.70	5.02
Cluster summaries			
Mean of cluster rates	5.28	5.80	4.80

Table 6.3 Baseline claims data, by urban/rural location

	Total	**Urban**	**Rural**
Number of clusters	28	12	16
Total claims	375	211	164
Claims - 3 conditions	145	71	74
Total person-years	2694	1456	1238
Individual-level data			
Claims rate/100 p-years	5.38	4.88	5.97
Cluster summaries			
Mean of cluster rates	5.28	4.58	5.80
Urban-rural comparison			
Rate difference	-1.22		
95% CI	(-3.62,1.17)		
p value	0.30		

Figure 6.1 Distribution of baseline claims rates in 28 clusters



A total of 3,340 women who were resident in the study area were insured at some time during the 18 month intervention period (Table 6.4). As at baseline, mean insured person-time per woman was less than one year over the 18 month period, in both intervention (0.81) and control (0.79) areas. Women submitted 140 claims for the three conditions over the study period, with a slightly higher claims rate in the intervention arm, 5.5, compared to 5.0 in control clusters (per 100-person years) (Table 6.5). Fitting a random effects model to individual-level data, the estimated rate ratio, adjusted for location and cluster-level baseline claims rate was 1.03 (95% CI: 0.81-1.30, p=0.81). There was no evidence that the effect of the intervention differed between rural and urban areas (test of effect modification (p=0.84). A test of clustering did not indicate evidence of between cluster variation in claims rates (p=0.23). To confirm the robustness of the analysis based on individual-level data, an analysis based on cluster level summaries was also performed. This resulted in similar estimates to the random effects analysis using individual data (Tables 6.6, 6.7). The distribution of claims rates is displayed in Figure 6.2.

Table 6.4 VimoSEWA membership during the intervention period (9/2010-2/2012)

	Intervention	**Control**
Total members	1,780	1,560
Total person-years	1,436	1,227
Mean person-years per woman	0.81	0.79

Figure 6.2 Distribution of claims rates by treatment arm

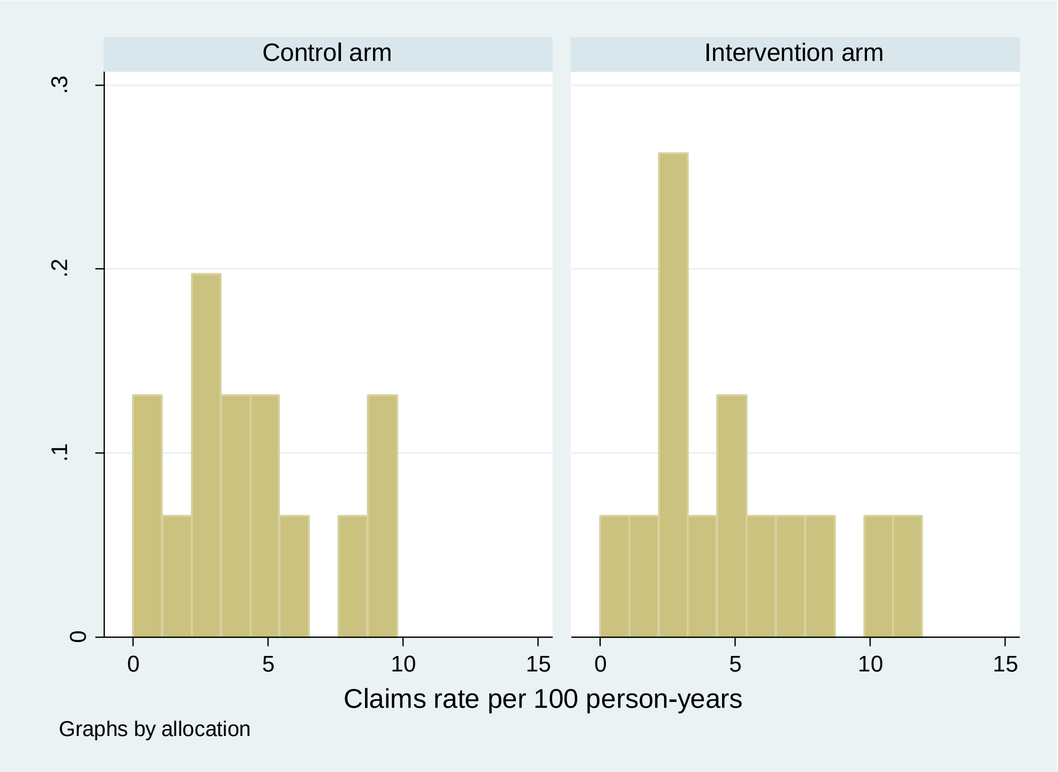


Table 6.5 Estimates of the effect of the intervention on claim rates for three focus conditions using individual-level data, Poisson regression random effects model

	Intervention arm	**Control arm**	**Effect estimate**	**95% CI**
Number of clusters	14	14		
Total claims	195	167		
Total claims for 3 conditions	79	61		
Total person-years	1,756	1,227		
Claims rate/100 person-years	5.50	5.04		
Unadjusted analysis				
Rate ratio			1.10	(0.78,1.54)
p value			0.60	
*Adjusted analysis**				
Rate ratio			1.03	(0.81,1.30)
p value			0.81	

*Adjusted for urban/rural location and cluster-level baseline claims rate

Table 6.6 Estimates of intervention effect using cluster level summaries

	Intervention arm	**Control arm**	**Effect estimates**	**95% CI**
Number of clusters	14	14		
Total claims for 3 conditions	79	61		
Total person-years	1,756	1,227		
Unadjusted analysis				
Mean of cluster rates	4.96	4.27		
SD of cluster rates	3.08	3.08		
Rate difference(/100 p-years)			0.69	(-1.70,3.08)
p value			0.56	
Rate ratio			1.16	(0.70,1.93)
p value			0.82	
*Adjusted analysis**				
Rate difference(/100 p-years)			0.13	(-1.93,2.20)
p value			0.90	

*Adjusted for urban/rural location and baseline rate, using analysis of variance

Table 6.7 Comparison of unadjusted effect estimates derived using random effects model with individual data and analysis of variance using cluster-level summaries

	Poisson Regression Random Effects	**Cluster-level analysis of variance**
Unadjusted analysis		
Rate ratio	1.10	1.16
95% CI	(0.78,1.54)	(0.70,1.93)
p-value	0.60	0.56

II. Effect of the health education intervention on hospitalisation rates amongst insured and uninsured adult women

Introduction

This analysis examines whether the community health intervention had an effect on hospitalisation and compares outcomes based on insurance status. Before and during the intervention, repeated household surveys were conducted to collect information on demographic characteristics, morbidity and treatment-seeking behaviour among both insured and uninsured women in the study area.

Methods

A sample of 35 insured and 35 uninsured women were selected per cluster; a total of 1,980 households were sampled across 28 clusters. Insured women were selected from the VimoSEWA member database, and uninsured women were sampled from household lists compiled in CHW work areas. A baseline survey was conducted from January to March 2010, followed by three survey rounds at six-month intervals over the course of the 18-month intervention. Women who were insured at baseline were considered insured throughout for the initial analysis. Separate analyses were conducted based on reported insurance status in subsequent rounds.

The statistical analysis adopted an intent-to-treat approach that accounted for the cluster randomisation. Assuming that fourteen clusters per arm were sufficient, random effects regression models were first fitted with individual-level data. These analyses were checked for robustness with effect estimates produced using analysis of variance of cluster-level summaries. The primary analysis adjusted for rural/urban location, insurance status, cluster level baseline rates and survey round. Sensitivity analyses adjusted for imbalanced variables identified at baseline. A detailed description of the household surveys and statistical methods is presented in Chapter IV.

Results

A total of 1,934 adult women were surveyed at baseline (Table 6.8). Attrition increased at each round, primarily due to demolition of slum pockets in Ahmedabad city and rural pre-monsoon seasonal migration in rounds 3 and 4 (Table 6.9). A total of 1,616 households were surveyed in round 4 (Figure 6.3).

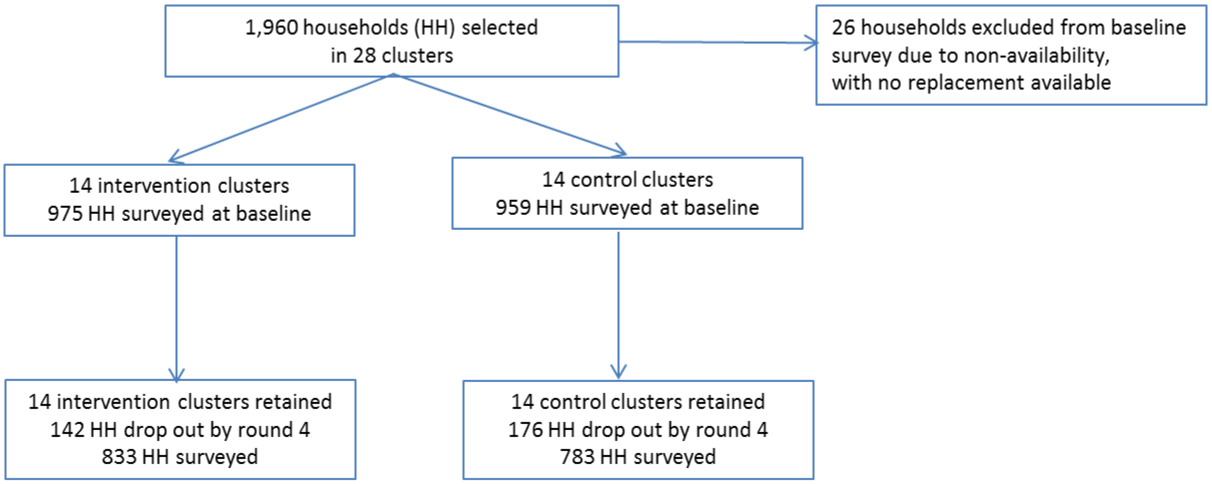
Table 6.8   Households surveyed, by round

	Baseline	Round 2		Round 3		Round 4	
	Surveyed	Surveyed	Dropout	Surveyed	Dropout	Surveyed	Dropout
Intervention	975	941	34	931	44	833	142
Control	959	945	14	885	74	783	176
Total	1934	1886	48	1816	118	1616	318

Table 6.9 Reasons for loss to follow-up, Rounds 2-4

	Round 2		Round 3		Round 4	
Reason	**Rural**	**Urban**	**Rural**	**Urban**	**Rural**	**Urban**
Migrated/demolition	4	32	12	82	54	185
Not present	0	2	2	1	5	4
Refused	1	3	7	7	36	19
Death	3	3	3	4	7	8
Total	8	40	24	94	102	216

Figure 6.3 Cluster and survey participation



Baseline demographic characteristics were largely balanced across intervention and control arms, with similar baseline rates of reported morbidity and hospitalisation (Table 6.10). However, latrine ownership was higher among intervention households than control households. Amongst insured women, a higher proportion had attended school and a higher proportion lived in a concrete home in the intervention arm.

Table 6.10 Baseline demographic characteristics in control and intervention arms, by insurance status

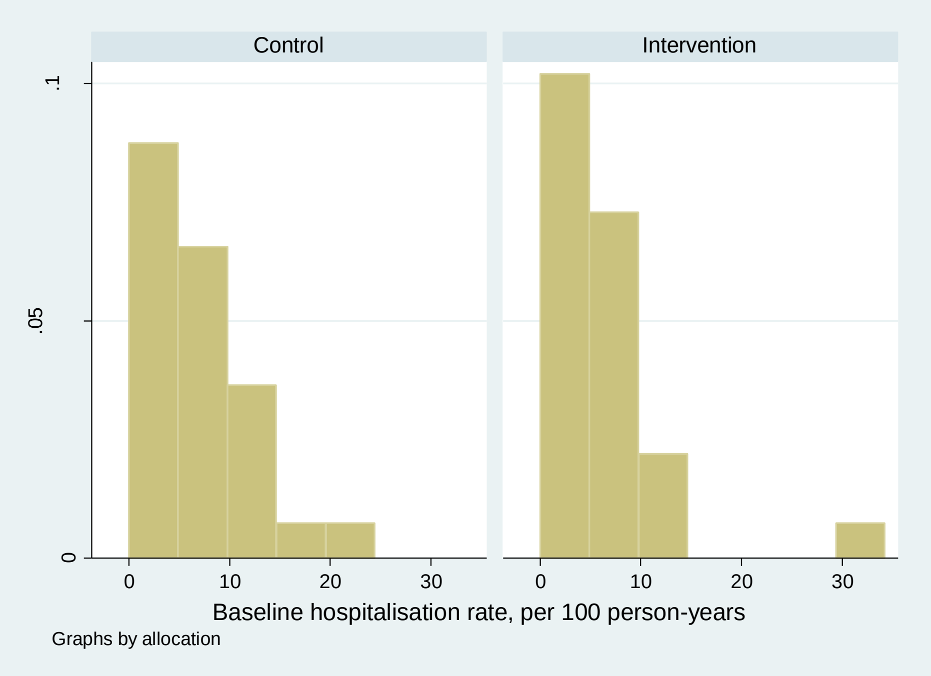
Variable	**Uninsured n=980**		**Insured n=954**	
	Control n=490	**Intervention n=490**	**Control n=469**	**Intervention n=485**
Mean age in years	35.9	37.0	39.1	39.8
Mean HH Size	5.8	5.8	5.8	6.0
% concrete home	24.9	26.1	24.1	35.1
% with toilet	51.8	60.0	46.1	63.1
% individual drinking tap	75.5	76.7	73.3	76.7
Mean annual income (INR)	80,812	82,707	76,637	82,747
Mean age respondent	35.9	37.0	39.1	39.8
% never attended school	53.9	50.2	62.7	50.1
% respondents reported Illness, in past 30 days	12.0	13.5	19.2	15.9
% respondents reported hospitalisation, in past 6 months	2.9	3.1	7.7	7.0

At baseline, the three focus conditions – fever/malaria, diarrhoeal illness and hysterectomy – comprised approximately half of all hospitalisations amongst both insured and uninsured women (48 of 99 hospitalisations) (Table 6.11). Of the three conditions, hysterectomy was the most common reason for hospitalisation. Hospitalisation rates among insured women were approximately double those among the uninsured. The distributions of cluster-level hospitalisation rates were positively skewed in both arms (Figure 6.4), but rates were not log transformed as eight clusters had zero hospitalisations for the three conditions (Annex 10). The between cluster coefficient of variation *k,* estimated using baseline data, was 0.49 (urban) and 0.56 (rural).

Table 6.11 Baseline hospitalisations in 28 clusters, amongst uninsured and insured women

Baseline hospitalisations and hospitalisation rates in 28 clusters									
	All hosp	**3 conditions**	**Fever**	**Diarrhoeal**	**Hysterectomy**	**% of hosp, 3 conditions**	**p-years**	**All hosp rate (per 100 p-yrs)**	**3 condition hosp rate**
Intervention, uninsured									
Urban	8	3	1	2	1	37.5	105.0	7.6	2.9
Rural	7	4	1	1	1	57.1	140.0	5.0	2.9
Overall	**15**	**7**	**2**	**3**	**2**	**46.7**	**245.0**	**6.1**	**2.9**
Control, uninsured									
Urban	3	1	0	0	1	33.3	105.0	2.9	1.0
Rural	11	7	0	0	7	63.6	140.0	7.9	5.0
Overall	**14**	**8**	**0**	**0**	**8**	**57.1**	**245.0**	**5.7**	**3.3**
Intervention, insured									
Urban	11	4	1	1	2	36.4	103.0	10.7	3.9
Rural	23	11	2	4	5	47.8	139.5	16.5	7.9
Overall	**34**	**15**	**3**	**5**	**7**	**44.1**	**242.5**	**14.0**	**6.2**
Control, insured									
Urban	13	7	6	0	1	53.8	95.0	13.7	7.4
Rural	23	11	1	2	8	47.8	139.5	16.5	7.9
Overall	**36**	**18**	**7**	**2**	**9**	**50.0**	**234.5**	**15.4**	**7.7**

Figure 6.4 ***Distribution of cluster-level baseline hospitalisation rates for 3 conditions*****, by allocation**



Total hospitalisation episodes are reported in Table 6.12. The overall post-intervention hospitalisation rate in the intervention arm was 2.7/100 person-years, compared to 2.4/100 person-years in the control arm. The crude rate ratio was 1.11 (CI: 0.61, 2.00; p=0.74). Among initially insured women, hospitalisation rates decreased by approximately half in both intervention and control areas compared with pre-intervention rates (Tables 6.13, 6.14), with smaller decreases observed among uninsured women.

Table 6.12 Total hospitalisation episodes

	Intervention		**Control**		**Total**	
Round	**All conditions**	**3 Focus**	**All conditions**	**3 Focus**	**All conditions**	**3 Focus**
Baseline	49	22	50	26	99	48
Round 2	47	16	35	14	82	30
Round 3	28	14	24	10	52	24
Round 4	17	6	25	7	42	13
Total	**141**	**58**	**134**	**57**	**275**	**115**

Table 6.13 Post-intervention hospitalisation rates in 28 clusters, survey rounds 2-4

Post-intervention hospitalisation rates in 28 clusters	All hosp	3 conditions	Fever/Malaria	Diarrhoeal	Hysterectomy	% of hosp, 3 conditions	p-years	All hosp rate (per 100 p-ears)	3 condition hosp rate
Intervention, uninsured									
Urban	16	10	0	5	5	62.5	267	6.0	3.7
Rural	24	5	1	0	4	20.8	393	6.1	1.3
Overall	**40**	**15**	**1**	**5**	**9**	**37.5**	**660**	**6.1**	**2.3**
Control, uninsured									
Urban	10	6	0	2	4	60.0	266.5	3.8	2.3
Rural	25	9	1	1	7	37.5	401.5	6.0	2.2
Overall	**35**	**15**	**1**	**3**	**11**	**44.1**	**668.0**	**5.1**	**2.2**
Intervention, insured									
Urban	13	5	3	0	2	38.5	285.0	4.6	1.8
Rural	39	16	2	7	7	41.0	410.0	9.5	3.9
Overall	**52**	**21**	**5**	**7**	**9**	**40.4**	**695.0**	**7.5**	**3.0**
Control, insured									
Urban	16	8	3	3	2	50.0	209.5	7.6	3.8
Rural	33	8	1	2	5	24.2	401.0	8.2	2.0
Overall	**49**	**16**	**4**	**5**	**7**	**32.7**	**610.5**	**8.0**	**2.6**

***Table 6.14 Hospitalisation rates for 3 conditions in insured and uninsured women*, pre- and post-intervention (95% CI) using individual data**

	Insured		**Uninsured**		**Overall**	
Time period	Intervention	Control	Intervention	Control	Intervention	Control
Baseline	6.19 (3.09,9.28)	7.67 (4.19,11.17)	2.86 (0.75,4.97)	3.27 (1.01,5.52)	4.51 (2.65,6.38)	5.42 (3.36,7.48)
Post-intervention	3.02 (1.73,4.31)	2.67 (1.41,3.93)	2.43 (1.25,3.62)	2.24 (1.11, 3.36)	2.74 (1.86,3.62)	2.44 (1.62,3.29)

A random effects regression analysis adjusted for initial insurance status, location, survey round and baseline hospitalisation rates provided no evidence for an intervention effect on hospitalisation for the three conditions (RR=1.05, CI: 0.58, 1.90; p=0.88) (Table 6.15). There was no evidence of effect modification by insurance status (p=0.91). Adjusting for imbalanced demographic characteristics identified at baseline and other potential covariates did not result in an important change in the point estimate or improve statistical efficiency (Table 6.16). Cluster level summaries provide unadjusted effect estimates similar to those obtained using individual data (Table 6.17). The nonparametric Wilcoxon rank sum test produced a p value (0.95) similar to the p value (0.80) derived from a *t-test* applied to the cluster-level rates.

Table 6.15 Estimates of intervention effect using Poisson regression with random effects, rounds 2-4

Poisson regression using random effects, individual data				
	Intervention arm	**Control arm**	**Effect estimate**	**95% CI**
Number of clusters	14	14		
Total episodes of 3 conditions	36	31		
Total person-years	1,355	1,279		
Hospitalisation rate/100 person-years	2.66	2.42		
Unadjusted analysis				
Rate ratio			1.11	(0.62,1.99)
p value				0.72
*Adjusted analysis**				
Rate ratio			1.05	(0.58,1.90)
p value				0.88

*Adjusted for insurance status, location, survey round and cluster level baseline rate

Table 6.16 Estimates of intervention effect, adjusted for imbalanced baseline characteristics

	Effect Estimate	95% CI
*Adjusted (toilet) **		
Rate ratio	1.06	(0.58,1.94)
p value		0.88
*Adjusted (education: none vs. any)***		
Rate ratio	1.13	(0.61,2.06)
p value	.	0.32
*Adjusted (income)****		
Rate ratio	1.06	(0.60,1.90)
p value		0.48
*Adjusted (concrete home)*****		
Rate ratio	1.08	(0.59,1.96)
p value		0.39

*Adjusted for insurance status, location, survey round, baseline hospitalisation rates and toilet
**Adjusted for insurance status, location, survey round, baseline hospitalisation and education level
***Adjusted for insurance status, location, survey round, baseline hospitalisation and income
**** Adjusted for insurance status, location, survey round, baseline hospitalisation and housing type

Table 6.17 Estimates of intervention effect on hospitalisation for 3 conditions, cluster level summaries

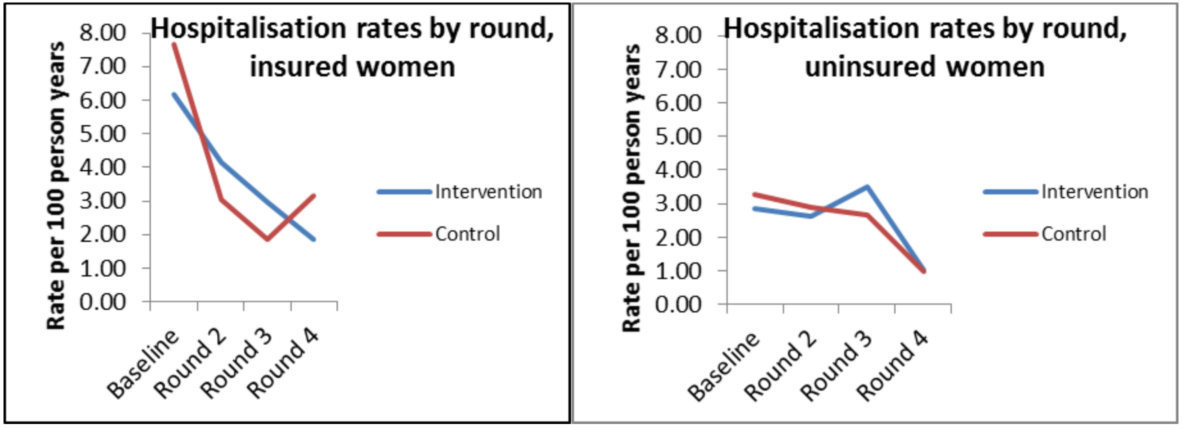
	Intervention		Control
Number of clusters	14		14
Total hospitalisation for 3 conditions	36		31
Total person-years	1,355		1,279
Unadjusted analysis			
Mean of cluster rates	2.74		2.56
SD of cluster rates	3.08		2.09
Rate difference(/100 p-years)		0.18	
95% CI		(-1.30,1.65)	
p value		0.80	
Rate ratio		1.07	
95% CI		(0.47,2.30)	
p value		0.94	
*Adjusted analysis**			
Rate difference(/100 p-years)		-0.02	
95% CI		(-1.31,1.28)	
p value		0.98	

* Adjusted for insurance status, location, survey round and cluster level baseline rate

Hospitalisation and insurance status over the intervention period

Households were recruited based on their insurance status at baseline, and this status was utilised in the initial analysis reported above. Hospitalisation rates amongst households insured at baseline decreased considerably over rounds 2 to 4. Rates in uninsured women remained steady until round 3, and then decreased substantially in round 4 (Figure 6.5).

Figure 6.5 Hospitalisation rates by survey round, using insurance status at baseline



Households were surveyed on their current insurance status in rounds 3 and 4, though not round 2. As presented in Table 6.18, the majority of initially insured households, sampled from VimoSEWA's database at baseline, did not report being insured by round 4 (34% insured). In an analysis of hospitalisations using only rounds 3 and 4 and reported insurance status, rather than status at baseline, there is still no evidence of an intervention effect (RR=1.03, CI: 0.54,1.94; p=0.94) (Table 6.19) or for effect modifcation by insurance status (p=0.56). A sensitivity analysis dropping round 4 and including data for rounds 2 (insurance status at baseline) and round 3 (reported insurance status) resulted in slightly different effect estimates, but did not provide evidence of an intervention effect (Table 6.19).

Table 6.18 Reported insurance status compared with baseline status (rounds 3 and 4)

	Reported Status, Round 3				**Reported Status, Round 4**			
Baseline	Insured	Uninsured	Don't know	Drop out	Insured	Uninsured	Don't know	Drop out
Insured (954 HH)	853	73	1	27	289	515	12	138
Uninsured (980 HH)	30	877	2	71	30	759	11	180

Table 6.19 Poisson regression using random effects, rounds 3 and 4 using reported insurance status

	Intervention arm	**Control arm**	**Effect estimate**	**95% CI**
Number of clusters	14	14		
Total episodes for 3 conditions	20	17		
Total person-years	878	825		
Hosp rate/100 person-years	2.08	2.06		
Unadjusted analysis				
Rate ratio			1.10	(0.59,2.07)
p value				0.76
*Adjusted analysis, rounds 3,4**				
Rate ratio			1.03	(0.54,1.94)
p value				0.94
*Adjusted analysis, rounds 2,3**				
Rate ratio			1.21	(0.60,2.43)
p value				0.59

*Adjusted for baseline hospitalisation rate, reported insurance status, location and survey round

Hospitalisation rates based on reported, rather than baseline, insurance status also decreased amongst the insured over the course of the survey (Table 6.20). A similar decrease in hospitalisation rates amongst insured women was not seen in the claims database (Table 6.21).

Table 6.20 Hospitalisation rates by round, using reported status and individual data

	Insured		**Uninsured**	
	Intervention	Control	Intervention	Control
Baseline	6.19 (1.57)	7.68 (1.78)	2.86 (1.07)	2.27 (1.15)
Round 3	2.95 (1.11)	1.85 (0.92)	3.51 (1.23)	2.65 (1.08)
Round 4	1.84 (0.92)	3.14 (1.27)	1.00 (0.71)	1.0 (0.70)

*Standard error is reported rather than confidence intervals, as the low number of events per round resulted in a negative value for the lower bound of 95% confidence intervals.

Table 6.21 Comparison of hospitalisation rates for 3 conditions among insured women using claims database and survey (95% CI)

	Intervention		**Control**	
	Baseline	Post-int	Baseline	Post-int
Claims database	5.76 (4.21,7.31)	4.96 (3.18,6.74)	4.78 (2.98,6.59)	4.27 (2.49,6.05)
Survey*	6.19 (3.09,9.28)	3.02 (1.74,4.31)	7.67 (4.19,11.17)	2.67(1.41,3.93)

*Post-intervention data from rounds 3 and 4

III. Effect of the health education intervention on 30-day morbidity rates amongst insured and uninsured adult women

Introduction

This section examines whether the community health intervention had an effect on morbidity rates for diarrhoea, fever/malaria and gynaecological conditions and compares outcomes based on insurance status. Information on morbidity episodes experienced in the past 30 days was collected in the household survey.

Methods

Statistical methods were similar to those utilised in the analysis of hospitalisation rates in Section II. Crude estimates were adjusted for rural/urban location, insurance status, survey round and cluster level baseline morbidity rates. A regression model with random effects was fitted using individual-level data, followed by analysis using cluster level summaries to check the robustness of the model.

Results

Fever/malaria, diarrhoeal illness and gynaecological conditions comprised between 35-56% of reported morbidity in the past 30 days at baseline (Table 6.22), with very few instances of gynaecological morbidity reported. Cluster-level morbidity rates were not normally distributed in either arm (Figure 6.6), but rates were not log transformed as one cluster had no episodes of any of the three conditions (Annex 11). The between cluster variation coefficient *k,* calculated using baseline data, was 0.40 (urban) and 0.19 (rural).

Table 6.22 Baseline 30 day-morbidity rates in 28 clusters

Baseline morbidity rates in 28 clusters									
	All morbidity episodes	3 conditions	Fever	Diarrhoeal	Gynaeco-logical	% of morbidity, 3 conditions	p-months	All morbidity rate (/100 p-months)	3 condition morbidity rate
Intervention, uninsured									
Urban	39	15	13	1	1	38.5	209.0	18.7	7.2
Rural	27	8	7	1	0	29.6	280.0	9.6	2.9
Overall	**66**	**23**	**20**	**2**	**1**	**34.8**	**489.0**	**13.5**	**4.7**
Control, uninsured									
Urban	34	17	10	5	2	50.0	210.0	16.2	8.1
Rural	25	16	13	1	2	64.0	280.0	8.9	5.7
Overall	**59**	**33**	**23**	**6**	**4**	**55.9**	**490.0**	**12.0**	**6.7**
Intervention, insured									
Urban	43	17	14	3	0	39.5	206.0	20.9	8.3
Rural	34	17	10	3	4	50.0	279.0	12.2	6.1
Overall	**77**	**34**	**24**	**6**	**4**	**44.2**	**485.0**	**15.9**	**7.0**
Control, insured									
Urban	44	20	16	2	1	45.5	190.0	23.2	10.5
Rural	46	18	14	3	1	39.1	279.0	16.5	6.5
Overall	**90**	**38**	**30**	**5**	**2**	**42.2**	**469.0**	**19.2**	**8.1**

Reported morbidity rates were slightly higher amongst insured than uninsured women at baseline; however, this difference may be due to chance, as discussed in Chapter V (adjusted OR = 1.2, 95% ci: 0.9,1.7; p=0.23). Reported morbidity rates were higher amongst insured than uninsured women after the intervention, but this also may be due to chance (Tables 6.23-6.25).

Figure 6.6 Distribution of cluster-level morbidity rates, per 100 person-months

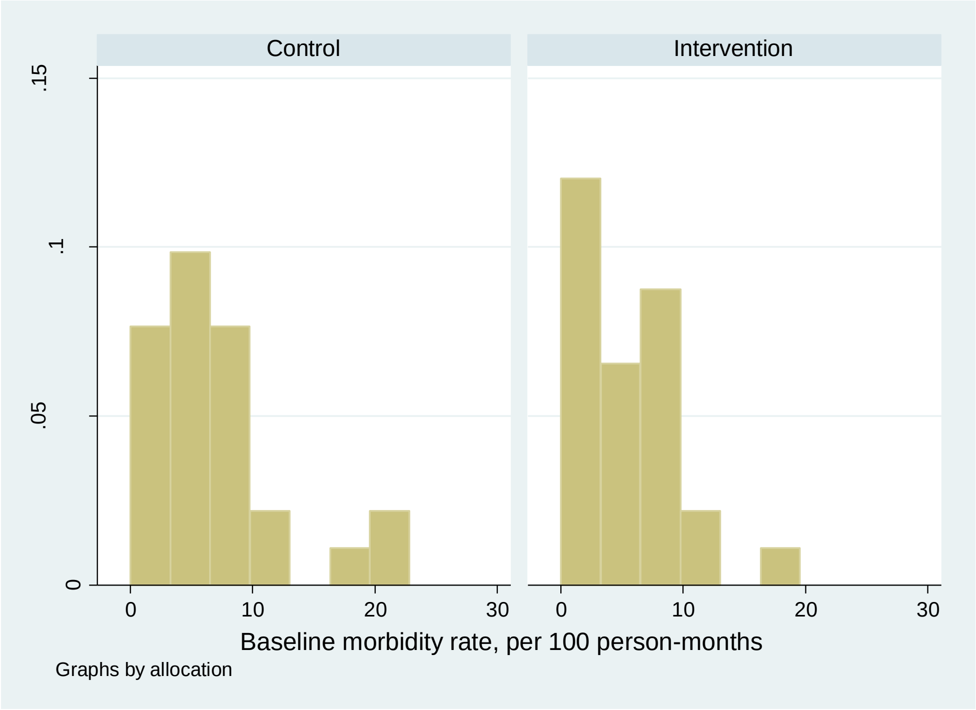


Table 6.23 Total morbidity episodes, by round

	Intervention		Control		Total	
Round	**All conditions**	**3 Focus**	**All conditions**	**3 Focus**	**All conditions**	**3 Focus**
Baseline	132	54	140	69	272	123
Round 2	147	63	151	60	298	123
Round 3	113	66	98	61	211	127
Round 4	57	28	42	19	99	47
Total	**449**	**211**	**431**	**209**	**880**	**420**

Table 6.24 Post-intervention morbidity rates, Survey rounds 2-4

Post-intervention morbidity rates in 28 clusters									
	All morbidity episodes	**3 conditions**	**Fever**	**Diarrhoeal**	**Gynaeco-logical**	**% of morbidity, 3 conditions**	**p-months**	**All morbidity rate (/100 p-months)**	**3 condition morbidity rate**
Intervention, uninsured									
Urban	73	34	23	11	0	46.6	529	13.8	6.4
Rural	64	28	21	7	0	43.8	786	8.1	3.6
Overall	**137**	**62**	**44**	**18**	**0**	**45.3**	**1315**	**10.4**	**4.7**
Control, uninsured									
Urban	62	30	25	4	1	48.4	533	11.6	5.6
Rural	62	32	24	7	1	51.6	807	7.7	4.0
Overall	**124**	**62**	**49**	**11**	**2**	**50.0**	**1340**	**9.3**	**4.6**
Intervention, insured									
Urban	90	43	36	6	1	47.8	570	15.8	7.5
Rural	90	52	38	13	1	57.8	820	11.0	6.3
Overall	**180**	**95**	**74**	**19**	**2**	**52.8**	**1390**	**12.9**	**6.8**
Control, insured									
Urban	84	43	39	4	0	51.2	472	17.8	9.1
Rural	83	35	29	6	0	42.2	794	10.5	4.4
Overall	**167**	**78**	**68**	**10**	**0**	**46.7**	**1266**	**13.2**	**6.2**

Table 6.25 Summary of 30-day morbidity in insured and uninsured women using individual data (per 100 person-months)

	Insured		**Uninsured**		**Overall**	
	Intervention	Control	Intervention	Control	Intervention	Control
Baseline	7.03 (4.73,9.28)	8.09 (5.62,10.55)	4.70 (2.82,6.58)	6.73 (4.51,8.96)	5.85 (4.38,7.33)	7.40 (5.74,9.05)
Post-intervention	6.83 (5.51,8.16)	6.12 (4.81,7.44)	4.71 (3.57,5.86)	4.63 (3.50,5.76)	5.80 (4.92,6.22)	5.37 (4.49,6.22)

The post-intervention morbidity rate in the intervention area was 5.8/100 person-years, compared to 5.4/100 person-years in the control arm. Fitting a random effects model adjusted for initial insurance status, location, survey round and cluster-level baseline morbidity rate did not provide evidence for an intervention effect on morbidity for the three conditions (Table 6.26). There was also not strong evidence of unexplained between-cluster variation of rates (p=0.34) or of effect modification by insurance status (p=0.54). Adjusting for imbalanced baseline variables did not improve statistical efficiency or change point estimates importantly (Table 6.27). Analyses based on cluster level summaries provide unadjusted effect estimates similar to those obtained using individual data (Table 6.28). The nonparametric Wilcoxon rank sum test provided a p value of 0.63, compared to 0.81 derived from a *t-test* applied to the cluster-level rates.

Table 6.26 Estimates of intervention effect on morbidity, Poison regression random effects

Poisson regression using random effects, individual data				
	Intervention arm	**Control arm**	**Effect estimate**	**95% CI**
Number of clusters	14	14		
Total morbidity episodes, 3 conditions	157	140		
Total person-months	2,705	2,606		
Morbidity rate/100 person-months	5.80	5.37		
Unadjusted analysis				
Rate ratio			1.08	(0.83,1.40)
p value				0.59
*Adjusted analysis**				
Rate ratio			1.06	(0.87,1.28)
p value				0.58

*Adjusted for insurance status, location, survey round and cluster level baseline morbidity rates

Table 6.27 Adjusted estimates of intervention effect, using baseline characteristics

Poisson regression using random effects, individual data	**Effect Estimate**	**95% CI**
*Adjusted (toilet) **		
Rate ratio	1.07	(0.87,1.30)
p value		0.68
*Adjusted (education: none vs. any)***		
Rate ratio	1.08	(0.73,1.58)
p value		0.50
*Adjusted (income)****		
Rate ratio	1.06	(0.87,1.29)
p value		0.54
*Adjusted (concrete home)*****		
Rate ratio	1.05	(0.86,1.28)
p value		0.59

*Adjusted for insurance status, location, survey round, baseline morbidity rates and latrine
**Adjusted for insurance status, location, survey round, baseline morbidity rates and education level
***Adjusted for insurance status, location, survey round, baseline morbidity rates and income
**** Adjusted for insurance status, location, survey round, baseline morbidity rates and housing

Table 6.28 Estimates of intervention effect on morbidity, cluster summaries

	Intervention	**Control**
Number of clusters	14	14
Total morbidity episodes,3 conditions	157	140
Total person-months	1,447	2,606
Unadjusted analysis		
Mean of cluster rates	5.83	5.64
SD of cluster rates	0.54	0.55
Rate difference(/100 p-years)	0.19	
95% CI	(-1.36,1.74)	
p value	0.81	
Rate ratio	1.03	
95% CI	(0.96,1.11)	
p value	0.65	
*Adjusted analysis**		
Rate difference(/100 p-years)	0.57	
95% CI	(-0.77,1.90)	
p value	0.41	

*Adjusted for location, insurance status, survey round, and baseline morbidity rate

IV. Discussion

Results of the statistical analyses, none of which suggested a positive effect of the intervention, depart from several studies that have reported evidence of an effect of CHW-led group health education on preventive health behaviours and some health outcomes. Evaluations of CHW-led group education in low-income settings have detected evidence of an effect on malaria control efforts and family planning uptake[76-78]. Studies in the United States have reported increased uptake of pap tests, breast cancer screening, lifestyle and behavioural changes amongst women belonging to ethnic minority groups in the United States [69, 72-75]. A complex intervention in Pakistan, in which group education was one component, detected an effect on neonatal mortality, while a Bangladeshi study did not report evidence of an effect of CHW-led group education on neonatal mortality[47, 79]. Chapter IX presents a process evaluation that explores why this evaluation did not detect evidence of an effect, both through examination of the intervention processes and comparison with findings in other settings. The section below focuses on the results of the statistical analyses reported in this chapter, followed by discussion of the strengths and limitations of the evaluation design and procedures.

Randomisation

Control and intervention arms were balanced with regards to age, occupational and marital status as recorded in the VimoSEWA member database. Utilising a wider range of demographic characteristics collected in the household survey, intervention and control arms were relatively well balanced, with some exceptions. Insured women in the control arm appeared worse off than insured women in intervention households, with lower education levels, household income, and fewer households with latrines. The proportion of households with a latrine was not balanced across arms for uninsured households either, but income and housing were similar. SEWA has implemented interventions to subsidise latrine construction across pockets of Ahmedabad city since 2005. Accordingly, latrine ownership may not be a consistent indicator of socioeconomic status in this population, though it may influence health status. The intervention outcomes – reported morbidity and hospitalisation rates and claims rates – were similar across arms at baseline for both insured and uninsured households, suggesting that randomisation achieved, in large part, its intended goal.

Pre-intervention membership, claims, hospitalisation and morbidity

In both the claims database and survey, mean person-time per insured woman during the period of interest was less than one year. Upfront payment of the annual fee for new members and renewals of individual products (life, asset or health) and bundled schemes that include a combination are processed monthly. Renewal rates are calculated annually, and not disaggregated by product. VimoSEWA reported an overall renewal rate of 60% before the intervention. Analysis of baseline membership data suggested that 1/3 of women renewed membership in a health scheme for two consecutive years. This observed renewal rate is consistent with earlier data from VimoSEWA indicating 22-30% renewal rates, when all products included health, as opposed to current policies that allow for single product purchase. Although VimoSEWA has implemented several measures to improve renewal, retention of members remains a challenge.

Before the intervention, 39% of all adult women claims in the VimoSEWA database were for the three focus conditions, responsible for 5.4 claims/100 person-years – confirming that a health intervention aimed at these conditions could potentially address a substantial proportion of claims. Similarly, approximately one-half of all reported hospitalisations amongst insured and uninsured women in the baseline survey were for the three focus conditions, of which hysterectomy comprised the largest proportion. Previous research at VimoSEWA has examined urban and rural areas separately, given differences in availability of health care services, distances to hospital and demographic differences[240]. Accordingly, randomisation was stratified on rural/urban location in this study as well. In this analysis, overall claims rates were higher in urban than rural areas, but this difference could have arisen by chance. Rural areas were observed to have a higher proportion of claims for the three focus conditions.

Hospitalisation rates at baseline were approximately twice as high amongst insured women compared to uninsured women. For insured women, hospitalisation rates were similar to claims submission rates, suggesting that barriers to claims submission were low. This is a new finding related to scheme management for VimoSEWA, as an earlier study – conducted before cashless reimbursement procedures were introduced – found that the rate of claims submission was considerably lower than hospitalisation rates, due to barriers such as difficulty negotiating claims procedures and paperwork[186].

The reported rates of morbidity in the past 30 days were slightly higher amongst insured women at baseline, which could have been due to chance. Higher reported morbidity could be suggestive of adverse selection into the scheme by women more likely to seek treatment. Fever and diarrhoeal illness comprised one-third to one-half of all reported illness events, with a very low rate of gynaecological morbidity. Given that hysterectomy was a common reason for hospitalisation, it was unclear if women did not experience, or did not report, gynaecological conditions in the same manner as common illnesses such as fever. A summary of seven studies on gynaecological morbidity in India suggested that under-reporting is common in household surveys; they recommend the use of experienced interviewers, the use of in-depth research to elicit perceptions of morbidity and detailed survey questions to improve reporting accuracy[241]. Further, some studies have identified limited consistency between clinical diagnoses and estimates based on self-reported gynaecological morbidity, suggesting that research requires multi-disciplinary approaches to estimate frequency of, and women's experiences with, gynaecological morbidity[241, 242].

Intervention effect

Statistical analyses were conducted using random effects models fitted to individual data, and confirmed with analysis based on cluster-level summaries. Both methods provided very similar results in each analysis, indicating that in this instance 14 clusters per arm appeared adequate to utilise individual data adjusted for clustering. Estimates of k using baseline data indicated different degrees of clustering in rural and urban areas; hence they were presented separately to inform future research. The coefficient k was also calculated using claims, hospitalisation and morbidity data for all conditions (rather than only the three focused on in this trial) to be 0.39, 0.57, and 0.14 for urban rates and 0.74, 0.26, and 0.30 for rural rates of the respective outcomes.

After 18 months of intervention, analysis of VimoSEWA's claims data detected no evidence of an effect on claims for the three focus conditions. Claims rates in intervention and control areas were similar at the end of the intervention and remained similar to those at baseline. Although an effect on membership was not expected, the similarity in mean person-time insured per woman across arms suggests that intensified contact with health workers, who also promote insurance membership, did not have any major effect on renewals.

The trial was designed to detect a 40 percent reduction in claims for the three focus conditions. Though the data do not suggest any effect of the intervention, the wide confidence intervals around the point estimates do not preclude the possibility of a smaller effect. All estimates suggest that any effect is likely to be less than 30 percent. VimoSEWA management had indicated that a reduction lower than 30-40 percent would not have significant financial bearing on the claims ratio, and in particular would not be enough to justify funding an education intervention.

Reported hospitalisation and morbidity rates were also similar in intervention and control areas during and after the 18-month intervention period. Statistical analysis indicated no evidence of an intervention effect on either outcome. Adjusting for *a priori* variables – urban/rural location, insurance status, baseline rates and survey round – as well as those identified at baseline did not change effect estimates importantly. There was also no evidence that the intervention had differential effects in insured and uninsured women, although this analysis had low power.

Insurance coverage and hospitalisation

At baseline, there was strong evidence of an association of insurance membership with increased odds of hospitalisation. Rates amongst insured women were approximately twice those of uninsured women, in both intervention and control arms. Over 18 months, however, hospitalisation rates amongst insured women decreased markedly in both arms. Seasonal variation did not explain this pattern, as rates generally decreased further with each round. Moreover, this decrease over time was not evident in the claims database: claims rates remained steady in both intervention and control areas over the intervention period.

If the intervention had an effect on insured women, but the health education messages were spread through population movement or by CHWs providing similar information in control areas, rates of hospitalisation could have decreased in both arms. In this case, the true effect of the intervention would have been underestimated or masked by contamination. Analysis of implementation processes indicates that contamination by CHWs was unlikely in rural arms, but possible in urban areas (discussed further in Chapter IX). Women associated with VimoSEWA may have met at organisational or community events and shared messages with others not exposed to the intervention. However, the lack of a corresponding decrease in claims rates suggests that contamination through population movement does not explain the decline in reported hospitalisation rates amongst insured women.

A decrease in reported hospitalisation rates, but not in the claims database, could have been a result of changes in insurance status over time amongst surveyed women. Insured women were recruited based on current insurance status before the intervention, with the assumption that the majority would remain insured over most of the study period. However, close to two-thirds of women insured at baseline reported being uninsured by round four, with minimal crossover of women uninsured at recruitment. Accordingly, hospitalisation rates amongst women insured at baseline could have decreased to rates typical of uninsured women when their policies expired. Analysis using reported insurance status in rounds three and four, rather than status at baseline, also indicated a decrease in hospitalisation rates among currently insured women. Thus, while women did change insurance status over the course of the intervention, it does not explain the decrease in reported hospitalisation rates among insured women.

Rates of hospitalisation decreased in both insured and uninsured women by round four, with the exception of an increase amongst insured women in the control arm. With a total of only 14 hospitalisations reported in round four, rate estimates are based on a very small number of episodes in each category. The marked drop in reported hospitalisation episodes from baseline is suggestive of survey fatigue, a known risk in cohort studies[191]. Reported morbidity was also relatively lower in round four in both arms, while the claims database did not reflect any change. By the last survey round, women may have reported no hospitalisations or illness episodes to shorten the interviewer’s visit. Survey fatigue, however, does not explain why the decrease in hospitalisation rates was restricted to insured women in rounds two and three.

Recall error may also explain some of the decrease over time and differences between insured and uninsured women. Insured women may have welcomed the baseline survey as an opportunity to report on insurance utilisation, or, as related by the survey team, as a medium to convey complaints about claims servicing. Thus insured women may have reported events that extended beyond the six month recall period at baseline, while uninsured women had no such incentive. The general consistency of hospitalisation rates at baseline with the claims database, however, limits the likelihood of extensive recall error at baseline as an explanation of the initially higher rate of reported hospitalisation amongst insured women. While the data available do not allow for a firm conclusion, the stability of rates derived from the claims database, compared with increasingly lower reporting of hospitalisation and morbidity, over survey rounds is most consistent with survey fatigue. Change in insurance status and recall error may also partly explain the differential decrease between insured and uninsured women, although the low numbers of reported events prevent further interpretation.

Strengths and limitations

This trial evaluated an add-on education intervention in an ongoing health insurance and CHW programme. A high proportion of hospitalisations in adult women for diarrhoea, fever and hysterectomy was confirmed through both insurance claims and a household survey – indicating that the intervention targeted conditions responsible for a significant proportion of treatment sought by adult women in the study population. Tracking both insured and uninsured women allowed the intervention to be examined from a community perspective, rather than solely for the insurance program.

Implementation of a survey embedded within a community-based organisation helped ensure the representativeness of the sample, as CHW work areas rather than government records were utilised to identify eligible households. Similarly, close collaboration with VimoSEWA and SEWA CHWs ensured that the intervention findings and interpretation of results would be relevant to practice. Lastly, the utilisation of two data sources, a claims database and household survey, offered several lessons for implementation of a community-based trial.

The use of routine VimoSEWA data had several advantages. The analysis of the effect of a health education intervention utilised claims data from the entire insured population, rather than a sample. The data were not compromised by survey fatigue, recall errors or other limitations of self-reporting common in household surveys. Administrative data provided a standardised categorisation of reasons for hospitalisation, as well as detailed information on membership history and product purchase. This analysis also carried no survey costs for 35 months of membership and claims information across 28 clusters. However, the number of clusters, and hence the extent of membership and claims data utilised from the database, was limited by the size of the CHW team available in the study area.

The analysis of the claims database had four potential limitations. One, the heuristic nature of the matching exercise between the VimoSEWA database and the CHW-defined trial clusters may have resulted in error related to cluster size and allocation. Women may have been omitted from the trial analysis due to inaccurate identification of addresses that fall into a CHW work area, resulting in smaller cluster sizes and thus lower power to detect an intervention effect. The baseline survey indicated that 2% of insured women were either misclassified or matched incorrectly. If a similar proportion of women were misallocated between clusters in the claims analysis, an intervention effect may have been masked. Rates of claims submission may have decreased amongst women exposed to the intervention, but some women may have been wrongly allocated to a control cluster in the membership database, leading to an underestimation of any difference in rates between intervention and control arms. Similarly, women wrongly allocated to treatment clusters in the membership database would not have been exposed to the intervention, thereby diluting a potential intervention effect. Claims data used in the analysis was linked to members identified in the matching process, thus errors were likely limited to one stage of categorisation. Further, errors related to cluster size or allocation were equally likely across intervention arms.

Two, person-time per woman may have been underestimated if a member was assigned more than one number, either due to data entry errors, administrative lapses or long periods of time between renewals. However, since rates were calculated using person time and at the cluster level, this issue should not alter effect estimates. Three, data on the reason for a claim depended on diagnoses that could be inconsistent between providers. For example, fever – a leading reason for claims – typically was not attributed to an underlying ailment in hospital discharge documents. Given high patient loads and limited diagnostic equipment, providers in this setting typically do not provide more detail for insurance claims. As there was no change in claims rates after the intervention, any diagnostic inaccuracy was equally likely in control and intervention areas. Four, the database maintained limited demographic information on members, limiting the extent to which balance across control and intervention arms could be assessed.

The household survey expanded the evaluation of the intervention beyond insurance claims to include hospitalisation and morbidity rates. The survey included more extensive demographic variables and allowed for analysis of whether the intervention had different effects among insured and uninsured women, although power to detect effect modification would have been low. The method of defining clusters and listing households by following CHWs on daily rounds ensured that households would not be left out or misclassified. The sample was thus likely to be inclusive of the most vulnerable, who are often left off municipal or election records typically used for sample selection procedures.

The survey was conducted in three rounds after the start of the intervention, at six month intervals over eighteen months. Multiple rounds allowed for shorter recall periods over the duration of the intervention to limit recall errors – and increased person time under consideration – as opposed to one endline survey. However, attrition was considerable: close to 300 urban households were lost to follow-up by round four due to government-led slum demolitions. The demolished households were primarily in areas close to Ahmedabad city's main river, the Sabarmati, where longstanding settlements of workers in the informal economy were displaced by a riverfront park for the growing middle class. The demolitions were unanticipated, and thus not accounted for in sample size calculations. A slightly higher number of households were lost to follow up in control areas compared to intervention (264 v. 220). Lastly, the survey was dependent on self-reported morbidity and hospitalisation, the accuracy of which has been debated extensively in India and beyond [229, 230, 243-247] . Moreover, self-reporting may have resulted in survey fatigue and potential recall errors, as discussed above.

The analysis was limited by three issues relating to sample size, all of which will have reduced the power of the trial below the planned level. The sample size should have accounted for higher attrition, and potentially could have included more insured members to address high membership turnover. Also, the number of hospitalisation events per cluster was lower than anticipated. Sample size calculations were based on a review of claims data. The study team assumed that claims data would be an underestimate of hospitalisation rates, and accordingly anticipated a higher number of hospitalisation events per cluster. Hospitalisation estimates based on the NSS were not utilised, as the last survey with hospitalisation data was conducted in 2004. Inclusion of more households per cluster could have been considered, notwithstanding budgetary issues that led to the initial sample of 70 households per cluster. Further, the initial estimate of 0.28 for *k,* considerably lower than that retrospectively calculated with baseline data, was based on aggregated rural and urban claims data that was not matched to clusters with the help of grassroots workers, and relied on database categories of illness, rather than manual categorisation into the three conditions as conducted during the trial analysis. Although the number of clusters was limited by the availability of CHWs, better estimation of between cluster-variation during the design phase would have made a stronger case to consider a higher sample size per cluster to improve power and precision, while noting the diminishing returns of increasing sample size given large values of *k.*

The analysis could have been strengthened considerably by better cross-verification between the two data sources. The claims database, which confirmed overall hospitalisation patterns, was accessed only twice (once before the intervention and three months following its completion). Not having anticipated the difficulty in linking members to clusters and to the survey sample, the team did not include a local data manager to access the database more frequently and verify information in the claims database with grassroots workers throughout the intervention period. Despite several attempts to link data, it was not possible to use the claims database to verify claims information reported by all of the insured women in the sample.

Conclusion

This cluster randomised trial did not detect evidence of an effect of the intervention on health insurance claims, hospitalisation and morbidity related to fever, diarrhoea and hysterectomy/gynaecological ailments. Accordingly, scale-up of the CHW-led health education intervention was not recommended to VimoSEWA or for other populations. The intervention process is explored in Chapter IX. The findings of this study also underscore the need to understand further treatment-seeking patterns related to the leading causes of hospitalisation amongst adult women in Gujarat. The following two chapters present results on expenditure and findings of an in-depth examination of hysterectomy.

Chapter VII. Out-of-pocket expenditure on hospitalisation and illness episodes amongst insured and uninsured women

Introduction

If the intervention had an effect on rates of claims, hospitalisation or morbidity, an effect on mean out of pocket expenditure at the cluster level would have been expected. Mixed effects linear regression models would have been fitted to individual data to estimate difference in mean expenditure, and then adjusted for rural-urban location, insurance status, survey round and mean cluster-level baseline expenditure to obtain an adjusted estimate[191]. As there was no evidence of a treatment effect on any of the above-mentioned outcomes, out-of-pocket expenditure was not expected to have changed due to the intervention. Thus, this chapter presents descriptive statistics on expenditure in the study population to provide more insight into women's treatment-seeking patterns and their associated costs.

Methods

All expenditure data from the baseline survey and three subsequent rounds were utilised for these analyses, as described in Chapter IV. The VimoSEWA claims database was utilised to calculate overall mean reimbursement, but total expenditure recorded in the database was not utilised, as claims records typically only include expenditure lower than or equal to the reimbursable amount. Since VimoSEWA-empanelled hospitals in the study area are paid directly before a member is discharged, costs reported by insured women reflect out-of-pocket expenditure as opposed to total expense of the treatment Expenditure on hospitalisation is the total cost reported for consultations, tests, inpatient admission, medicine, tips and transportation associated with a hospitalisation incident in the preceding six months. Breakdown of expenditure into these six categories is presented for women who provided details accordingly. Expenditure on ambulatory care–which includes chemists, health workers, outpatient providers and clinics–associated with illness episodes in the past 30 days excludes costs for hospitalisation that exceeded 24 hours; those costs were categorised with hospitalisation expenditure. Mean data on reported expenditure is presented below, along with box whisker plots to present variations in expenditure by urban/rural location, insurance status and facility type. Plots are presented on the log scale. Linear regression, using robust standard errors to account for non-normality of the expenditure data, was performed to compare expenditure patterns across rural-urban location and insurance status. Illness expenditure data were missing in 17 cases (15 in round 3; 2 in round 4), either because respondents chose not to report, or could not recall, expenditure details. Reported costs are presented for all conditions, followed by an analysis of the three focus conditions. Insurance status as reported was utilised for expenditure in rounds 3 and 4, while insurance status at baseline was utilised for events reported in rounds 1 and 2.

Findings

I .Hospitalisation expenditure

The average reported out-of-pocket cost of a hospitalisation episode in adult women was Rs. 7,377. No woman reported more than one episode in the period between the baseline survey and the final round. As illustrated in Figure 7.1, both mean expenditure per episode and variation in expenditure across episodes were similar in intervention and control areas. Mean expenditure per episode was similar in rural and urban areas, although rural women reported a slightly higher average number of days spent in the hospital (Table 7.1). Variation in expenditure across episodes was also similar in urban and rural locations, including when disaggregated by type of facility (Figures 7.2,7.3).

Private care, where the majority of women sought treatment, was almost twice as expensive as government facilities. Mean costs incurred in non-profit trust hospitals did not appear to be much lower than private facilities, but the length of stay (LOS) was slightly longer than in government or private hospitals (Table 7.2). Insured women tended to report higher expenditure than uninsured women across all facility types (Tables 7.3,7.4), with similar variation around the mean (Figure 7. 4). However, a linear regression model with robust standard errors did not provide evidence for a difference in expenditure by insurance status, adjusted for place of treatment and rural/urban location (mean difference=Rs. 1,081; 95%CI: 881,3043; p=0.28).

Figure 7.1 Variation in hospitalisation expenditure, by treatment arm

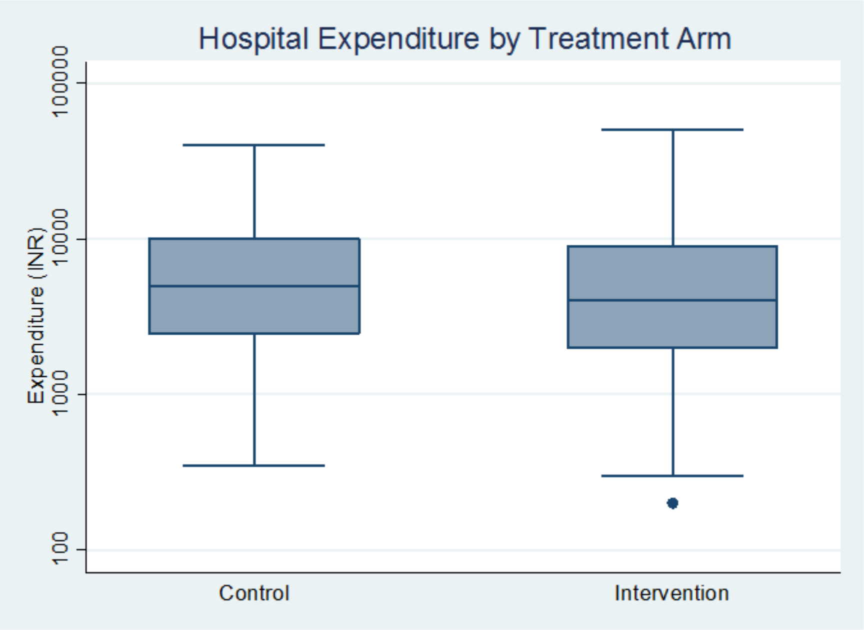


Table 7.1 Hospitalisation expenditure by rural/urban location

Location	n	Mean LOS (days)	Mean OOP	Median	Min, Max
Urban	90	5.0	7810	4050	350,50000
Rural	185	3.8	7167	5000	0,40000*
Overall	275	4.2	7377	5000	0,50000

*There was one reported case of free care, for a hysterectomy conducted in a rural private hospital, with no other reported expenditure.

Table 7.2 Hospitalisation expenditure by type of facility

Type of Facility	n	Mean LOS (days)	Mean OOP	Median	Min, Max
Government	83	3.0	4831	3000	200,30000
Private	169	3.3	8618	5200	0,50000
Trust	23	5.3	7452	5000	494,35000

Table 7.3 Hospitalisation expenditure by insurance status

Insurance status	n	Mean LOS (days)	Mean OOP	Median	Min, Max
Uninsured	104	4.2	6662	4320	0,50000
Insured	171	4.2	7806	5000	200,50000

Figure 7.2 Variation in hospitalisation expenditure by location

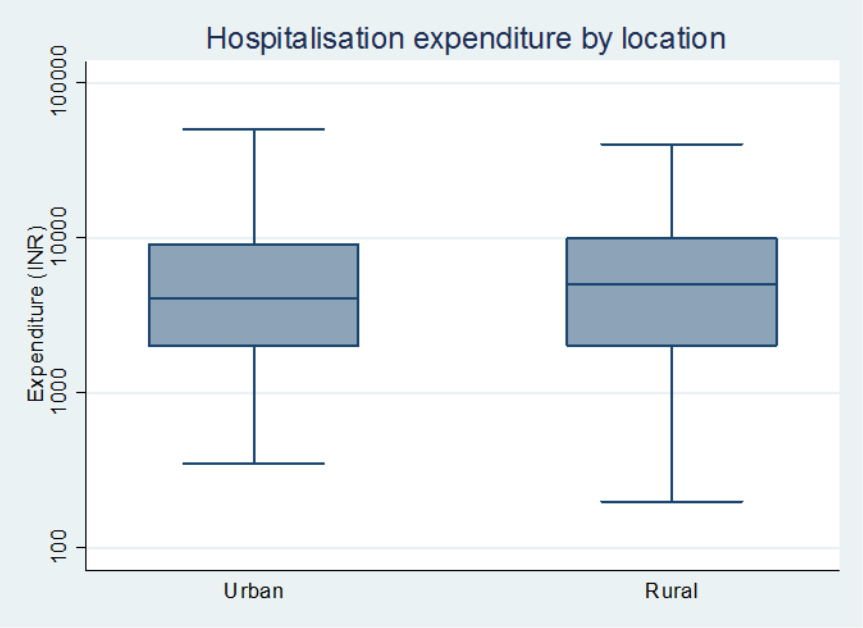


Figure 7.3 Variation in hospitalisation expenditure by type of facility and location

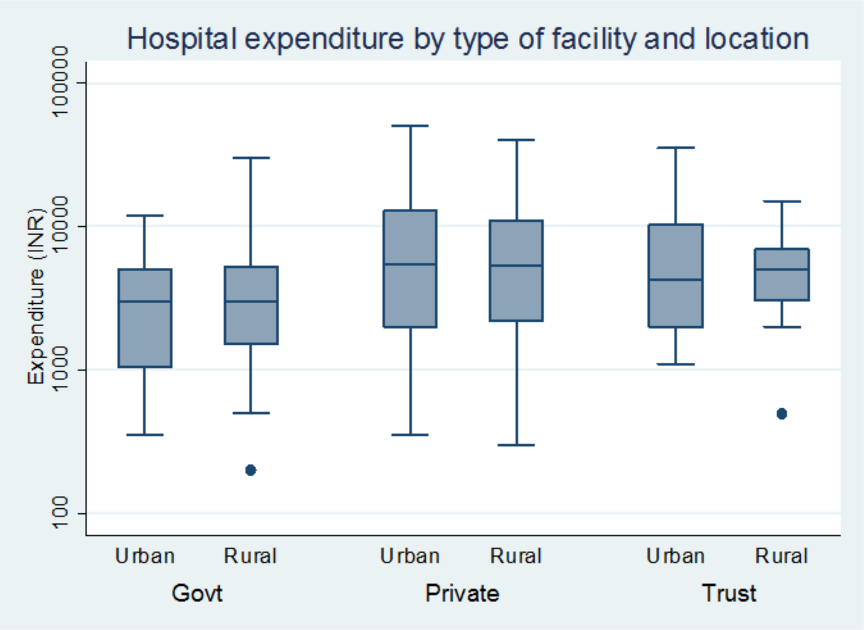


Figure 7.4 Variation in hospitalisation expenditure by insurance status

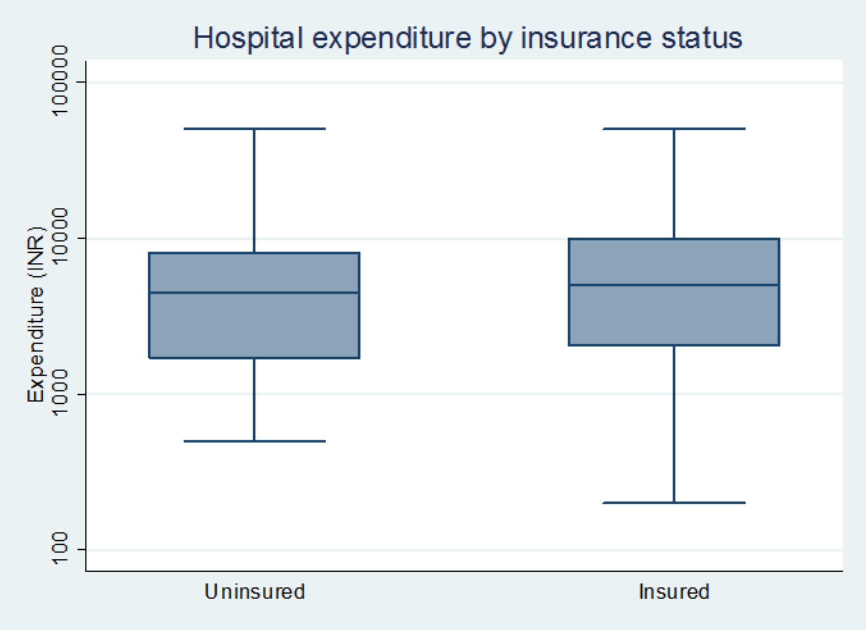


***Table 7.4 Mean hospitalisation expenditure by insurance status*, by place of treatment (INR)**

Insurance status	**Government**	**Private**	**Trust**
Uninsured	3796 (n=36)	8257 (n=65)	6400 (n=2)
Insured	5624 (n=47)	8842 (n=104)	7752 (n=20)

Table 7.5 presents the expected number of claims, calculated based on the claims rate recorded in the VimoSEWA database in the study clusters during the same two-year period. Eighteen of 171 insured women who reported being hospitalised over the survey period were aware of and reported reimbursement by VimoSEWA, while others may have not been aware of, did not report or did not use, VimoSEWA benefits.

Table 7.5 Claims amongst insured women – expected and reported

			Reported by insured	
Person-years	**Claims rate/100 p-years***	**Expected claims**	**Hospitalisation**	**Claims**
1,783	13.0	231	171	18

*Claims rate for all conditions in 28 study clusters over two years, using VimoSEWA claims database

Detailed breakdowns of reported out-of-pocket expenditure were reported for 175 hospitalisation cases amongst all women (Table 7.6). Expenditure on medicines comprised almost half of costs incurred by women who utilised public hospitals. In the private sector, expenditure was more equally distributed between medicines, consultation and facility costs, while hospital costs comprised a slightly lower proportion of costs compared to medicines and consultation fees in trust facilities. The proportion of expenditure spent on medicines was higher in urban areas compared to rural areas, and amongst the uninsured compared to the uninsured.

Table 7.6 Breakdown of hospitalisation expenditure **(Mean % of total expenditure, per episode)**

	n*	**Meds**	**Tests**	**Consult**	**Hospital**	**Tips**	**Transport**	**Other**
Govt	56	46.0	8.0	10.9	20.0	2.9	12.2	0.0
Private*	105	27.4	9.6	28.6	23.4	0.2	6.7	4.2
Trust	14	36.3	7.8	29.3	19.0	0.0	7.6	0.0
Urban	65	39.7	9.7	21.9	19.5	0.3	8.3	0.6
Rural	110	30.9	8.5	23.7	24.0	1.5	8.7	2.8
Uninsured	61	39.1	5.4	24.1	21.5	2.6	7.8	0.0
Insured	114	31.5	10.8	22.4	22.8	0.2	8.9	3.4

*Expenditure breakdown was available for 175 of 275 hospitalisation cases. The remaining 100 only provided total expenditure. Mean reported total expenditure for the 175 cases was Rs. 7,006, compared to Rs. 8,177 for the 100 cases for which breakdowns were not reported.

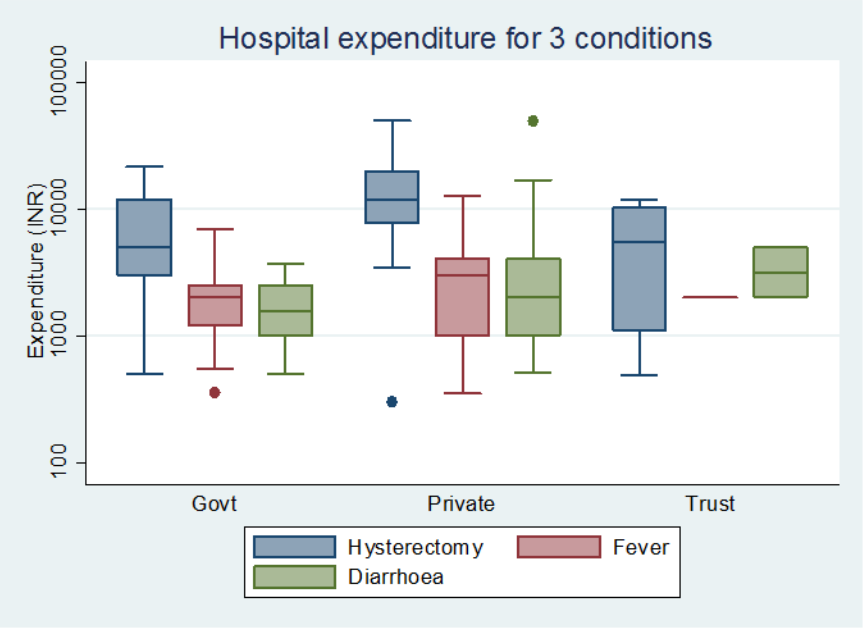
Comparing the three focus conditions, average expenditure on hysterectomy was higher than that for diarrhoea and fever (Table 7.7). Fever and diarrhoea had similar mean costs and variations in expenditure that were similar to one another, while variation around hysterectomy costs was generally wider (Figure 7.5).

Table 7.7 Hospitalisation expenditure by condition (INR)

Reason for Hospitalisation	**n**	**Mean LOS (days)**	**Mean OOP**	**Median**	**Min, Max**
Fever	23	3.0	2977	2300	350,12815
Diarrhoeal	30	3.3	4519	2000	500,50000
Hysterectomy	62	5.3	10590	10000	0,50000
All other*	160	4.2	7157	5000	200,40000

*****Annex 12, Table 1 presents all reasons for hospitalisation. Outside of delivery (n=30), no other single condition was as common as fever, diarrhoeal disease or hysterectomy.

Figure 7.5 Variation in hospitalisation expenditure for 3 focus conditions, by facility type



Focusing on hysterectomy, reported mean expenditure was similar across insurance status, higher in urban areas compared to rural, and higher in private facilities compared to government or trust hospitals (Table 7.8). The variation between costs was similar across insurance status, location and type of hospital (Figures 7.6,7.7). Fitting a linear regression model with robust standard errors, adjusted for location and insurance status, there is strong evidence that the cost of hysterectomy in private hospitals was more expensive than government hospitals (mean difference=Rs. 6,702; 95% CI: 1676,11729; p=0.01). There was no evidence of a difference by urban/rural location (p=0.18), after adjustment for insurance status and place of treatment.

Table 7.8 Hysterectomy expenditure **(n=62)**

	n	Mean	Median	Min, Max*
Uninsured	30	10941	8600	0,50000
Insured	32	10261	10000	300,25000
Urban	17	12715	8050	950,50000
Rural	45	9787	10000	0,28200
Govt	19	7232	5000	500,21500
Private	37	13089	11000	0,50000
Trust	6	5816	5500	494,12000

*One uninsured woman reported no costs incurred for a hysterectomy in a rural private hospital, while one case, the maximum cost reported in this survey, cost Rs. 50,000 in a private urban hospital for a woman with no insurance.

Figure 7.6 Variation in hysterectomy expenditure by insurance status

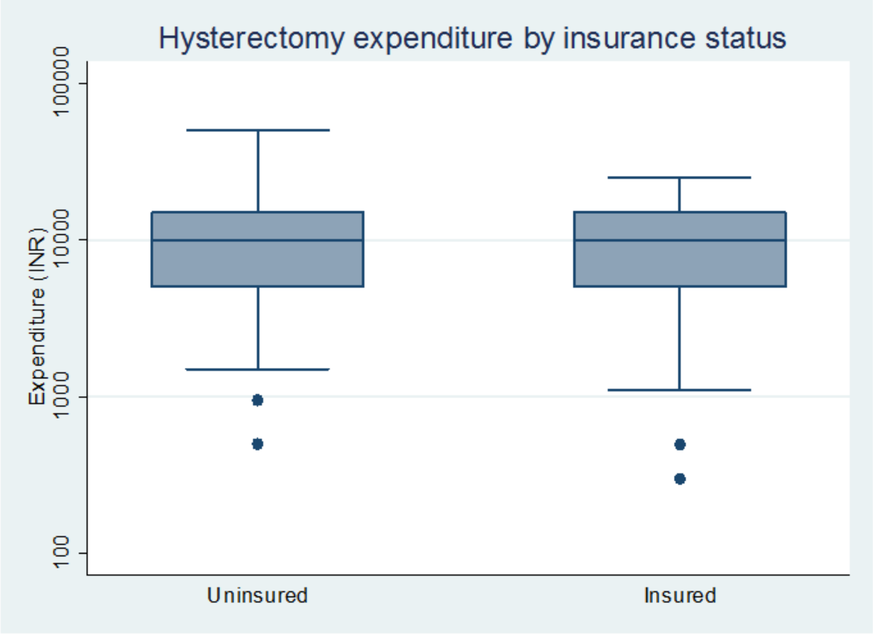
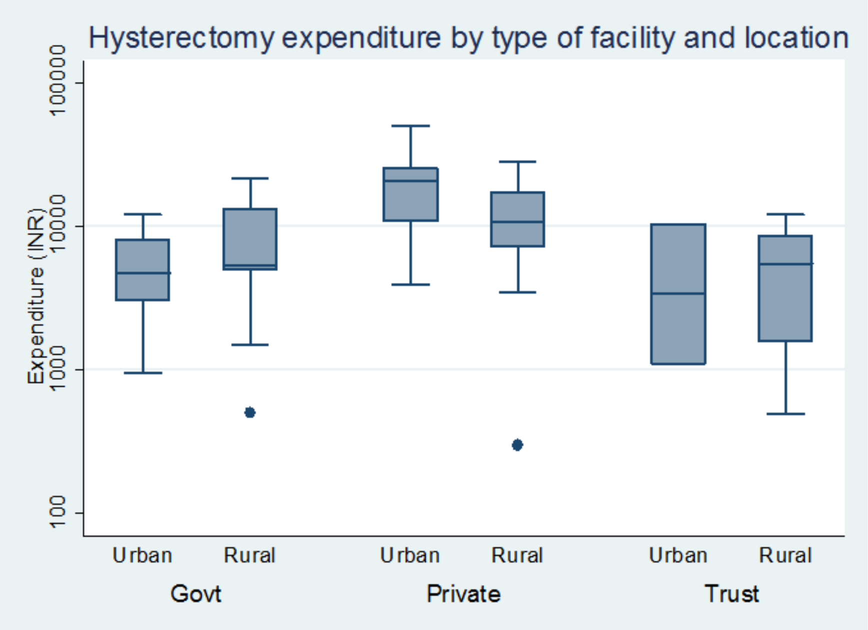


Figure 7.7 Variation in hysterectomy expenditure by urban/rural location and facility type



II. Expenditure on ambulatory care related to illness episodes in the past 30 days

Women reported an average overall expenditure of Rs. 1013 on illness episodes in the past 30 days, excluding hospitalisation that exceeded 24 hours. There were seven cases of expenditure higher than Rs. 20,000, all of which were for outpatient/ambulatory treatment of fractures or outpatient surgical procedures. Free treatment with no other reported expenditure was reported in 12 cases, which are included in the tables but not presented in the box whisker plots. Reported expenditure was similar in intervention and control arms (Table 7.9). Rural women appeared to incur higher mean expenditure per illness episode than urban women, with wider variation around the mean amongst rural women (Table 7.10, Figure 7.8). Government facilities had the highest reported cost, followed by private hospitals. Home-treatment or treatment by a chemist/CHW was considerably lower (Table 7.10).

Table 7.9 Outpatient/ambulatory care expenditure by intervention arm

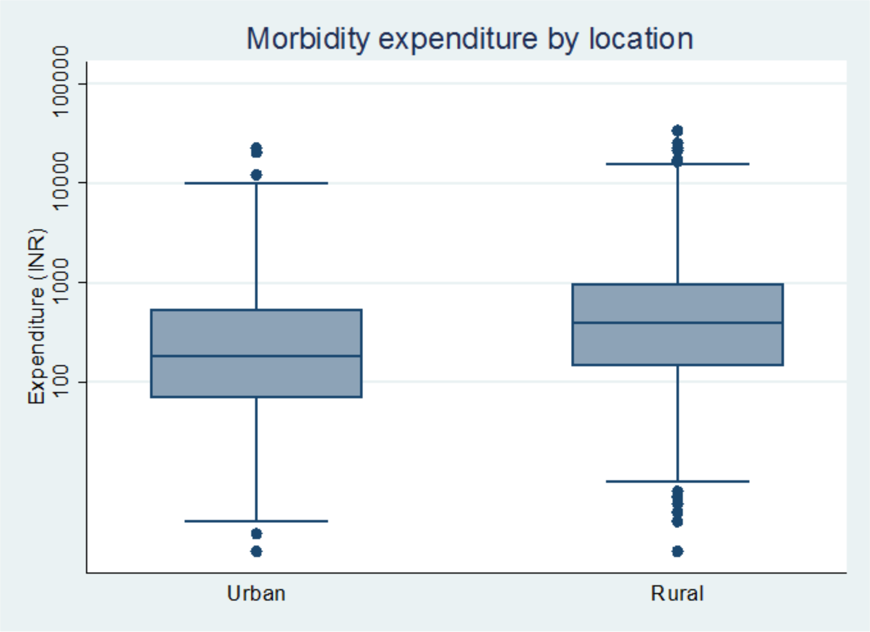
Intervention arm	**n**	**Mean OOP**	**Median**	**Min, Max**
Intervention	440	928	250	0,20500
Control	423	1101	250	0,33300
Overall	863	1013	250	0,33300

Table 7.10 Ambulatory care expenditure by location, facility type and insurance status

Variable	**n**	**Mean OOP**	**Median**	**Min, Max**
Location				
Urban	454	776	180	0,22400
Rural	409	1276	400	0,33300
Facility type				
Self-treatment	50	424	155	0,4800
Chemist/CHW	70	218	50	0,2200
Private*	613	1038	300	0,25000
Government*	130	1551	297	0,33000
Insurance status				
Uninsured	366	932	366	0,20500
Insured	497	1073	497	0,33300

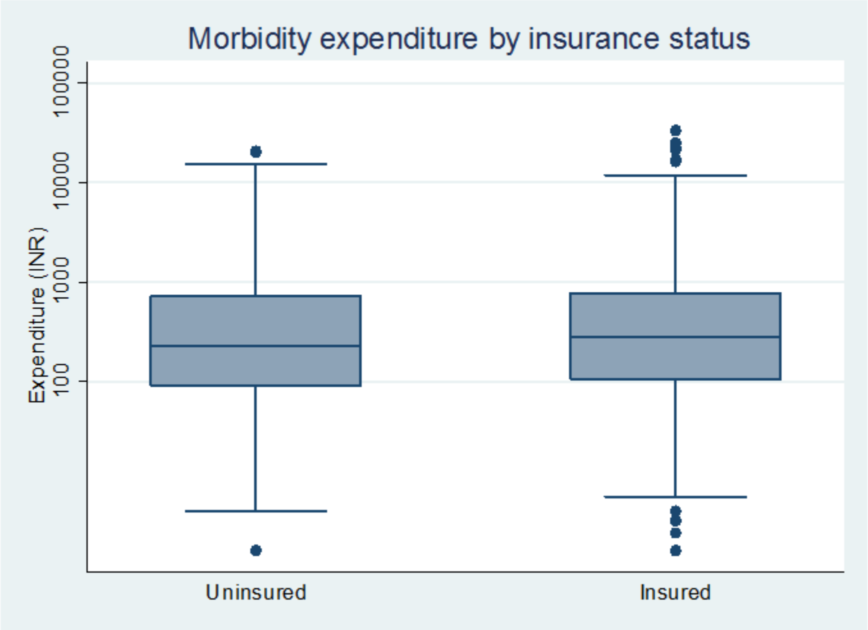
*The categories private and government may include a range of types of facilities; data on exact type of facility was not collected. Private may include small private clinics and larger nursing homes, and government could include local government primary health clinics as well as larger sub-district facilities.

Figure 7.8 Variation in ambulatory care expenditure by urban/rural location



Insured women reported slightly higher expenditure than uninsured women, with wider distribution of costs amongst the insured (Figure 7.9).

Figure 7.9 Variation in ambulatory care expenditure by insurance status



Comparing fever, diarrhoea and gynaecological conditions, fever – the leading cause of reported morbidity – resulted in mean expenditure of Rs. 482, while less common diarrhoea and gynaecological ailments were associated with higher average costs (Table 7.11).

Table 7.11 Ambulatory care expenditure by condition

	n	Mean OOP	`Median	Min, Max
Fever	320	482	180	0,16360
Diarrhoea	74	767	378	2,5300
Gynaecological	16	1296	930	0,5960
All other*	453	1418	350	0,33300

*Annex 12, Table 2 presents all reasons for ambulatory care. Fever was the most common reason for treatment, followed by cough/cold (n=85), and diarrhoea (n=74).

Focussing on fever, rural women reported higher mean expenditure on ambulatory care than urban women (Table 7.12), with wide variation around both means (Figure 7.10). Average reported costs for self-treatment and chemist/CHW care were considerably lower than for treatment at private and government facilities. Uninsured women reported average higher expenditure than insured women, with wider variation around the mean amongst insured women (Figure 7.11).

***Table 7.12 Fever expenditure* (n=320)**

	n	Mean OOP	Median	Min, Max
Location				
Urban	170	404	120	4,11900
Rural	150	571	270	0,16360
Facility type				
Self-treatment	9	196	160	70,425
Chemist/CHW	27	203	40	0,2000
Private	247	505	200	0,16360
Government	37	607	130	0,7000
Insurance status				
Uninsured	129	528	150	0,7000
Insured	191	416	200	0,16360

A linear regression model with robust standard errors adjusted for type of treatment does not provide evidence that expenditure for treatment of fever was higher in rural areas than in urban areas (mean difference=Rs. 182, 95% CI: 103,468; p=0.21) or differed by insurance status (mean difference = Rs.128, 95% CI: 149,405; p=0.91).

Figure 7.10 Variation in fever expenditure by urban/rural location

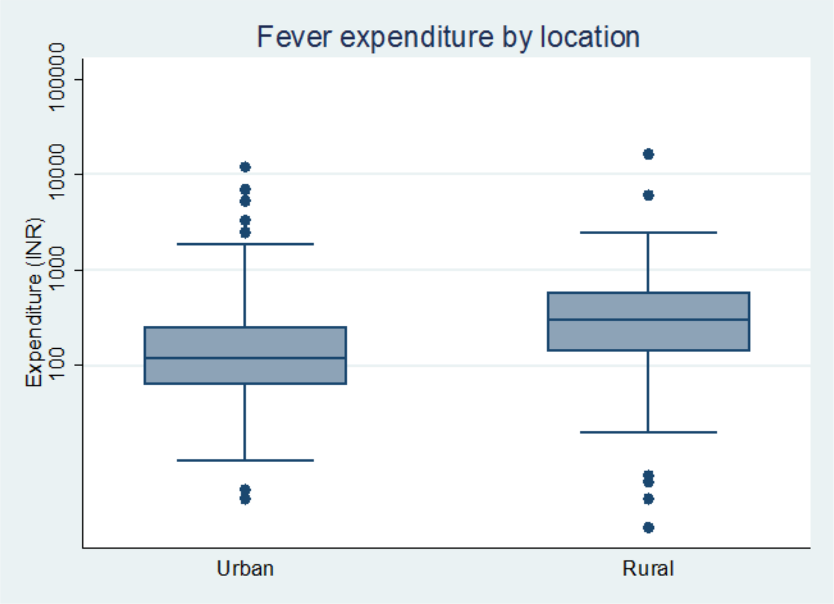
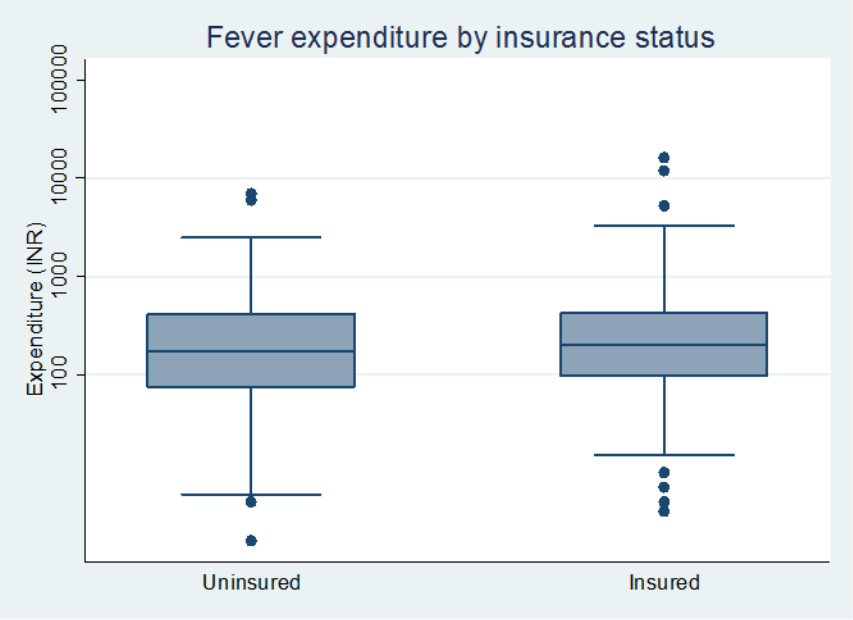


Figure 7.11 Variation in fever expenditure by insurance status



III. Discussion

This section describes out-of-pocket expenditure associated with hospitalisation and recent illness episodes in the study population and compares patterns by rural-urban location, facility type and across insurance status. The findings are broadly consistent with national patterns as reported by the 2004 NSS report on consumer expenditure and health care in the past decade. Private care, for example, is well established to be more expensive than public facilities: the NSS estimates private hospitals to be twice as expensive as government inpatient care [248]. Although public hospitals are intended to be free, the NSS, like this study, reports considerable out of pocket expenditure in government hospitals, particularly on medicines. The finding that medicines comprise a large proportion of expenditure is also consistent with national patterns: 70% of out of pocket expenditure on treatment in India, corresponding to 42% of inpatient care, is spent on medicines [249, 250].

Hysterectomy, the most common reason for hospitalisation amongst adult women in the population, was also reported to be the most expensive. Expenditure on hysterectomy was at least three times higher on average than an episode of hospitalisation for fever or diarrhoea, with a longer length of stay, as expected for surgical procedures. Urban women who underwent the procedure in private hospitals incurred the highest expenditure, consistent with national trends. Trust hospitals, although defined as non-profit charitable institutions, were not significantly cheaper than private facilities for hysterectomy.

Expenditure on ambulatory care for recent illness episodes was much lower than on hospitalisation, as expected. While the NSS estimates outpatient care to be 1.5 times higher for private care compared to government services, women in this study population reported similar mean expenditure for fever, the most common reason for outpatient treatment, in both private and public facilities. While outpatient care is less likely to be catastrophic in a single episode, research suggests that aggregate outpatient expenditure can be a significant burden on household welfare over time[249, 251]. Ambulatory care provided in outpatient clinics – treatment that is not covered by almost any form of insurance in India – occurs much more frequently than hospitalisation; in this survey, ambulatory care frequency was approximately twenty times higher than hospital admission.

Financial security provided by insurance

Although an assessment of the impact of out-of-pocket expenditure on household financial security is beyond the scope of this study, the data suggest that a single hospitalisation could have significant financial implications for a household. The average cost per episode (Rs. 7,432) is slightly higher than the average household monthly income (INR 6,000-7,000), indicating that women may have had to utilise savings, borrow from others, or sell assets to finance treatment. The average expenditure on hysterectomy, close to Rs. 11,000, would constitute approximately 15 percent of the average household's annual income. Previous research at VimoSEWA and other CBHI schemes in India indicated that insurance coverage can provide partial protection from catastrophic health expenditure[34]. A household survey in 2000 found that VimoSEWA members spent 54% less on hospitalisation than uninsured women, a pattern that remained consistent even if cases were not reimbursed[187].

In this survey, however, insured and uninsured women reported similar expenditure on hospitalisation (adjusted for place of treatment and rural/urban location), with a similar proportion of overall expenditure spent on hospital costs. During the survey period, VimoSEWA's claims database indicates that claimants were reimbursed an average of Rs. 2,763 for claims for the three focus conditions and Rs 2,598 for all conditions during the two year period. Accordingly, expenditure reported by insured women would be expected to be lower than that reported by uninsured women.

Factors related to utilisation of VimoSEWA benefits, reporting and recall errors and moral hazard may explain similar levels of expenditure amongst insured and uninsured women. Specific to VimoSEWA, insured women may not have utilised their cashless coverage by seeking care in a non-empanelled hospital or by choosing not to submit a claim at all. VimoSEWA workers either sit in, or regularly visit, empanelled facilities to ensure claims are adjudicated before a patient is discharged. If an insured woman did not make contact with VimoSEWA during the admission process or utilised a non-empanelled hospital, she would have to submit a claim for regular, non-cashless processing, which could take up to one month for reimbursement. In the survey, 18 of 171 insured women reported knowing they were reimbursed by VimoSEWA. It is possible that the remainder either (i) were awaiting reimbursement at the time of the survey (approximately 45 percent of claims utilise the non-cashless route, which typically adjudicates claims within one month) (ii) did not recall receiving reimbursement, possibly because it was cashless and did not require extensive paperwork (iii) did not submit a claim for the reported hospitalisation or (iv) were rejected for reimbursement. Approximately 15 percent of VimoSEWA claims were rejected for reimbursement during the same period in Ahmedabad city and district.

Another possibility is that women may not have been aware they had VimoSEWA coverage and did not utilise cashless services or submit a claim, although as primary policyholders this is unlikely. Administrative procedures involved in submitting a claim, previously identified by VimoSEWA as a primary barrier to claims, should have been eliminated with the introduction of cashless reimbursement services [252]. Further research would be required to explore why women would not use a scheme for which they paid a premium, such as whether they are dissatisfied with the quality of services provided under the scheme.

Regarding reporting, comparison of VimoSEWA's claims rate with survey reports indicates a likelihood of underreported hospitalisation and claims. Applying the claims rate at the time of the survey to the person-time of insured women surveyed, 293 claims would have been expected. However, insured women reported only 171 hospitalisations, of which 18 were reported reimbursed. Women may have underreported hospitalisation or claims due to recall errors, survey fatigue or unwillingness to share personal health and financial information. While such a pattern would have been equally likely in intervention and control areas, in these circumstances this analysis of out of pocket expenditure would result in an underestimate of actual expenditure in this population. Further, insured women may have recalled expenditure differently due to their interaction with VimoSEWA –or uninsured women recalled expenditure more carefully due to lack of coverage –resulting in either group inflating or underestimating expenditure. However, the proportion of insured and uninsured women who reported breakdowns of expenditure, reflective of detailed recall, was similar.

Lastly, if VimoSEWA-insured women indeed utilised (and did not report) reimbursement, but still reported similar expenditure, it is possible that insured women were provided more expensive treatment or charged more for similar treatment, because a portion would be covered by VimoSEWA. Suggestive of moral hazard, providers or women may have undertaken more tests, for example, which may explain why insured women also incurred higher expenditure in government and trust facilities than uninsured women. In this scenario, VimoSEWA may in effect increase risk of catastrophic medical expenditure. Similar findings emerged in an evaluation of China's national health insurance program, in which covered members were found to be more likely to incur higher expenditure on health care costs [253]. Investigation of the actual costs incurred and the role VimoSEWA in either increasing or reducing medical expenditure is required, which would entail review of medical records at empanelled facilities to capture both the total cost and amount covered by reimbursement.

This expenditure data, similar to reports of hospitalisation and morbidity, was self-reported and subject to recall errors, some possible examples of which are discussed above. Breakdowns of expenditure, available for slightly more than one-half of cases, may not reflect population patterns due to systematic differences between those who recalled expenditure and those who did not. Mean reported expenditure for women who could not provide a breakdown was over 15 percent higher, suggesting either recall errors or different characteristics/treatment-seeking behaviour of women who reported detailed expenditure. Further, the recall period may have affected the accuracy of reported expenditure. As hospitalisation was recalled over a six month period, the length of time elapsed since an event may have limited accuracy, as compared to a shorter recall period. A shorter recall period, however, would have elicited a lower number of reported hospitalisation episodes. Moreover, if the respondent was not directly involved in payment procedures–as may be the case with women if they do not manage family finances–the reliability of reported expenditure data may vary according to dynamics in the household.

The survey could have been improved through more detailed documentation of overall cost incurred, types of reimbursement sought and why and how payment was financed, notwithstanding concerns regarding length of the survey instrument. As discussed in the previous chapter, this analysis would have been strengthened by systematic cross-verification of use of insurance and amount covered by VimoSEWA with the claims database. A manual search on the 18 women who reported reimbursement only matched in nine cases to names of claimants recorded in the VimoSEWA claims database. The reason for hospitalisation matched in all nine cases.

Overall, patterns of out-of-pocket expenditure in the population suggested that costs incurred by women for hospitalisation for fever, diarrhoea and hysterectomy were considerable, even in the public sector.   Accordingly, an intervention aimed at reducing the incidence of hospitalisation for these conditions could have also impacted on financial security. The following chapter explores hysterectomy, the most expensive, as well as most common, cause of hospitalisation for women in the study population.

Chapter VIII. In-depth examination of hysterectomy

This chapter presents two papers that are intended to be submitted for publication. The first paper presents the findings of an in-depth qualitative study of hysterectomy, followed by a mixed methods analysis of the incidence and determinants of hysterectomy in the second paper. Tables and figures are numbered in the same sequence as the thesis.

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RESEARCH PAPER COVER SHEET

PLEASE NOTE THAT A COVER SHEET MUST BE COMPLETED FOR EACH RESEARCH PAPER INCLUDED IN A THESIS.

SECTION A – Student Details

Student Sapna Desai

Principal Supervisor Simon Cousens

Thesis Title

Community health worker-led education to change women's treatment-seeking behaviour: A cluster randomised trial and qualitative investigation in Gujarat, India

If the Research Paper has previously been published please complete Section B, if not please move to Section C

SECTION B – Paper already published

Where was the work published?

When was the work published?

If the work was published prior to registration for your research degree, give a brief rationale for its inclusion

Have you retained the copyright for the work?*

Was the work subject to academic peer review?

SECTION C – Prepared for publication, but not yet published

Where is the work intended to be published? Social Science and Medicine

Please list the paper's authors in the intended authorship order: Sapna Desai

Stage of publication Not yet submitted

Student Signature: Date: 6.2.2015

Sapna Desai

Supervisor Signature: Date: 6.2.2015

I. Qualitative study of hysterectomy

Pragmatic Prevention, Permanent Solution:
Women's Experiences with Hysterectomy in Rural India

Introduction

Hysterectomy, the removal of the uterus, has recently emerged at the centre of health policy debates in India. In 2013 the Supreme Court, responding to a public interest litigation, ordered three States to respond to allegations of hysterectomy being performed in unethical circumstances in Bihar, Rajasthan and Chhattisgarh [254]. The litigation cited a lack of medical indications for hysterectomy, poor quality of care and no alternative treatment options presented to low-income, rural women. Many media reports have suggested that unnecessary hysterectomy amongst young women is on the rise, as a result of profit-motivated practices by private hospitals [116, 117, 255]. In most reports, women are characterised as passive victims of profit-seeking medical practitioners: headlines read "Forced hysterectomies, unscrupulous doctors" and "The Indian women pushed into hysterectomies" [118, 256]. Accordingly, hysterectomy has become a powerful tool to critique both privatisation and publicly-funded health insurance [257, 258].

In 2012 I began exploring hysterectomy in rural Gujarat as a case study of how the medical establishment interfered unnecessarily with women's bodies. An epidemiological survey in the area had estimated low population prevalence – 7 to 9 percent amongst women age 15 and older – but supported suspicion of unindicated procedures: the majority of cases were conducted in the private sector, at a relatively young mean age of 37[122]. Yet one-third of women reported utilising public hospitals, casting doubt on provider profit as the sole motivation. Further, local community health workers identified biological and social drivers of the procedure, such as agricultural labour resulting in uterine prolapse, an increase in gynaecological ailments and women's demand due to menstrual taboos. Women expressed considerable difficulties due to gynaecological morbidity, particularly excessive bleeding for which treatment was not available. Most critically, women's own treatment-seeking narratives reflected complex negotiations between bodily suffering, socioeconomic structures and the "micro-physics" [198] of power around them – rather than that of women as submitting to unilateral medical authority.   Accordingly, my approach broadened beyond theories of medicalisation, to examine hysterectomy within the competing concerns and contestations that shape women's lives[37].

This paper explores the individual, household, socio-economic and health system factors that influence women's decisions to undergo hysterectomy, from the accounts of low-income, rural women workers in the Indian state of Gujarat. I present findings from in-depth qualitative research on the processes through which women underwent hysterectomies, within the context of their daily lives and broader environments. I argue that, given the structural and systemic constraints in this setting, women exhibited "pragmatic agency" in the decision to remove the uterus as treatment for gynaecological ailments[198]. Positioned within power structures related to labour and work security, gender roles and a maternal-centric health system, hysterectomy represented a means of freedom from bodily suffering and future risk – and illustrated how women negotiate medical treatment in spheres beyond the clinical encounter.

Methodological and analytical approach

Theoretical framework

Medicalisation, the extension of medical power and interference into everyday life[259], has been contested and expanded through empirical study of its influence on women's lives. Ethnographies of women's health, for example, have explored how cultural, social and political processes shape medical practice and decision-making [260].   Using Michel Foucault's distinction of dispersed 'bio-power' that infiltrates daily life, as opposed to power expressed as authoritative control, analyses have positioned women's medical experiences beyond that of the physician-patient relationship[261].   This lens draws attention to, for example, gender dynamics and historical biases that shape medical actions. Towghi's exploration of the normalisation of hysterectomy in rural Pakistan is one illustration, in which embedded gender biases, rather than biological need, influenced practitioners to devise permanent solutions for the uterus and its ailments[262]. Further, rather than assume women are subjective recipients of providers' authority, bio-medical treatment has been conceptualised as defence against other forms of power[198]. For example, sterilisation in India has been interpreted as a marker of a woman's transition to an older generation, thereby allowing a younger woman to establish her position vis-à-vis her mother in law in a joint family setting [263]. In Brazil, seemingly high rates of caesarean sections reflected low-income women's assertions of resources in the face of socio-economic and political inequalities, a narrative which nuances one-way medicalisation of childbirth by providers [199]. Research that has examined women's experiences with hysterectomy in high-income countries has similarly identified the complexity of decision-making processes, as well as the expected variation in influences across settings and populations [264] [113, 265].

Women's interactions with medical authority and technology have also been characterised as fluid, interactive engagements not amenable to dualistic categories such as passive or active bodies, or risk-benefit calculations [266]. As proposed by de Bessa, drawing on theories of decision-making to contextualise Brazilian women's actions to undergo sterilisation, women engage in ongoing "monitoring and rationalization of options and actions as they emerge in a particular setting" rather than narrow, one-time treatment decisions [267, 268]. Accordingly, individual perception of bodily risk, not necessarily based on scientific evidence alone, is a nuanced calculation defined by "cultural beliefs, moral values, feelings and life circumstances" [203]. This investigation of hysterectomy in rural Gujarat situates women in their specific cultural, social and political context, wherein they emerge as pragmatic actors engaged in multi-layered negotiations and decision-making processes [198, 203].

Setting

The study was conducted in a rural district of Gujarat, while I was based at the Self-Employed Women's Association (SEWA), a trade union of over 1.7 million women that has been active for over forty years. SEWA's members are women workers in India's vast informal economy: they do not have formal employer-employee relationships and by default, survive on precarious livelihoods without basic social protection. As members of SEWA, they access microfinance, health services delivered by local women, literacy programs and engage in collective bargaining for fair wages and rights to services. A community-based survey conducted in 2010 with SEWA found that hysterectomy was the leading reason for hospital admission amongst women in Ahmedabad city and district, both for women insured by SEWA's health insurance scheme and for women without insurance, at an average age of 36 [145].

Comprehensive reproductive and sexual health services are limited in Gujarat. Fifty-five percent of births in Gujarat occur in a health facility, with institutional birth more common amongst women who are in the highest wealth quintile, have at least ten years' education, attend antenatal care visits, and live in urban areas [4]. Choice in family planning services is narrow: forty-three percent of currently married women are sterilised, accounting for 64 percent of all contraceptive use. According to the National Family Health Survey, lower-income women utilise sterilisation as the primary form of contraception, while better educated and wealthier women are more likely to utilise temporary methods. Eighty-two percent of sterilised women utilised a government facility for the procedure, which includes a financial incentive[4]. The state employs six gynaecologists, with 267 unfilled posts at the time of this study [172]. In 2009, Gujarat initiated roll-out of the Rashtriya Swasthya Bima Yojana (RSBY), a national health insurance scheme that provides hospitalisation coverage up to Rs.30,000 in public and private hospitals for households designated below the poverty line.

Research on the sociocultural determinants of gynaecological morbidity has suggested that Indian women live in a 'culture of silence[147]' – fuelled by gender inequality and social norms – that proscribes women from using household resources for treatment related to reproductive and sexual health[148-152]. For example, less than half of women studied in rural Rajasthan, Maharashtra and Tamil Nadu as well as in urban Mumbai reported seeking treatment for vaginal discharge, menstrual disorders or abdominal pain[149, 153-156]. However, these findings vary by setting: two studies amongst low-income women in rural Gujarat and rural Karnataka reported that the majority of women sought multiple sources of treatment for gynaecological ailments [157, 158]. An ethnography of women in rural Gujarat attributed reproductive ailments to excessive *garmi* – heat in the body[158]. *Garmi* was linked to ingestion of hot food, allopathic medicines, alcohol consumption and sexual intercourse, as well as to sterilisation. Women reported avoiding treatment that involved allopathic oral medicines, due to fear of excessive heat production.

Field approach

The fieldwork employed an ethnographic approach to qualitative data collection, drawing on ten years' previous experience working as a health program director and researcher with SEWA in the study areas, and six months of fieldwork focussed on investigating hysterectomy. I was already familiar with modes of daily living, village dynamics, health services and local terminology in the study setting. Longstanding familiarity allowed me to interact informally with women: I observed them and their families in daily life, particularly health-related activities. I accompanied community health workers on home visits, health care referrals and to group meetings. I also reviewed quantitative data from a household survey and discussed findings with women and their families, grassroots SEWA health and health insurance workers and government heath staff. Through this process, I identified seven provisional themes to explore in-depth: women's experiences with gynaecological morbidity; drivers of women's demand; socioeconomic/occupation-related determinants; family/household and intergenerational dynamics; health insurance status; health provider practices; and physical, emotional and economic consequences of hysterectomy. Interview guides were utilised to cover *a priori themes*, but were modified to explore new themes as they emerged, such as fear of cancer or experience with menstrual difficulties.

Women who had undergone hysterectomy were identified through SEWA's local community health workers and referrals from interviews and key informants. I conducted interviews with women who had hysterectomies until (i) the group represented variation in length of time since the procedure and insurance status and (ii) no new analytical themes emerged. Thirty-five women were interviewed, eleven of whom were insured by SEWA and/or the government. Nineteen women had the procedure in the past five years (seven in the past year) and could provide specific details of the treatment-seeking process. The remainder offered perspective on longer term effects of hysterectomy. I interviewed five local gynaecologists, who accounted for 20 of the 35 hysterectomy cases conducted in the area. It was not logistically feasible to link a specific woman's case history with her provider to develop case studies, although I was able to conduct analysis linking women's cases with the viewpoints of the identified provider. Where possible, I also read women's medical case histories and test results if they agreed. Interviews were conducted individually with 13 key informants and three women with gynaecological ailments who did not proceed with the operation, as well as in groups with three sets of younger women who have not had a hysterectomy.

Table 8.1 Demographic characteristics of women interviewed

Women interviewed (n=35)	
Mean age at hysterectomy	36
Years since procedure	
<1 year	7
<5 years	12
5-10 years	7
>10 years	9
Occupation	
Agricultural worker	18
Daily wage labourer	6
Home-based work	8
Health worker	3
Any education	
Yes	10
No	25
Insurance status	
Insured	11
Uninsured	24

Interviewees provided written consent after reviewing a study information form with the author. Ethics approval for this research was provided by the Executive Committee of the SEWA Health Committee and the London School of Hygiene and Tropical Medicine. I conducted all interviews in Gujarati, with parts of provider interactions in English. Interviews were audio recorded with permission and transcribed in Gujarati. All names have been anonymised in presenting findings. Analysis was inductive using a framework approach. Open coding was conducted to identify thematic patterns using findings from women, providers and other key informants. Women were then compared across sub-themes and variables to identify determinants and causal pathways of hysterectomy in this setting.

Findings

Normalisation of hysterectomy

Women, their family members and providers did not view hysterectomy as a rare event in the community. The average age at the time of hysterectomy was 36 years old, ranging from 22 to 60 years. Seen as a normal, common treatment, almost all women quickly recounted other family members or women in the village who had undergone the procedure. Madhuben, an agricultural labourer in Simej village, recalled that after she had undergone the procedure she learned of many others who had as well: "*Many people have had the operation here. Just recently, Anita in our village, a friend in the next village, and many more I know have had it.*"

Each of five gynaecologists interviewed defined hysterectomy as a common intervention for dysfunctional uterine bleeding, cysts and fibroids in women 40 years or older after hormonal management was tried. When asked about younger women, providers stated that they typically tried hormonal treatment first and only advised hysterectomy after women had completed childbearing. Hysterectomy was, according to providers, most commonly used amongst rural, low-income women because it was simultaneously curative and prophylactic, as well as a one-time expenditure. Dr. Patel, private hospital: "*Generally it is better to do hysterectomy [than other procedures] because the [rural] patient is not going to take continuous treatment and medical management gets costly…and we can't say how much that will help anyhow. So it's better that they have a hysterectomy. And ultimately the problem gets solved.*" In contrast, urban women, as well as wealthier rural women, were seen to undergo the procedure at lower rates: According to a government doctor, "*In the government city hospitals, a patient has to get many tests. Blood, sonography, medical fitness, etc, and then gets a date for the surgery. It takes so long, and she gets tired of it. There is a much heavier case load in the city. Here [in rural practice], I can do a hysterectomy the next day.*"

Treatment negotiations

Treatment-seeking patterns were neither linear nor uniform, consistent "behaviour" for an individual woman. The path to hysterectomy typically started, stopped and wavered over a period of time and across medical opinions. Although there was variation in the onset, type and severity of symptoms, all women related the experience of gynaecological morbidity as the initial catalyst for seeing a doctor and eventually undergoing hysterectomy. Excessive or prolonged bleeding and pain were the most common complaints, followed by excessive white discharge.

Women's representations of their thought processes and rationale for hysterectomy varied across a spectrum. For some, hysterectomy was a last resort, utilised only because other treatment options had failed. For most women, hysterectomy was seen as a pragmatic means of treating gynaecological ailments and concurrent prophylaxis to prevent future suffering, while a smaller group viewed it as a permanent method to attain bodily freedom from menstruation. Menstrual regulations, particularly for but not necessarily limited to Hindu women, included not being able to cook, pray or enter a temple. In some families, women were also forbidden from touching anyone else or sleeping in their own bed.

Diversity in women's decision-making processes was not clearly associated with socioeconomic, educational or health status. Further, how and where women treated gynaecological ailments typically departed from previous history of seeking health services, including for childbirth. There was little indication that women who underwent the procedure had a predilection towards medical intervention. For example, Manjuben avoided medicine and doctors for most ailments, and had delivered both of her children at home. Outside of sterilisation in a government health centre, she had never undergone a surgical intervention. When I first met her, she had just recovered from severe back pain for which she had sought herbal treatment for two months. She typically did not seek allopathic treatment from hospitals or private providers, primarily because it was too expensive. She had a hysterectomy at age 35 in a non-profit trust hospital for severe abdominal pain, a complaint for which she neither sought traditional medicine nor was offered less invasive procedures.

Renukaben, a SEWA health worker for eight years, was previously an agricultural labourer in her home village of Rithila. As a SEWA health worker, she promotes preventive health practices in her village and provides doorstep primary care services, to help women avoid unnecessary hospitalisation. Her first two children were delivered at home by a midwife. Her third child was delivered at a local charity hospital, two weeks after which she was sterilised in a government hospital. After battling severe menstrual pain and bleeding for several years, she underwent a hysterectomy when she was 30 years old, in a private hospital.

Few women settled upon the first provider who suggested hysterectomy; they sought two to three opinions, determining the best situation for their personal health, financial security and familial convenience. Manjuben, for example, chose the provider whom her in-laws trusted and helped her choose. She had seen two providers, one close to her village and one in the city, and considered her choices over the course of several months. Similarly, Renukaben spent over six months seeking opinions: "*After my diagnosis from the SEWA doctor, I went to the government health centre, where they confirmed I had a cyst. Then I went to a private trust and one more private hospital. All four providers said I had a big cyst, and that I needed a hysterectomy.*"

Hysterectomy as counter to medicine

Hysterectomy was articulated as a one-stop intervention which enabled women to lead an otherwise *un-medicalised,* healthy life. According to Manjuben, "*I thought that I'll have problems again with my body, [if I don't take it out]….after the operation, I am completely fine. After the operation, I knew I will have my body back. I knew that my health would not suffer anymore. I would have no more worries."*

Nakviben, an agricultural labourer was 22 when she had a hysterectomy, when eldest of her three children was four years old:

> *"I had heavy bleeding and a lot of pain. Working was a problem, so I thought to remove it. I went to a doctor, who said even if you don't remove it now, after two years you will have to. I went to three hospitals, who said it was not an emergency but I should remove it later. I tried the medicine but started vomiting. I hate medicines; even if I have a fever, I don't take any [oral] medicine… You see, I had a problem and I didn't want medicine. So at last, out of frustration, I removed it. I needed it [the operation] to be healthy."*

Bakuben, an agricultural labourer whose cyst was confirmed by four doctors, believed that that "*my problem will be solved entirely with a hysterectomy. I thought no matter what, I have small children and I need to do this operation. I need my health to be strong for them."*

The fear of developing cancer in the future was a common reason to undergo hysterectomy as prophylaxis. Savitriben, a local government child care worker explained that most women were more scared of cancer, and it was a common topic of conversation in the area. Gajaraben, age 36 at her hysterectomy four years ago, explained: "*I had my periods for 15 days at a time, for 4 months. I went to two doctors...They said to do the test (sonography) and then said that if I don't remove it I will definitely have cancer. You will have problems in the future, whether you take medicines or not….I did not want cancer in the future. Now I am okay again.*

Ishaben, an agricultural labourer had a similar experience after seeing a doctor for excessive white discharge: *"I went to the doctor who explained that I have an infection in my uterus. If the infection spread, it might have resulted in cancer. So I thought….In the future, cancer will surely come. I had a* *problem in the present, and I needed to find an immediate and permanent solution. No matter where I had to find the money from; I had to remove the uterus immediately."*

History of surgical sterilisation was common, however, and appeared to be a normalised exception in the narrative of an otherwise unmedicalised life. The large majority had undergone tubal ligation in their mid-twenties – about ten years before undergoing hysterectomy. Like Manjuben and Renukaben, most women related sterilisation as the normal course of events after childbirth. Women who had delivered at home later visited a government health centre to undergo sterilisation, for which both women and health workers received a financial incentive. Family planning options were extremely limited in government health centres: sterilisation was the primary (and only) family planning method available. Dr. Meena, an experienced gynaecologist with a history of working with community organisations reflected on government policy: "*Sterilisation is the only way. These people do not understand family planning or how to plan. This is the answer to the population problem.*"

Freedom to work

Women's identities as workers and caregivers dominated their descriptions of decision-making regarding hysterectomy. All women were low-income workers, engaged in agriculture, daily wage labour, home-based work or health/child care work with the government or SEWA. They depended on their physical strength to earn daily wages and to care for their families. They typically worked long days, beginning before sunrise to attend to animal husbandry or agricultural duties, before setting out to labour in other fields, construction sites, or to work at home. After taking a break at midday to prepare meals, women returned to income-earning activities or turned to household duties till the night. Most lived in joint families and managed housework – cooking, cleaning, care for children and the elderly – for at least five to six other family members. Gynaecological ailments were marked by heavy bleeding, severe pain and weakness. When faced with conditions that caused considerable suffering and disturbed daily life, women acted to preserve their productivity.

Renukaben had a history of severe menstrual pain, for which she used to take home-based remedies such as garlic-based mixtures and heat applications. She once collapsed from pain while working in the fields, and a farmer had to bring her home on his bicycle. After one month of continuous menstrual bleeding – fifteen years after her symptoms began –she felt she could no longer afford to miss more work or not contribute at home. She went to a SEWA-affiliated doctor and was diagnosed with an ovarian cyst.

Without any social protection or paid sick leave, women articulated the loss of physical productivity as a greater risk than the side effects of a surgical procedure. Manjuben was a widow who lived alone; her two grown sons lived in the city. She depended on her own income from agricultural labour to survive. When she experienced severe abdominal pain, diagnosed as a symptom of an ovarian cyst, she weighed her options: *"The doctor said the cyst has to be removed. But he said it can return in twelve months, after which you will have the same problems again. You can try medicines for 4-5 months first to see if that takes care of it. I thought, instead of having a problem again in six to twelve months, if I just remove it I can go back to work and earn money. At the age of 35, I do not want to risk the pain returning, as I have to work for many more years. So I removed it."*

Fear of *not* undergoing hysterectomy was also rooted in the loss of earning capacity. Women consistently framed the consequences of failing seriously ill or dying prematurely, either from eventual cancer or untreated gynaecological morbidity, in terms of loss of productivity. Gajaraben, who labours in a brick kiln summarised: "*You can have a fever, cold, cough or weakness and go to work. But with these [gynaecological] problems, you can't work unless you take care of it.*" Removal of the uterus, therefore, represented preservation of a woman worker's chief resource – her body.

Further, women's decisions were related to their children's well-being. Particularly for women in their mid-thirties who had long-standing ailments, the fear of premature death due to cancer and leaving their children to fend for themselves was motivation enough to remove their uterus as prophylaxis. The development from morbidity into cancer was perceived to be inevitable by almost all women. Bakuben, an agricultural worker who had a hysterectomy at age 32, experienced both pain and excessive bleeding that sent her to a doctor. She had two children, and had previously worked part-time as a village midwife. A strong, tall woman, she chopped her crops with a heavy sickle, often one-handed. "*I removed it [my uterus] due to fear of cancer. We have farm work – but when the pain increased I couldn't go to the land. I had small kids at home. If I died from cancer, who would take care of them, feed them?"*

Informed risk

Women recounted financial difficulties as a result of having the surgery, but in most cases, felt the benefits–health and work security–outweighed the financial and physical costs. Bakuben, amongst the poorest of the women I interviewed, took a bond from a money-lender against her land. *"My children are more important than the risk [of mortgaging our possessions and land]."* Amongst women with health insurance, hysterectomies were evenly spread between private, government and trust hospitals. Three insured women chose not to use their existing insurance coverage because they preferred hospitals outside of the preferred network. Further, the financial protection offered by SEWA was minimal, as Champaben explained: "*I only got Rs. 2000 from SEWA insurance. That doesn't even cover the medicines*." Kariben, insured by SEWA and the government: *"After 3 reports, I decided to get the surgery. I had the Rs. 30 card too [RSBY government insurance], but did not use it because I wanted the operation only in Teen Murti"* [a non-profit charity hospital that was not yet enrolled in the RSBY].

In addition to debt, hysterectomy entailed considerable physical risk before, during and after surgery, such as blood transfusions, weakness or signs of menopause. Women related little regret, however, as the initial morbidity was cured. Manjuben, after deciding to have a hysterectomy, was told that she was too anaemic to undergo surgery.

> *"Actually I had to stay in the hospital for 1 month. Because I had less blood in my body I had to wait. The doctor also gave me milk powder for 1 month to drink so that I could gain some energy. After one month, I still had no blood in the body. I ended up having to take blood."*

After the surgery, she reported having "no tension" now that the pain was gone. Renukaben, who suffered side effects such as loss of sexual drive and intermittent pain after a hysterectomy, nevertheless maintained that her health as a whole improved, as the bleeding and severe pain stopped.

Recovery periods were organised well in advance to arrange child care, help with household chores and if possible, support in income-earning activities. Providers were typically chosen based on convenience of the designated helper, resulting in some women having surgery near their maternal home if necessary. Renukaben returned to work at SEWA in one month, while Bakuben and Manjuben waited two to three months to return to agricultural duties. They relied on family within the household or female relatives who would visit to help with daily chores in the initial weeks post-surgery.

The permanent –and only—solution

Women acted in response to the burden of untreated morbidity and within the confines of limited health care options. Suffering due to fibroids, cysts and menstrual disorders and the fear of cancer propelled the belief amongst women that the uterus is a site of risk; hysterectomy became both treatment and prophylaxis. For providers, the perceived unlikelihood of rural, low-income women to travel for follow-up visits resulted in the promotion of hysterectomy as a convenient, one-time cure for menstrual problems, cysts, fibroids and other gynaecological ailments. Willingness to undergo surgery serves as testament not just to the severity of morbidity in women's lives, but also to a lack of treatment options.

When gynaecological morbidity emerged, many women waited to seek treatment. Upon seeing doctors – typically more than one – some tried medicines for long periods of time, and in one case, a less invasive procedure to remove cysts. For those with the financial resources or inclination, medical alternatives to surgery were tried first. Women who had waited to seek treatment primarily had home births and about half were sterilised. Not being sterilised either reflected an aversion to interventions or socioeconomic status that nullified the financial incentives of sterilisation. They eventually chose to have hysterectomies when their symptoms did not improve through hormonal treatment and providers presented no other option. For many women, medicines were not an option because they were considered "heat-producing" – seen as an unnatural intervention that could cause imbalance in the body's natural functioning, commonly in the form of acidity or stomach problems– as well as prohibitively expensive (approximately Rs. 700/month) over a longer duration.

Providers, with almost no infrastructure or preparedness to provide gynaecological care outside of hormonal treatment – which most women could not afford –by default offered hysterectomy as a 'permanent solution.' The profit motivation for providers was also seen as an incentive. According to Manjuben: "*We go to doctors with our symptoms. What will they say, except that they will remove the uterus and cure it? And they make money this way….otherwise how will the doctors eat? They will never tell you the whole story, because they know you will have a hysterectomy anyway. So they tell you there is no option…you have to do it.*"

Some women also expressed demand for the operation as a permanent method to stop menstruation, particularly due to rules related to menstruating women. When Renukaben got married: *"My mother-in-law bought a separate bed for me to sleep on during menstruation. Up until my father-in-law was alive, I had to follow certain rules; I couldn't go to the kitchen or to pray. That's all over now, and anyway I don't have my period anymore."* In Manjuben's case, freedom from menstruation was a welcome side effect of a hysterectomy, particularly from rules prohibiting menstruating women from entering the kitchen or providing religious offerings: *"Before the operation, I couldn't touch anything for five days….but now, I can prepare food anytime, khichdi-roti, and offer it to God….now some people even remove it due to frustrations with menstruation."*

Women who explicitly cited menstrual rules as a motivation for hysterectomy were less likely to seek second opinions or use hormonal treatment. Culturally, menstruating women are considered 'polluting': particularly in rural India, they cannot enter the kitchen, temples or sacred places, with more stringent rules in some communities[14, 158, 159]. Champaben, a manual labourer aged 40 when she underwent hysterectomy: "*I used to have to follow all the [menstrual] rules and became totally frustrated with the limitations…I did the operation for peace."* Renukaben's experience as a health worker reflected this view: *"Out of frustration of cleaning everything related to menstruation* [cotton cloths and towels used]*, some women just get the operation. Where they may not have years ago, today they have an easy option to stop periods."*

Productive only when reproductive

A cultural emphasis on women's role as mothers has translated into a conviction – amongst both women and providers – that the uterus is productive only when reproductive. With the exception of young women who had not undergone hysterectomy, almost no women, including key informants, believed the uterus performed essential body functions after childbearing was complete. Manjuben: *"Since we've already had our children, our work is done. So we can remove the uterus."*

Provider practices and health system priorities reflected both gender and class biases that render women to be reproductive agents, devoid of value outside of their role as mothers. According to Gauriben, a woman who had no children and went to the doctor with severe menstrual pain:

> *"We didn't know what the reason was for my problem, and the doctor said the uterus will have to be removed eventually. We also told her that we don't have any kids. She said that, since you don't have the capacity [to have children] there is no point in keeping the kothri* [uterus]*."*

Dr. Samir, a private doctor, stated of low-income rural women: "*They start bleeding a lot and don't take the proper [hormonal] treatment course. And they are already sterilised. So somehow, the uterus is neglected or not needed. Ultimately they convert into hysterectomy cases.*" Not only did providers suggest that hysterectomy was appropriate treatment for low-income women because they 'don't need the uterus' once childbearing was complete, ovaries were also routinely removed to prevent future cysts. When questioned regarding side effects, while they were aware of effects of premature menopause on bone density and mental health, most also believed that both the uterus and ovaries were of limited value by age 40. These organs, like an appendix, were instrumental to a point. Dr. Gaurang, government doctor: *"Basically, if a woman is above 35-36 years, with her kids done, I do a full hysterectomy with oophorectomy. I do this to be safe, otherwise if they get a cyst they come back and say what kind of operation was that? So to be safe, I remove everything. […regarding side effects] Premature ovarian failure anyway happens by 37, 38 years. It's genetically determined."*

The post-reproductive uterus quite literally served as an instrument, a site of practice, for some providers. All providers related the popularity of hysterectomy as a method for young, particularly rural, government doctors to gain surgical skills. Two providers admitted to conducting many hysterectomies during early career rural postings, acquiring experience which helped perfect their 'hand'. As a result, one doctor boasted of being able to conduct eight hysterectomies in one day.

Dr. Samir, a private doctor who previously worked in the government:

> *"Rural doctors – yes, young doctors should go to rural areas, haath saaf karva mate* [to perfect their 'hand']. *Why else would they stay there? Job satisfaction comes from doing operations and learning independently. Earlier they would have only assisted a surgery. I also did a lot more hysterectomies earlier in my career."*

Another, Dr. Jitin, chose to spend more time in lower-paid rural hospitals because he 'enjoyed' conducting hysterectomies, a surgical satisfaction he could not find in his urban practice with lower case loads and more options available. The objectification and dispensability of the uterus was peculiarly literal in one case: a government provider had covered his office walls with photographs of removed cysts, fibroids and other relics of uterine surgery. "*Hysterectomy karvarnee majaa aavee - I was really enjoying doing so many hysterectomies here. Nothing compares to the case load here in government.* [While showing me photographs on walls]: *I've done all of this, all of these cases.* [He points to an ovarian cyst, 8 cms large and a massive cervical growth – five times bigger than the uterus, in photos on the wall. "Was it cancer?" I ask] *No one does pathology here."*

Skewed health system

Interviewed providers reported that between five to fifteen percent of their patients came to their clinics for gynaecological ailments, while the remainder were obstetric cases. Three of the providers, two in the private sector and one in government, conducted approximately 15-20 hysterectomies per month. Two doctors in non-profit charity hospitals conducted one to five hysterectomies per month, both because they did not feel equipped to operate and because their busy obstetric practices did not allow time for gynaecological care. None of the clinics was equipped for gynaecological exams. Pap tests were not available and, at best, women were referred to government-sponsored camps held twice a month. Trans-vaginal ultrasounds which could detect cysts were not available, nor were basic ultrasound machines. For example, Renukaben's cyst was diagnosed through abdominal ultrasound conducted in an external laboratory.

Locally available public health programs included village health workers delivering iron supplementation and doorstep antenatal care, along with financial incentives for institutional delivery in both public and private hospitals. Yet if a woman had non-maternal health concerns, reproductive and sexual health services were neither locally available nor easily accessible in both public and private facilities. In the local primary health centre, I observed that pregnant women were weighed, vaccinated and counselled on specific days, while gynaecological exams were not available as a regular service. Some local HIV/AIDS centres provided exams and tests to detect sexually transmitted infections.

Women's fear of cancer reflected further weakness in the health system. Many referred to someone in their family or village who had died of cancer, presumably due to causes related to the cervix or uterus. Twelve percent of deaths amongst rural women aged 30-69 years old are attributed to cancer, the leading cause of which is cervical cancer[269]. Yet observation indicated that virtually no cervical cancer screening programs operated in the area, and health messaging in villages – on health centres, billboards and on television – primarily focused on maternal and child health, with some space dedicated to HIV/AIDS and female infanticide. Providers, when questioned if women's common fear of cancer was proportionate to local prevalence, felt that poor women were in fact more vulnerable to cervical cancer due to poor hygiene. None, when specifically asked, cited the human papilloma virus as connected to cervical cancer. Given the lack of diagnostic equipment in clinics, they could not provide specific figures on cancer cases detected.

The clinics and hospitals offered few preventive services or minimally invasive procedures for gynaecological ailments. Private practitioners cited the introduction of a consumer protection act as motivation for hysterectomy rather than removal of cysts and fibroids which would return, as women could complain of inadequate treatment when symptoms returned. Another, however, felt that medical management must be tried first to protect doctors from consumer complaints of unnecessary hysterectomy. None of the practitioners felt technically equipped to conduct a laparoscopic procedure such as cystectomy. Updated technical knowledge of non-obstetric care also seemed limited, echoing earlier findings in India and other developing country settings where doctors reported difficulties accessing scientific articles and knowledge through the internet and otherwise[270]. Further, none of the five doctors were aware of the research being conducted globally on the long term effects of hysterectomy, including the widely researched associations with cardiovascular disease. According to Renukaben: *"Of course doctors have a role in all of this. If they give you proper guidance and give you medicine, you don't always have to remove your kothri* [uterus]*. For example, if you are having menstruation for a month and no other problem, the doctor should explain all the reasons that this could happen. Instead he will tell you to remove kothri. He gets the money, but doesn't give us proper information."*

Discussion

The striking normalisation of hysterectomy of women in their mid-thirties reflects women's life circumstances and the various power relationships they negotiate. Women emerged as *pragmatic* actors who negotiate their choices, however constrained or narrow the circumstances [198]. Their identity as caretakers, workers and producers drove many to seek hysterectomy as freedom from risk, illness or menstruation, with the understanding that the benefits outweighed both present and future costs [198]. The equating of women's lives and bodies with motherhood provided an enabling, if not instrumental, social and health system environment to remove the uterus as routine treatment for gynaecological ailments.   Personal motivations of providers, whether for skill-building or financial profit, emerged as further evidence of the biases that normalised hysterectomy amongst women in their mid-thirties. Further, women's low socioeconomic status appeared to preclude doctors from offering them other treatment options.

A range of accounts of women's actions to undergo invasive or potentially unnecessary technological interventions have cited a myriad of social, cultural and political influences, such as social acceptance, assertion of the right to quality health care, or to preserve their capacity to labour or manage their family that drove women's decisions [199, 263, 271, 272].   As Lock and Kaufert summarise:

> "*At the site of the individual body, therefore, biopower may be experienced as enabling, or as providing a resource which can be used as a defense against other forms of power. At the centre….stands a pragmatic woman willing to use whatever biomedicine can provide in pursuit of her own goals or the protection of her own independence*" [198].

Women's treatment-seeking paths were rarely a one-stop, or one-way, journey: they assessed options and considered financial, personal and familial implications over time. Women workers in the informal economy do not work for extra income for the household; their earnings are typically critical to survival. Thus gynaecological morbidity not only represented the loss of income, but also the loss of identity as a productive family member. In this way, bio-medicine and its negotiations were enacted in spheres of work and family, beyond the provider-patient interaction. By seeking multiple opinions, women in effect distilled the power imbalance typically ascribed to one provider: they equipped themselves to make informed decisions.

While women's accounts indicated they were not passive recipients of medical authority nor embedded in a 'culture of silence', characterisation of their actions solely as resistance or agency must be qualified – both because they were not expressly articulated as such [273] and in light of the health system. For women faced with often painful, untreated gynaecological morbidity, a public health system focussed on maternal health offered few options for gynaecological care[158]. Health services for women in

Gujarat have largely been focused on maternal health, particularly recent investments through the National Rural Health Mission and large donor-funded programmes[169]. As a result, the health system and providers provide an array of services through pregnancy and childbirth. Yet once women who had fulfilled their reproductive duties experienced morbidity, providers advised hysterectomy–forgoing prevention, first-line treatment and referral to alternative services–because it offered a permanent solution to the now problematic uterus. They seemed neither inclined towards, nor capable of, managing women's non-maternal health issues without surgical intervention. The vast majority of health care in India is sought in the private sector[2]; hysterectomy is not an exception, although it reflected greater use of public services than for other ailments. While expressing agency in deciding the terms of a hysterectomy, women in this context were simultaneously constricted by structural, health system weaknesses. By altogether removing the perceived root cause of illness, providers and women absolved the health system of its failure to address women's gynaecological concerns in a primary care setting.

A focus on women's agency and decision-making risks ignoring or minimising the importance of why they sought treatment in the first place. A substantial body of literature over the past two decades has estimated the prevalence of reproductive and sexual health–related ailments amongst women in rural India and the lack of appropriate, accessible treatment [151, 152, 274-277]. The extent of the disruption of gynaecological and menstrual disorders to women's work has also been documented in low-income settings [128, 278, 279]. Interviews in this study quickly revealed that women experienced considerable gynaecological and menstrual ailments – illnesses that compromised their ability to work and conduct daily activities. Further, agricultural labourers with history of childbirth without skilled attendance are likely at higher risk of uterine prolapse[280, 281]. Local midwives also perceived an increase in menstrual irregularities in the study area, ascribed to relatively recent, unrestricted use of fertilisers and lifestyle changes.

Lastly, the local specificity of risk factors for hysterectomy deserves consideration. The predominance of sterilisation as contraception amongst young women in India is an extreme pattern, not seen elsewhere in the world, that has both demographic and health implications [282]. While the immediate health risks of poor quality sterilisation have been documented, longterm biological effects require more research [283]. Tubal ligation has been associated with increased risk of menstrual disorders and hysterectomy in studies conducted in the United States, although the evidence is not consistent [284-288]. Combined with a lack of labour security and very limited treatment options, women in this setting, particularly those who have undergone sterilisation, may be at a higher biological risk for the gynaecological morbidity that ultimately leads to hysterectomy. Further, women in previous research have perceived sterilisation to be the cause of subsequent gynaecological morbidity[154, 158]. Localised risk factors for (and side effects of) hysterectomy and early menopause in this population are reminder of how social, cultural and political factors affect, and are affected by, biological processes [289, 290].

Thus, situated and localised accounts of women's experiences are critical to identifying determinants of hysterectomy as well as engaging meaningfully with interventions. In Towzi's ethnography in rural Pakistan, women were unlikely or unable to seek multiple opinions for treating gynaecological ailments. Hysterectomy reflected medicalisation processes enacted through a power-imbued colonisation of rural women's bodies, fuelled by attitudes towards the uterus and poor women [262]. Women's experiences did not suggest the space to negotiate as observed in Gujarat – perhaps reflective of differences in sociocultural and health care environments. Further, biological vulnerabilities and the experience of gynaecological morbidity may have differed. Women without access to SEWA's activities or those in less developed health systems environments such as Rajasthan and Chhattisgarh are faced with different negotiations – as underscored by variations in sociocultural determinants of, and treatment-seeking patterns for, gynaecological ailments observed in different parts of India[153, 154, 156-158, 166]. As a result, interventions and approaches may, and should, vary: in rural Gujarat, a lack of appropriate, quality gynaecological care emerges as an immediate area for intervention, along with advocacy to promote women's health care beyond reproduction, significantly improved family planning services and deeper analysis of provider incentives.

Conclusion

This account aimed to nuance the conceptualisation of hysterectomy as solely a provider-driven, top-down interference in women's bodies. Women's decisions to undergo hysterectomy in rural Gujarat were complex negotiations across individual, socioeconomic and health system-related compulsions. Women's own perceptions stood in stark opposition to that of the systems around them: they identified themselves as workers and caretakers, charged with both responsibility and duty. Gender and class biases, however, defined them as essentially reproductive contributors with few options in a weak health system. When faced with uterine-related ailments that disturbed daily life, these two opposing characterisations in fact aligned – and normalised hysterectomy as treatment and prophylaxis. Viewed beyond the medical encounter, hysterectomy is a symptom of the gendered health services, socioeconomic inequities and insecure labour conditions that marked women's lives. Accordingly, both its underlying determinants and long-term effects demand structural, systemic interventions.

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Principal Supervisor Simon Cousens

Thesis Title

Community health worker-led education to change women's treatment-seeking behaviour: A cluster randomised trial and qualitative investigation in Gujarat, India

If the Research Paper has previously been published please complete Section B, if not please move to Section C

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II. Incidence and determinants of hysterectomy in a low-income setting in Gujarat, India

Introduction

Hysterectomy, the removal of the uterus, is the leading reason for non-obstetric surgery in many high-income settings[30, 33, 291]. Like caesarean sections[292], frequency of hysterectomy varies widely between and within countries. An estimated 5.1 women per 1,000 women above age 15 underwent the procedure in 2004 in the United States, compared to 3.1 per 1,000 women in Australia [33, 95]. Within Germany, incidence varies across federal republics, ranging from 2.1 to 3.6 per 1,000 women [96]. The procedure is most commonly performed in women over the age of 45 [97, 98]. Medical indications include uterine fibroids, dysfunctional uterine bleeding, uterine prolapse and chronic pelvic pain[93]. Physician assessments on appropriate use of the procedure diverge widely–contributing to variation in rates as well as suspected misuse in some settings [100, 109, 110, 112]. Hysterectomy has also been associated with women's demographic characteristics such as race, education and socioeconomic status, as well with insurance status, physician sex, training and geography, suggesting that hysterectomy is a product of both biological risk and the broader social and health system environment[99-105]. Further, in light of the high lifetime risk in some settings–one in three women in the United States for example– the procedure has been scrutinised and contested as unnecessary medical intervention in women's bodies [113-115].

Until recently, research and debate on hysterectomy have largely been limited to high-income countries. There are nine estimates of prevalence in low and middle income countries, based on community-based research in India, El Salvador and Jordan[120-128]. In the absence of age-standardised estimates to compare across settings, it appears that prevalence–ranging from 1.7 to 9.8 percent of adult women–of hysterectomy in these three countries is similar to estimates in Taiwan and Singapore (8.8% and 7.5%, respectively)[162, 293] and considerably lower than the United States (26.2%), Australia (22.0%) and Ireland (22.2%)[105, 294, 295]. In 2012, however, media reports in India raised suspicion of the increasing misuse of hysterectomy as routine treatment for gynaecological ailments, particularly in young, premenopausal women [117, 118]. Analysis of facility and insurance data has suggested that hysterectomy is correlated with profit incentives under the national health insurance scheme and unregulated private health care [257, 258]. Moreover, a recent study in rural Andhra Pradesh found that hysterectomy, conducted at an average age of 29 years, also included removal of both ovaries (and thereby induced premature menopause) in 59% of cases[296]. In response to such findings, two states have already restricted publicly-funded insurance coverage for the procedure in private facilities[256].

There is very limited population-level evidence on hysterectomy to inform policy decisions in India. Our own earlier research in Gujarat identified hysterectomy as the leading reason for hospitalisation in the past six months amongst both insured and uninsured women, but cross-sectional data prevented comparison with other settings or conclusive findings related to determinants[145]. In light of (i) the lack of data in India and (ii) the social and health systems factors associated with hysterectomy in other settings, we conducted a mixed methods analysis, integrating a cohort study and qualitative research, to estimate incidence, identify predictors and explore the underlying determinants of hysterectomy in a low-income setting in Gujarat, India.

Setting

Gujarat, a state of 60 million people on India's Western border, is amongst the top five contributors to India's economic growth, with the third highest GDP[168]. The National Rural Health Mission (NRHM), India's flagship health programme to improve rural health infrastructure and human resources, was initiated in 2005 and followed by Rashtriya Swasthya Bima Yojana (RSBY), the national health insurance scheme that provides hospitalisation coverage up to Rs.30,000 in public and private hospitals for families with below poverty-line cards. Indicators suggest common use of medical interventions for reproductive health : fifty-seven percent of births in Gujarat occur in a health facility, with institutional birth more common among higher-income, educated urban women[3]. Forty-four percent of currently married women have undergone sterilisation, accounting for 70 percent of all contraceptive use amongst reproductive aged women. Lower-income women are more likely to utilise sterilisation as a primary form of contraception, and 85 percent of sterilised women utilised a government facility for the procedure[3].

This study was conducted alongside a two-year evaluation of a community health intervention conducted by the Self-Employed Women's Association (SEWA) in Ahmedabad district and city in Gujarat between 2010 and 2012. SEWA, a trade union of over 1.5 million women workers in the informal economy, works towards members' full employment and self-reliance. It operates a voluntary health insurance scheme (VimoSEWA) that offers coverage for hospitalisation that exceeds 24 hours. Previous research based at SEWA has identified hysterectomy as a leading reason for insurance claims and hospitalisation at an average age of 36, as well as identified poor quality of care provided to women for gynaecological ailments and surgery[138, 141, 145].

Methods

The nature of the research questions called for a mixed methods design. While a quantitative survey could estimate measures of frequency and individual-level predictors of hysterectomy, understanding the complexity of social and behavioural factors that influenced women to undergo hysterectomy required integration of a qualitative approach[297]. Given the lack of previous research in low-income settings, a mix of quantitative and qualitative data also allowed for triangulation of findings and more extensive exploration of determinants in this setting[207]. This study utilised two data sources: (i) a quantitative, population-based cohort study amongst adult women (ii) in-depth ethnographic research amongst women, health care providers and key informants. As part of the trial, the quantitative survey was designed first, and included basic questions to estimate prevalence of ever hysterectomy in the study population. After analysing baseline findings, we decided to (i) add survey questions pertinent to hysterectomy and reproductive health history to subsequent rounds and (ii) initiate a qualitative study to explore individual, social and health systems determinants of hysterectomy. The mix of providers and average age reported in the baseline led to inclusion of in-depth interviews with government health providers and younger women. All participants reviewed a study information form with researchers and provided consent to participation and sharing of findings. Identities of all sources have been anonymised. Ethics approval for quantitative and qualitative components was provided by the Executive Committee of the SEWA Health Cooperative and the ethics committee of the London School of Hygiene and Tropical Medicine.

(i) Cohort study

Quantitative data came from four household surveys that collected demographic, health and treatment-seeking information in a cohort of adult women, as part of a two-year cluster randomised trial to evaluate the effect of a SEWA health education intervention. The intervention was designed to reduce insurance claims and hospitalisation for diarrhoea, fever and hysterectomy amongst adult women. The trial was conducted in 28 clusters over two years. Seventy households were surveyed in each cluster, 35 of which were randomly selected from SEWA's insurance membership database. The remaining 35 were randomly selected from household listings. 1,934 women were recruited in the first round. The trial was registered as ISCRTN 21290274.

Analysis of the trial indicated no evidence of an effect of the intervention on rates of claim submission, hospitalisation or morbidity. Accordingly, a cohort analysis to estimate incidence and identify predictors of hysterectomy included data from both treatment and control areas over all four rounds of the household survey. Data were entered into a Microsoft Access database and analysed using Stata 11. The svyset command was utilised to take into account the cluster sampling and sampling weights for insured and uninsured households. Insured households were over-sampled as part of the trial design, and all tables except Table 8.2 present weighted proportions so findings are representative of the general population. Women who reported past hysterectomy prior to the period covered by the baseline survey were excluded. The incidence of hysterectomy, based on cases reported by the primary adult respondent over the two-year survey period, was estimated using the exponent of the Poisson regression coefficient. Crude rate ratios for a range of demographic characteristics such as income, location, education, insurance status, number of living children and sterilisation history, were estimated using Poisson regression. Wald tests were utilised to obtain p values for variables with more than one level. A multivariable Poisson regression model was fitted including variables with crude rate ratios observed to be associated with ($p \leq 0.05$), or those that could be theoretically associated with, hysterectomy. Effect modification was investigated for sterilisation status, education, income and insurance status.

(ii) Qualitative study

Qualitative fieldwork was conducted by SD, who had worked in the study areas for ten years. Women who had undergone a hysterectomy were identified over time and through interactions in the community, as well as through health workers and referrals from other interviewees. Women interviewed were resident in two rural blocks that were also covered by the quantitative study, but were not chosen from the survey sample. Women were recruited and interviewed until no new analytical themes emerged and there was variation in the length of time since the procedure. Thirty-five women with previous hysterectomy were interviewed. Five gynaecologists, who had performed the hysterectomy for 20 of the 35 cases selected, were interviewed along with 16 other key informants, including three women with gynaecological ailments who did not proceed with hysterectomy. Three group discussions were conducted with young women who lived in the study areas.

Interviews were conducted and transcribed in Gujarati. Thematic patterns regarding the decision to undergo hysterectomy that emerged during interviews were identified using codes. Women were then compared across individual sub-themes and variables to identify heterogeneity and new themes, which ultimately led to identification of broad typologies across women's treatment seeking patterns. Interview content was also specifically analysed to examine if SEWA health insurance affected the decision to undergo hysterectomy.

Mixed methods analysis

The mixed methods analysis was both inductive and deductive, in an iterative approach using triangulation and by 'following a thread'[208]. The quantitative cohort data were analysed first to estimate incidence and identify predictors of hysterectomy. A thematic analysis of qualitative data was conducted next to examine processes and determinants. Next, findings from both sets of data were triangulated to identify convergence, dissonance and gaps. New analytical themes in either set of data also led to further analysis in the other. For example, in-depth interviews with women suggested that views on hysterectomy varied by sterilisation history (a 'thread'), which prompted quantitative analysis of effect modification by sterilisation status. Finally, predictors and underlying determinants were examined together to identify intersections.

Findings

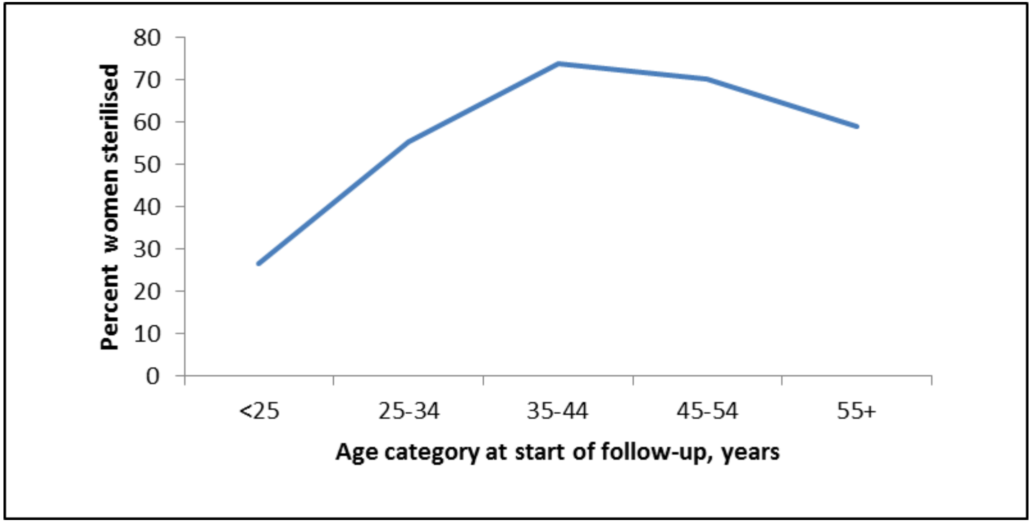
Of the 1,934 women recruited, 318 were lost to follow-up by round four, 239 of whom either migrated or lost their homes due to slum demolitions during the survey period. 191 women (10%) had undergone hysterectomy before the period covered by the baseline survey and were excluded from the cohort analysis. Surveyed women contributed 3,259.4 woman-years at risk. Women surveyed were low-income women workers of the informal economy, most between the ages of 25-44, and married with at least two children (Table 8.2). Sixty-two percent of women who were surveyed in round 4 reported having undergone sterilisation, with mean age at time of sterilisation 27.5 years. Over 70 percent of women between the ages of 35-54 years reported having been sterilised (Figure 8.1).

Table 8.2 Overview of study sample at risk of hysterectomy (n=1,743)

Overview of study population	**n**	**%**
	1,734	(unweighted)
Age group		
<25	132	7.6
25-34	541	31.2
35-44	596	34.4
45-54	359	20.7
55+	115	6.6
Demographic characteristics		
Insured	908	52.4
Rural location	986	56.9
Currently married	1536	88.6
Have individual latrine in home	950	54.8
Hindu	1543	89
Never attended school	932	53.7
Agricultural worker	697	40.2
Annual income below Rs. 60,000	790	45.6
Partial mud and solid house	1040	60
Have 2+ children	1598	92.2
Have undergone sterilisation*	884	61.7
Report average health	1254	71.9

*310 women with missing information; data from survey round 4

***Figure 8.1 Proportion of women sterilised, by age category* (n=1,433)**



Predictors of hysterectomy

Sixty-two women reported undergoing hysterectomy during the two-year study period, an incidence of 20.7/1,000 woman-years (95% CI: 14.0-30.8 per 1,000 woman-years), at a reported mean age of 36.0 years (95% CI: 33.8,36.2). Crude analyses indicated little evidence that hysterectomy rates varied by rural or urban location, insurance status, education, religion, occupation or perception of one's own health (p>0.2 in all cases, Table 8.3). There was strong evidence that the incidence of hysterectomy was higher amongst women with relatively lower incomes (RR=0.12 for annual household income of Rs. 120,000+; p value =0.001). The incidence of hysterectomy was highest amongst women between 25 to 54 years, and very low amongst women older than 55 (0.06/100 woman-years). There was also strong evidence that women who have two or more surviving children had a higher rate of hysterectomy than women with fewer children. Women who had not been sterilised reported lower rates of hysterectomy than sterilised women, but evidence for this association was weak (RR=0.41, 95% CI: 0.14,1.21; p=0.09).

Table 8.3 Baseline characteristics associated with incidence of hysterectomy (n=62)

Variable	**n**	**Rate** /100 w-years	**95% CI**	**Rate ratio**	**95% CI**	**p value**
Uninsured	30	2.09	(1.37,3.12)	(b)		
Insured	32	2.08	(1.39,3.20)	1.01	(0.62,1.64)	0.98
Location						
Rural	45	2.43	(1.39,4.24)	(b)	(0.33,1.29)	0.21
Urban	17	1.58	(1.02,2.47)	0.65		
Age at start of follow-up						
<25	4	0.74	(0.13,4.16)	0.33	(0.05,2.14)	0.008
25-34	16	2.35	(1.26, 4.41)	1.06	(0.46,2.43)	
35-44	28	2.22	(1.32,3.74)	(b)		
45-54	13	2.69	(1.38,5.25)	1.21	(0.63,2.34)	
55+	1	0.06	(0.001,0.50)	0.03	(0.003,0.21)	
Marital status						
Married	58	2.19	(1.47,3.30)	(b)		0.06
Unmarried	1	0.15	(0.01,1.57)	0.07	(0.01,0.66)	
Widowed	3	1.16	(0.18,7.48)	0.53	(0.08,3.66)	
Primary occupation						
Self-employed/service	22	1.73	(1.11,2.66)	0.59	(0.33,1.06)	0.20
Agriculture	36	2.91	(1.56,5.45)	(b)		
Salaried	4	1.13	(0.25,5.10)	0.39	(0.06,2.45)	
Education						
Never attended school	32	1.96	(1.37,2.81)	(b)	(0.67,1.81)	0.69
Attended school (primary+)	30	2.17	(1.26,3.69)	1.10		

Table 8.3 (cont)

Mean annual HH income (INR)						
0-60,000	29	2.70	(1.59,4.58)	(b)		0.001
60,001-120,000	26	2.03	(1.08,3.80)	0.75	(0.33,1.70)	
120,001+	7	0.31	(0.10,9.70)	0.12	(0.31,0.44)	
Religion						
Hindu	55	2.15	(1.51,3.05)	(b)	(0.20,2.75)	0.65
Muslim	7	1.61	(0.35,7.32)	0.75		
House type						
Mud house	15	3.34	(2.02,5.50)	(b)		0.33
Partial mud and solid	31	2.04	(1.23,3.37)	0.61	(0.29,1.27)	
Solid construction	16	1.51	(0.52,4.36)	0.45	(0.13,1.60)	
Individual latrine						
No	30	2.55	(1.56,4.18)	(b)		
Yes	32	1.76	(1.13,2.74)	1.45	(0.87,2.41)	0.15
*Number of surviving children**						
0-1	1	0.05	(0.01,0.02)	0.03	(0.003,0.26)	0.006
2-3	36	2.47	(1.65,3.68)	(b)		
4+	18	1.98	(1.39,5.15)	0.80	(0.37,1.72)	
*Sterilisation status**						
No	10	1.15	(0.51,2.58)	0.41	(0.14,1.21)	0.10
Yes	45	2.79	(1.78,4.37)	(b)		
Perception of own health						
Very poor	1	0.93	(0.09,9.46)	0.45	(0.05,4.36)	0.76
Average	48	2.08	(1.11,3.89)	(b)		
Very good	13	2.12	(0.96,4.69)	1.01	(0.31,3.32)	

*Note: (b) is baseline group for calculation of rate ratio. *Data collected from round 4; 7 cases missing.*

Multivariable regression (Table 8.4) indicated that the incidence ratio of hysterectomy was independently associated with age, with highest incidence between 25 and 54 years, lower income and greater number of surviving children. There was no evidence of clustering of hysterectomy rates (p=0.11). Sterilisation history was not independently associated with hysterectomy, but there was evidence that the effect of income varied by sterilisation status (p=.018). Amongst sterilised women, hysterectomy rates drop markedly amongst women in the highest income group (>Rs.120,000/year), but were relatively constant at income levels below that (RR=1.06). Amongst women who were not sterilised, hysterectomy rates drop markedly at incomes above Rs. 60,000.

Treatment-seeking patterns and expenditure

Nearly two-thirds of women (62%) utilised private hospitals for hysterectomy, while the remainder used government (34%) or non-profit trust hospitals (5%). Mean out-of-pocket expenditure on hysterectomy (Rs. 11,068) was similar across insurance status, higher in urban areas compared to rural, and higher in private facilities compared to government or trust hospitals (Table 8.5). Fitting a linear regression model with robust standard errors, adjusted for location and insurance status, there is strong evidence that the cost of hysterectomy in private hospitals was more expensive than government hospitals (mean difference=Rs. 6702; 95% CI: 1676-11729; p=0.01). There was no evidence of a difference by urban/rural location (p=0.18), after adjustment for insurance status and place of treatment.

Table 8.4 Baseline characteristics associated with hysterectomy; multivariable regression

Variable	**Rate ratio**	**95% CI**	**p value**
Age at start of follow-up			
<25	0.56	(0.09,3.39)	0.010
25-34	1.09	(0.48,2.45)	
35-44	(b)		
45-54	1.43	(0.77,2.65)	
55+	0.03	(0.003,0.23)	
Mean annual HH income (INR)			
0-60,000	(b)		0.007
60,001-120,000	0.66	(0.28,1.59)	
120,001+	0.06	(0.01,0.22)	
Number of surviving children			
0-1	0.03	(0.002,0.22)	0.009
2-3	(b)		
4+	0.81	(0.40,1.63)	
Income by sterilisation status			
Income, amongst sterilised women			
0-60,000	(b)		0.0008
60,001-120,000	1.06	(0.43,2.60)	
120,001+	0.08	(0.02,0.33)	
Income, amongst unsterilised women			
0-60,000			0.003
60,001-120,000	0.03	(0.003,0.36)	
120,001+	0.02	(0.002,0.28)	

Table 8.5 Expenditure on hysterectomy by insurance status, location and hospital type **(INR)**

	n	Mean	Median	Min, Max	p value
Uninsured	30	11746	10000	0,50000	0.76
Insured	32	10510	10000	300,25000	
Urban	17	14285	10300	950,50000	0.36
Rural	45	10341	10000	0,28200	
Govt	19	5325	4700	500,21500	0.004
Private	37	15284	15000	0,50000	
Trust	6	9390	10300	494,12000	

Qualitative findings

Each of the 35 women interviewed who had undergone hysterectomy had broadly similar demographic characteristics as women in the cohort study (Table 8.6). Most women and key informants (health workers, midwives and family members) felt the procedure was normal and increasingly common; all easily recounted cases of others who had had the surgery in the surrounding areas. All 35 women reported gynaecological morbidity, typically experienced as severe pain, excessive bleeding and disruption to daily life, as the catalyst for seeking care from a gynaecologist. Two local midwives perceived an increase in menstrual disorders in the area, ascribed to use of fertilisers in the soil and dietary changes. They also believed younger women no longer relied on traditional medicines for menstruation-related ailments in particular, as the new generation desired quicker treatment.

The majority of women sought at least two medical opinions for gynaecological morbidity (Table 8.7), over a period of several weeks or months, during which time they considered the financial, logistical and familial implications of hysterectomy once it was suggested as an option (See Box 1). Slightly more than half of women utilised private hospitals (Table 8.8), while the remainder used government and trust facilities, similar to the survey findings. Most women were unsure if their ovaries were removed with the uterus, except for the two women who were aware they underwent oophorectomy. Almost all women shouldered debt, mortgage or other financial difficulties to finance treatment and surgery.

Table 8.6 Demographic characteristics of 35 women who underwent hysterectomy

Women interviewed		
Mean age at hysterectomy	35.8	
Years since procedure	**n**	**%**
<1 year	7	20
<5 years	12	34
5-10 years	7	20
>10 years	9	26
Occupation		
Agricultural	18	51
Health worker	3	9
Manual (non-farm) labourer	6	17
Housework	8	23
Any education		
Yes	10	29
No	25	71
Insurance status		
Insured	11	31
Uninsured	24	69

Table 8.7 Women's treatment-seeking patterns (n=35)

Treatment-seeking	
Previously sterilised	
Yes	26
No	9
Reason for hysterectomy	
Bleeding	9
Cyst/fibroid related pain	15
Pain	6
Prolapse	5
Waited to seek any treatment	
Yes	11
No	24
Sought 2+ medical opinions	
Yes	27
No	8
Place of hysterectomy	
Government	13
Private	16
Trust	6

Women's experiences

Using thematic analysis, women's experiences and attitudes regarding hysterectomy (See Box 8.1) were categorised along a spectrum–last resort, pragmatic treatment/prophylaxis or permanent freedom – based on their reproductive health history, treatment-seeking patterns and representations of hysterectomy (Table 8.8). While attitudes toward hysterectomy did not appear to be linked to observable socioeconomic or demographic characteristics, desire for work security and freedom from future health risks such as cancer or continued morbidity led most women to view it as a 'permanent solution.'

Box 8.1 Women's experiences with hysterectomy

Hansaben, an agricultural labourer, age 40 when she underwent a hysterectomy last year:
I had severe pain in my stomach for two years, but I was scared to see doctors. I have never even had a bottle (IV fluid). I went to Vasna (private doctor)…and then to a trust [hospital]*for a second opinion. The doctor said there was no way out….the cyst was so big it could not be removed alone. I kept crying, and finally went to one more private doctor who said my blood was low and I could not have surgery right away though I needed it. I took iron pills for 12 months…and then finally had the operation.*

Gajaraben, who labours in a brick kiln, age 36 when she underwent hysterectomy four years ago:
I had my periods for 15 days at a time, for 4 months. I went to two doctors...They said to do the test (sonography) and then said that if I don't remove it, I will definitely have cancer. You will have problems in the future, whether you take medicines or not….I did not want cancer in the future. Now I am okay again, I can lift big bricks and work. You can have a fever, cold, cough or weakness and go to work. But for this you can't work unless you take care of it.

Gauriben, age 40, who could not have children and had severe pain and bleeding:
We didn't know the reason for my problem, and the doctor said the uterus will have to be removed eventually. We also told her that we don't have any kids. She said that, since you don't have that capacity [to have children] *there is no point in keeping the kothri* [uterus].

Madhuben, an agricultural labourer was 25 years old when she had a hysterectomy:
My periods would stay for 20-25 days. I used to have a lot of pain. I took medicine prescribed at Civil Hospital [large urban govt hospital]...*for one and a half years. I then had a cyst, which they told me when went back to Civil. I took medicines for one more year but nothing improved. I went to 2-3 doctors after that. A year later I finally had a hysterectomy.*

Nakviben, an agricultural labourer who was 22 when she had a hysterectomy:
I had heavy bleeding and a lot of pain. Working was a problem, so I thought to remove it. I went to three hospitals, who said it was not an emergency but I could remove it later. I tried the medicine but started vomiting. I hate medicines; even if I have a fever, I don't take any [oral] *medicine… not even home-based remedies. You see, I had a problem and I didn't want medicine. So at last, out of frustration, I removed it. I needed it [the operation] to be healthy.*

Table 8.8 Treatment-seeking spectrum

Grouping	Childbirth	Sterilised	Waited to seek treatment	Sought 2+ opinions	Tried Medicine /Alternatives	Perceived risk of surgery	Main drivers of procedure
Last resort (11)	Primarily home	Half	Yes	Yes	Yes	Fear of surgery	No other option – work and health security
Pragmatic (15)	All home birth	All	Yes	Yes	No	Minimal risk; concerned with future morbidity	Work and health security
Freedom (7)	Institutional	Most	No	No	No	None	Relief from menstruation

Very few women related side effects of hysterectomy and oophorectomy, if they knew the latter was performed. Almost all women who had the surgery several years ago did not report experiencing any difficulty associated with premature menopause, although none had taken hormone replacement therapy. Only one woman, a SEWA community health worker, related difficulties with sexual function and hot flushes after her hysterectomy. Midwives and local health workers felt that the removal of the uterus could be dangerous, but each had supported local women and family members in their decision to undergo hysterectomy.

Providers' views

All providers who were interviewed primarily provided obstetric care in their practices. They viewed hysterectomy as a one-time cure for menstrual problems, cysts, fibroids and other gynaecological ailments for rural, low-income women (See Box 8.2). In contrast, they felt urban women, as well as wealthier rural women, had the resources and awareness to try medicines or less extreme procedures such as cystectomy. A consistent theme was that, once reproduction was complete, the uterus was not an essential or required organ. With one exception, interviewed providers shared the opinion that side effects of hysterectomy are limited. Private practitioners cited the introduction of a consumer protection act as a motivation for hysterectomy instead of less invasive treatment, to ensure women would not complain of incomplete treatment if a cyst or fibroid returned. One felt such an act was a deterrent, due to potential complaints of unnecessary hysterectomy. The two non-profit providers felt private doctors were motivated by profit to conduct unnecessary procedures, but felt that demand from women was also a factor.

Box 8.2 Providers' views

Dr. Nikhil, non-profit charity hospital:
Women are different there [in the city] – *more literate, and they know and understand the indications and problems associated with hysterectomy*

Dr. Samir, private doctor:
They start bleeding a lot and don't take the proper [hormonal] *treatment course. And they are already sterilised. So somehow, the uterus is neglected. Ultimately they convert into hysterectomy cases.*

Dr Gaurang, government doctor:
Basically, if a woman is above 35-36 years, with her kids done, I do a full hysterectomy with oophorectomy. I do this to be safe, otherwise if they get a cyst they come back and say what kind of operation was that? So to be safe, I remove everything.[regarding side effects] *premature ovarian failure anyway happens by 37, 38 years.*

Local clinics and hospitals offered few preventive services such as diagnosis of reproductive tract infections through microscopy or less invasive procedures like laparoscopic removal of cysts, either due to lack of equipment or skills. Pap tests were not available outside of government sponsored camps held twice a month. Trans-vaginal ultrasounds which could detect fibroids and cysts were not easily available. All providers related the popularity of hysterectomy as a method for young, particularly rural, government doctors to gain surgical skills. Two providers had conducted many hysterectomies during early career rural postings, to help 'perfect the surgical hand'.

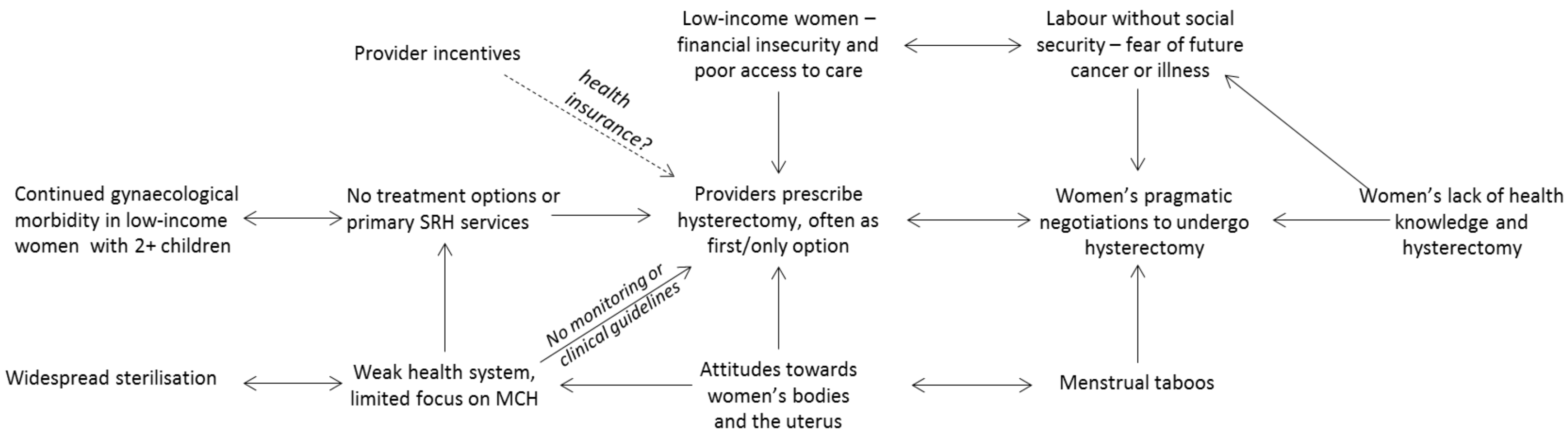
Pathways to hysterectomy: mixed methods analysis

Comparing and synthesising findings from both data sets, we identified pathways to hysterectomy that stem from: (i) work and economic insecurity (ii) lack of treatment for gynaecological morbidity and (iii) attitudes towards the post-reproductive uterus and to a lesser extent, (iv)history of sterilisation (Figure 8.2). Aligned with strong evidence from the survey that incidence of hysterectomy is higher amongst lower-income women, providers reported that hysterectomy is more likely to be prescribed as a first or second-line treatment option for low-income rural women who would not return for follow-up appointments associated with less invasive treatment. Although women with no work security underwent hysterectomy with considerable financial and physical risk, they believed removing the uterus – deemed a permanent cure for gynaecological ailments – would in fact secure their future productivity.

Qualitative findings pointed to health systems weaknesses, particularly the lack of reproductive and sexual health services, as a rationale for why hysterectomy was commonly prescribed as treatment for gynaecological ailments. Lack of knowledge, amongst both women and providers, about side effects of the procedure further contributed to its normalisation.   Notably, approximately one-third of women utilised public services for hysterectomy, and almost all women interviewed in-depth reported seeking at least two opinions before undergoing the procedure – suggesting that provider profit motivations are not the primary health systems-related driver of hysterectomy in this setting. Moreover, there was no evidence of an association of hysterectomy with being insured by VimoSEWA.   Women did not report seeking services in a primary care setting for gynaecological ailments, due to lack of availability. Findings also suggested that both women and providers viewed the post-reproductive uterus as a dispensable organ, which may explain why women with more than two children were more likely to undergo hysterectomy. Menstrual taboos, either a product of or contributor to attitudes towards the uterus, further strengthened some women's desire to undergo hysterectomy.

Qualitative data suggested an association between history of sterilisation and hysterectomy, while there was weak evidence in the quantitative analysis. From a decision-making perspective, women who had undergone previous sterilisation were less likely to try alternative treatment options such as hormonal medicine for gynaecological ailments. They expressed greater comfort with gynaecological surgery and a permanent solution, despite not having sought medical intervention for other health issues including childbirth. Although sterilisation history was not independently associated with hysterectomy, further analysis after the qualitative findings emerged indicated that the effect of income varied by sterilisation status.

Figure 8.2 Overview of determinants and pathways associated with hysterectomy



Discussion

Summary of findings

Our incidence estimate of 20.7/1,000 woman-years (95% CI: 14.0, 30.8), the only estimate of incidence in India to our knowledge, is at least four times higher than the highest global rates, such as the United States (5.1/1,000), Germany (3.6/1,000) and Australia (3.1/1,000) [rates in woman-years] [33, 95, 96]. This comparison must be interpreted cautiously, however, due to the demographic characteristics of the cohort population. Over 85% of respondents were women between the ages of 25-54, comprised mostly of SEWA members who worked in the informal economy. Since this is also the age group wherein women have typically completed childbearing and may have higher risk of menstrual disorders compared to postmenopausal women, they may be at higher risk of hysterectomy than older or younger women. Accordingly, this study may have overestimated population incidence compared to studies in high-income countries that include all adult women. Inclusion of respondents' mother-in-laws and adult daughters in the household, for example, may have produced lower estimates of hysterectomy incidence.

There was strong evidence that lower-income, rural women who have completed their families undergo hysterectomy at higher rates than other women. Our findings suggest that hysterectomy is prescribed commonly as the first or second-line treatment option for gynaecological ailments, particularly for low-income rural women. After seeking multiple opinions, women underwent hysterectomy with considerable financial and physical risk, but with the belief that removing the uterus would secure their future health and productivity. Attitudes towards the uterus as a dispensable organ – aligned with a health system that does not provide comprehensive sexual and reproductive health services – have rendered hysterectomy a 'permanent solution' to women's gynaecological ailments.

Implications for women's health

In this setting, neither women nor providers were aware of potentially adverse side effects of hysterectomy–supporting the perception that removal of the uterus and ovaries at young age was generally beneficial or protective. However, even without removal of the ovaries, hysterectomy has been associated with earlier onset of menopause[298]. Women who undergo hysterectomy at a mean age of 36 are at risk of menopause considerably earlier than the estimated global median age at natural menopause, 51 years [299]. Evidence on the longterm effects of hysterectomy, though inconsistent, also suggests hysterectomy is associated with higher risk of cardiovascular disease, with higher risk amongst younger women and women who have undergone oophorectomy[300-303]. Recent research in Taiwan suggests that women who undergo only hysterectomy before age 45 are at a higher risk of stroke (RR: 2.29 (95% CI, 1.52,3.44)[302]. Further, hysterectomy has been associated with urinary incontinence and problems with sexual functioning, psychosocial wellbeing and self-image [304-309].

Social and biological determinants

A 1997 editorial in the British Medical Journal opined, *"To study the indications for hysterectomy is to study the interface between medicine and society*[310]." Variations in hysterectomy rates by socioeconomic status, ethnicity and education in high-income settings such as Italy, New Zealand and the United States [102, 104, 294, 311, 312] generated the notion that hysterectomy is a product of both social and biological processes[290]. Our data from Gujarat suggests a similar condition in India. Higher rates amongst lower-income women are of particular concern, as they reflect both immediate health risks and embedded inequality. Women workers in India's vast informal economy typically survive on precarious incomes. As women articulated, gynaecological and menstrual disorders disrupt their work security, similar to findings in other low-income settings [128, 278, 279]. They therefore viewed hysterectomy as both pragmatic treatment and prophylaxis, a permanent solution that secured their future earning capacity. Providers provided differential care based on socioeconomic status, effectively rendering hysterectomy the 'only' treatment option for rural, low-income women as compared to their urban or wealthier counterparts.

The high proportion of women sterilised in India, most common amongst low-income women, is an extreme situation not seen anywhere else in the world[282]. In addition to significant health and demographic implications, sterilisation appears to be related to an increased risk of hysterectomy. Biologically, tubal ligation has been associated with higher risk of menstrual disorders and gynaecological ailments in the United States, although evidence is mixed [284-288]. From a decision-making perspective, women who were sterilised seemed less likely to try alternative treatment options such as hormonal medicine. They expressed greater comfort with gynaecological surgery and a permanent solution, despite not having sought medical intervention for other health issues including childbirth. Widespread, normalised surgical sterilisation may in fact be a precedent for the idea of a permanent solution to reproductive ailments, for both women and providers. Our finding that the effect of income varies by sterilisation status emphasises the need to understand these linkages further.

Further, belief that the uterus is productive only when reproductive reflected underlying gender biases, as well as a widespread cultural prioritisation of women's identity as mothers[260]. Almost no women, including key informants, believed the uterus performed essential body functions after childbearing was complete. Moreover, women viewed it as a potential site of cancer – a liability – for which hysterectomy represented a solution. These findings concur with emerging research in South Asia on the rationale for hysterectomy to prevent future health problems [262, 313], as well as reflect women's pragmatic actions to use bio-medicine as a tool to reduce physical and socioeconomic risk[198].

Implications for health policy and programs

Our findings suggest that hysterectomy is performed without appropriate diagnostic evaluation or alternative treatments tried. Similar to findings of medical audits in the United States, the lack of clear clinical guidelines for hysterectomy may leave it subject to misuse[298]. Differential treatment of lower-income women and use of hysterectomy as 'practice' in this setting point to embedded biases in health care for women–and reflect a culture, including beyond this setting, of unnecessary medical intervention in women's reproductive systems[113-115]. The normalisation of hysterectomy also underscores the complex negotiations between women's agency and medically unindicated procedures, as well as the ethical obligations of providers --- both of which require further consideration in the Indian context[267, 271, 272].

The use of public facilities by over one-third of women in this setting suggests that profit alone is not the most important driver of hysterectomy. However, health financing incentives may play a role in promoting hysterectomy amongst low-income women. While SEWA insurance was not associated with higher hysterectomy incidence–women and providers both cited its low benefit package as why it could not be a financial incentive–research is required to investigate possible influences of higher coverage packages offered by government schemes. Further, publicly-funded health insurance can arguably skew the health system further away from primary care, as it only covers tertiary care procedures or admission that exceeds 24 hours rather than outpatient services[314].

The characterisation of hysterectomy as both prophylaxis and treatment highlights the need to address the physical and emotional burden of untreated gynaecological morbidity, as reported in several studies in rural and urban India[151, 152, 274-277]. Providers' practices in the private, government and trust facilities were predominantly obstetric; they reported having neither the equipment, time, nor experience to diagnose or treat gynaecological ailments.   Moreover, the health system in Gujarat, as reflected in policy documents and observation during this study, focuses on maternal and child health without integrated reproductive and sexual health services at the primary level [169].   Without access to timely treatment in a primary care setting, women likely approach gynaecologists when conditions have become significantly more serious, and at a point when only surgical interventions are offered. Faced with a lack of preventive services for cancer, hysterectomy appears to serve as a prophylaxis – similar to findings reported in Mexico[315]. Lastly, the potential linkages between sterilisation–already widely criticised for poor quality of care and coercive policies—and hysterectomy further emphasises the need for comprehensive reproductive and sexual health services[283, 316].

Strengths and limitations

A primary strength of this study was its mixed methods design, which identified risk factors, suggested pathways for associations, and raised new hypotheses to explain hysterectomy patterns in one setting. The use of a cohort to estimate incidence, despite not being representative of all adult females, is an important contribution to examining hysterectomy in India. The sample, however, was in a low-income area which limits generalisability to different socioeconomic settings within India or to national estimates in other countries. Similarly, health is a state subject in India and services vary accordingly; these findings may be specific to the Gujarat health system. Self-reported hysterectomy is subject to reporting error, although the short recall periods and importance of a major surgery likely limit recall errors. Qualitative research may have been biased by the researcher's affiliation with SEWA, as interviewees may have felt differing levels of comfort based on their own relationship with the organisation. Triangulation of results, therefore, provided another means to limit bias in identification of determinants[207].

Conclusion

The burden of untreated morbidity, combined with attitudes towards the uterus and a health system ill-equipped to manage women's gynaecological health needs, has rendered hysterectomy both medically rational and socially acceptable for low-income women. The incidence and determinants of hysterectomy in this setting call for urgent intervention to curb its seemingly common use for conditions amenable to less-invasive procedures. Improved access to sexual and reproductive health services within primary health care services is a first step, including contraceptive choice to reverse the predominance of sterilisation. Health education on gynaecological ailments and the potential side effects of hysterectomy, as well as provider training (and health financing) for alternative procedures also emerge as important needs.

Research at the population level on gynaecological morbidity and hysterectomy is required across India to monitor trends, identify local determinants and track longterm health effects. Encouragingly, the National Family Health Survey will initiate collection of population-based data on hysterectomy in its next round, from which prevalence, facility choice and the association with health insurance can be examined across settings and over time[317]. Unlike for caesarean sections, there is no globally recommended appropriate rate of hysterectomy against which Indian trends can be compared[318]. However, experience in other settings suggests that national surveillance and medical audits can evaluate appropriateness of the procedure and monitor misuse, as well as support development of clinical guidelines[319, 320]. Most critically, a rights-based approach to women's health is essential to promote high quality prevention and treatment choices for women through the life cycle, rather than 'permanent' solutions.

Chapter IX. Process Evaluation

Introduction

After 18 months of the health education intervention, the cluster randomised evaluation detected no evidence of an effect on utilisation of health insurance, hospitalisation or morbidity related to diarrhoea, fever and hysterectomy. This chapter examines why the intervention did not have an effect, with a focus on the intervention processes and outcomes related to hysterectomy. Although I did not conduct qualitative research or analyse the intervention processes related to diarrhoea and fever, they are briefly discussed at the end of this chapter.

Analysis of the trial data estimated an annual incidence of hysterectomy of 21/1,000 women in this population, approximately four times higher than rates in the United States or Germany[33, 96]. Concurrently conducted qualitative research, presented in Chapter VIII, on the determinants of hysterectomy suggested that a lack of treatment options – supported by beliefs amongst women and providers that the post-reproductive uterus is dispensable – normalised hysterectomy as a 'permanent' solution for common gynaecological ailments.

The intervention was based on two assumptions: (i) health education was delivered effectively resulting in increased knowledge and (ii) knowledge translates into behaviour change regarding treatment-seeking for gynaecological ailments and hysterectomy. The approach to the intervention and evaluation was to assess effectiveness within existing resources, rather than test efficacy through an intensive, potentially non-scalable, intervention[321]. This process evaluation synthesises findings from the evaluation, in-depth research on hysterectomy and mixed methods process data to explore whether and how CHW-led group education can reduce the incidence of hysterectomy, with a view towards improving practice.

Methods

As described in Chapter IV, the process evaluation was based on the principles of theory-based impact evaluation as described by White (2009), particularly the use of a causal chain to understand how the intervention was intended to have an impact, understanding context and use of mixed-methods[209].

Based on the conceptual framework initially designed with CHWs, I developed an intervention causal pathway (Figure 9.1) after reviewing baseline findings and relevant literature. Quantitative and qualitative data were collected and analysed at each step, to examine each assumption between inputs and outcomes, such as: who actually participated in the intervention, whether implementation differed from the intended plan, and changes in intermediate outcomes that may affected the final outcomes. Findings from the in-depth qualitative study on hysterectomy (Chapter VIII) provided context on the social, economic and health systems factors relevant to the intervention, as well as insight into barriers and facilitators related to treatment-seeking for hysterectomy.

Data sources included: (i) CHW registers and monitoring data (ii) short interviews with 379 participants to test message recall (iii) qualitative, in-depth interviews with ten participants, 14 CHWs and 2 program managers (iv) household surveys utilised for the evaluation and (v) observation of intervention sessions. Process data were interpreted in three steps. Data were: (i) assessed along the causal chain to identify achievements and breakdowns (ii) contextualised with findings from qualitative research and (iii) interpreted with a view towards improving practice. Different data sources were triangulated at specific points in the causal chain, such as using both process and survey data to estimate outreach, or by combining qualitative interviews and session observations to understand effectiveness. More detail is found in Chapter IV.

Findings

Intervention implementation

Program managers related that the intervention was readily integrated within existing activities because it was delivered by experienced, established CHWs. They had longstanding relationships in their communities; there was no reported difficulty in recruiting women to attend sessions or building rapport with participants. The senior project manager, who concurrently managed two long term CHW initiatives, believed implementation surpassed other projects, largely due to comparatively more intensive monitoring, collection of process data and ongoing research. *"They* [CHWs] *had the mentality that someone is going to come back and check, to ask us if the work had been done. So this was different from regular projects – and the* [output] *results showed for it"* Salma, project manager. *"The work on this project is more serious than our regular activities. On other projects, we do not have such sustained and repeated inputs"* (Pramilaben, CHW).

However, given that CHWs were also engaged in other, incentive-driven activities such as insurance promotion and medicine sales, the health managers viewed monthly meetings as critical to building CHW engagement with the project. Each meeting included a capacity building component to help strengthen CHWs' knowledge and skills. CHWs consistently cited the new information on hysterectomies as knowledge which built their capacities and, in some cases, felt it strengthened their role vis-à-vis women in the community. According to Sunandaben: *I have new information. When women come to ask me about hysterectomy, I feel I can now give them the correct information. They can make the right decisions and even save money.* And Leelaben: *Regarding hysterectomy, women can tell me their private issues. Other workers like ASHAs and Anganwadis don't ask them questions in such detail. We can now explain everything about hysterectomy to them, to help them with their problems and decisions. And they come to us.*

The following section review processes and breakdowns in the intervention pathway, as presented in Figure 9.1.

Session implementation and coverage (Steps A,B)

CHW schedules and task allocation allowed for one health education session on hysterectomy per month along with regular home visits. CHWs organised 338 sessions, with a total of 4,969 participants (Table 9.1). Registers indicated that attendance ranged between 12-20 women, with an average of 14-15 participants attended per session. These records suggest that each CHW may have reached between 350-400 women over the course of the intervention, which would represent 25 to 50 percent of their coverage area population. However, given that some women may have attended more than one session, this figure should be considered as an upper bound on coverage.

Table 9.1 Hysterectomy session outreach, CHW registers

Process indicator	**Outreach**
Hysterectomy sessions	338 sessions
Total number of participants	4,969 women

Table 9.2 Reported attendance at hysterectomy sessions(95% CI)***, endline survey*** *(*n=1,616)

	Intervention n=833	Control n=783
Urban	9.4 (6.2,12.6)	7.9 (4.8,11.1)
Rural	10.2 (7.6,12.9)	3.5 (1.9,5.1)
Overall	9.9 (7.9,11.9)	5.1 (3.6,6.7)

In the endline household survey, approximately ten percent of women in intervention areas reported attending an education session on hysterectomy, with little difference between urban and rural areas. Amongst women in intervention areas, a higher proportion of insured women (13.2%) reported attendance compared to uninsured women (6.3%). About five percent of women in control areas reported attending a hysterectomy session, which could reflect contamination or recall error, both of which are discussed in the next section.

Figure 9.1 Intervention casual pathway

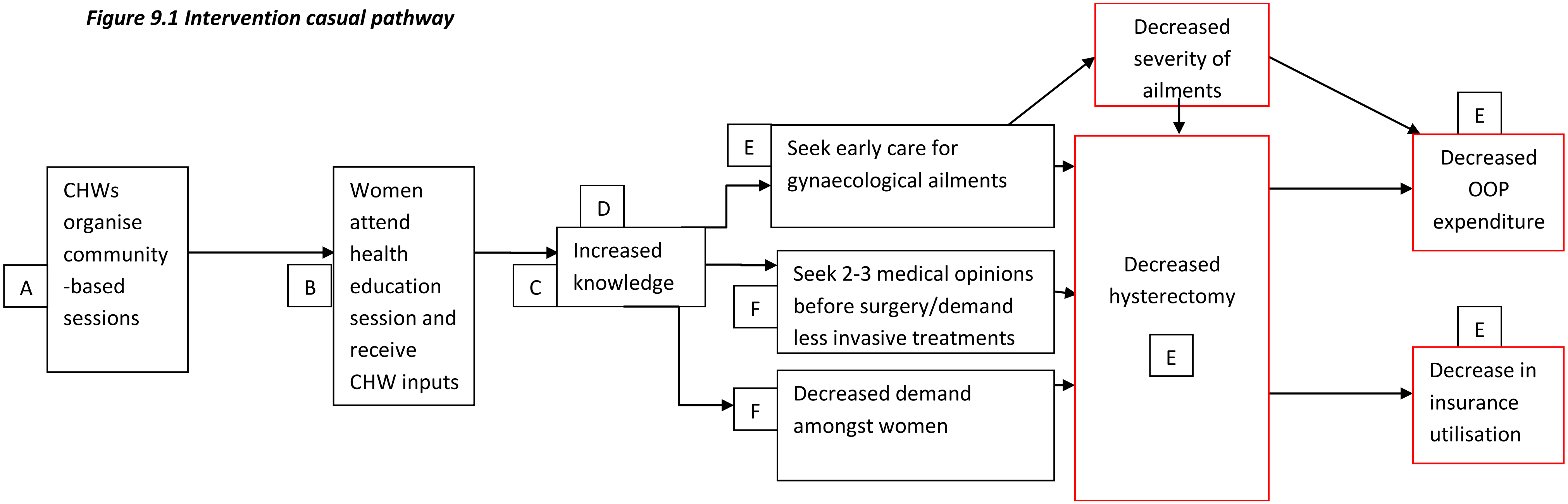


Diagram key	**Data sources**
A. Session implementation	Monitoring data, CHW/manager interviews
B. Session attendance	CHW registers and HH survey
C. Session effectiveness	Participant observation
D. Participant knowledge of key messages	Health education spot checks
E. Reported treatment-seeking behaviour	HH survey
F. Attitudes towards hysterectomy	In-depth interviews with women and CHWs

CHWs identified two primary implementation challenges. Logistically, finding space for group meetings was often difficult or caused delays, particularly in urban slums where most spaces were too small. Further, the film proved difficult to show during sessions. At first, CHWs depended on renting a DVD player from a local home, as SEWA interventions had done in the past. Monitoring reviews however, indicated that the film was not consistently used. Urban CHWs found rental feasible, while rural CHWs experienced more difficulty with finding DVD players and with intermittent electricity. Mid-way through the intervention, two DVD players were purchased for use during the project, to ensure availability was not a barrier. Analysis of process data indicated that 142 sessions (42 percent) had utilised the film.

Session quality (C)

Most CHWs identified the media tools as the key difference between this intervention and their regular activities. They felt the film in particular was potentially very effective, because it shared local women's stories and generated discussion. According to Seemaben, an urban CHW: *"Many women are illiterate; but they can see a film and understand everything"* and Chandrikaben, a rural CHW with 22 years' experience: *After we showed the DVD, women who wanted to have a hysterectomy started to talk about it, whereas they would not have earlier. Some even asked me if they could take it home to show their children, to start a discussion at home.* Bhanuben: "*When we watch the DVD, we know that this is real and happening to women around us."* Several CHWs also noted their satisfaction with the single topic of hysterectomy in a session, rather than earlier health education programs that covered several topics at once.

Early observations noted a lack of uniformity in meeting structures and content, partially due to different delivery styles and communication skills. Thereafter, a communications consultant was recruited and training focused on how to structure sessions and emphasise key messages through multiple interactions. Some CHWs had much more experience than others providing health education in groups, which appeared to help them hold an audience and deliver messages more effectively. Session observations noted three main findings: (i) message quality improved after the additional training sessions - a uniform, structured message was provided and reinforced by print media by most CHWs (ii) sessions that included a film viewing had much livelier and engaged discussion than those without the film and (iii) variation between CHWs was primarily related to delivery style, rather than session content. Communication skills varied greatly, with no correlation with education or previous training. Rather, we observed that some women had an innate skill, a sense of how to connect with others while the remainder imparted information. Although the trial and subsequent analysis detected no evidence of differences in incidence of hysterectomy across CHW clusters, qualitative observation suggested that skills levels varied. When two CHWs, Ranjanben and Basantiben, were followed on their daily rounds, a key difference that emerged was the level of community engagement and trust (See Box 9.1).

Short interviews – spot checks with two questions – with a sample of participants found that 82% of urban women and 68% of rural women who attended a session recalled that hysterectomy is not the only treatment option for gynaecological morbidity. 90% of both rural and urban women reported they would seek at least two opinions before undergoing hysterectomy. There was no notable difference by CHWs in responses; women in sessions facilitated by either Ranjanben or Basantiben had almost identical recall scores. In-depth interviews with ten participants indicated that recall of messages was generally consistent. Four women who were previously not aware of what a hysterectomy entailed could explain the procedure and what organs would be removed. However, some did not recall: Ramolaben, a participant in a session one month before I met her again: *"I don't know where the uterus is. I remember the lady* [CHW] *telling us about the operation and what can happen, but the doctor knows everything, we can just ask them…if a doctor says it has to be removed, then you have to remove it."*

Eight women interviewed, none of whom had undergone hysterectomy, related that the opinion of doctors would be the most important factor in such a situation. Recall of potential side effects was low, and understanding of the risk of premature menopause was not clear amongst women interviewed. Lalitaben, after attending a session, felt that "*The CHW said we should not remove the uterus if not necessary. But if someone has a problem, what else can we do? After the session, I would tell other women in my family or village, if they can get treated by medicine that is better. If you remove the uterus you can have other problems too, such as in sexual relations... but if someone has a lot of pain and problems they may have to remove it, there is no other way. After you remove the uterus you can still have pain and food won't digest properly – gas will form."*

Two strengths of the sessions were identified as: (i) confidence in the local CHW as a resource person on hysterectomy and (ii) the emphasis on the importance of seeking multiple opinions. Hansaben, a health education participant, explained: *"I learned that the period goes one day naturally; we don't have to remove the uterus for that. Some of our village women just get scared and remove it. After seeing Ranjanben* [CHW] *speak, I realised that she will understand and be there to help if I ever have this problem."* Education sessions were also seen as a catalyst for new conversations on hysterectomy that can address women's attitudes towards hysterectomy. CHWs also felt the information was discussed not only between women but also in the home, now with detailed information on options and side effects. Salma, the project manager, felt that *"Women demand hysterectomies because they don't have complete information. Their demand is associated with many old beliefs. If they receive proper information, there could be a change in demand."*

Box 9.1 Summary of two CHWs followed on daily rounds

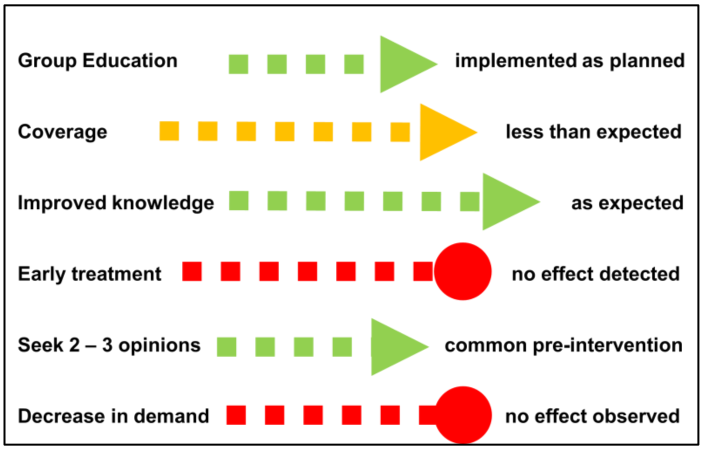
Ranjanben, a SEWA CHW for over a decade, knew the name of every woman who had had a hysterectomy in her village Rampur and the surrounding four villages. When she walked through the area, women stopped her to ask questions, to request her help for a doctor's visit, or just to invite her home for a chat. Almost every woman seemed to have a gynaecological complaint – white discharge, excessive bleeding, or pain. When she announced she was holding an education session, women quickly agreed to attend. During education sessions, it was common to have six to seven women stay on afterwards to discuss further with her and with each other. I observed three instances where she suggested and made plans to accompany a woman for a check-up. Ranjanben, who had herself had a hysterectomy several years ago, wished she had known more about hysterectomy earlier, as she felt it was a serious issue in the area. During her sessions, she used personal experience, diagrams and discussion to help explain reproductive anatomy and the implications of a hysterectomy. She made it a point to follow up on all questions, either after the session or at a woman's home.

Basantiben, also an experienced CHW, conducted daily rounds in her rural outreach area in a comparatively mechanical manner. Women stopped to ask her about an insurance claim or medicine sales, but not to ask questions about their health. She approached women or asked to visit them, but the discussion typically did not turn to gynaecological issues. She walked house-to-house to recruit women to attend sessions, often convincing them up until the last moment before the session. She employed the help of the local ASHA worker, who often stayed on in sessions and offered advice to women. Basantiben conducted the session competently, according to the session plan suggested in the trainings. She imparted the correct information, but several women left sessions before they concluded. Some women stayed on to discuss further, or to ask Basantiben to read their medical reports for them. I observed one woman request her help in seeking doctors' opinions. Basantiben felt that she was performing an important service by teaching women about hysterectomy, but did not pursue the issue with the same vigour as Ranjanben.

For women who attended sessions, participant recall tests suggested that message delivery was adequate. Although baseline knowledge was not measured, qualitative observation and interviews suggested the information imparted during group education sessions was new for participants. We expected this knowledge to translate into three possible changes in behaviour, which in turn could decrease the incidence of hysterectomy. Findings, however, identified a breakdown in the intervention pathway beyond improved knowledge. The endline household survey included questions on gynaecological morbidity and treatment-seeking, as well as on gynaecological exams, to capture differences in women's behaviour across arms. Of 48 women (2.2 percent) who reported gynaecological morbidity in the six-month period covered by the endline survey, 38 reported seeking any treatment. There was no difference in place of treatment by treatment allocation (p=0.92). One percent of all women (n=17) reported undergoing a gynaecological exam for any reason in the past year. CHWs did not report any observation of community action or advocacy regarding hysterectomy.

The survey results indicated no difference in treatment-seeking behaviour for gynaecological ailments between intervention and control areas. Qualitative research on the determinants of hysterectomy, as reported in Chapter VIII, indicated that women in the area typically sought two to three medical opinions; this left little scope for the intervention to affect this particular step on the path from knowledge to behaviour change. Lastly, qualitative interviews with CHWs and participants did not suggest a change in women's demand for hysterectomy, to the extent that such interviews could assess women's attitudes.

Figure 9.2 Summary of process evaluation findings



Discussion

This intervention was designed to decrease the incidence of hysterectomy through effective delivery of health education by CHWs. There is limited research on the effect of group education in community settings on adult health outcomes. Published findings (reviewed in Chapter II) suggest positive effects, but their limited number also suggests publication bias. A review of research on health education suggests that this intervention had potential to change behaviour, for three reasons. First, non-randomised evaluations in India report increased health knowledge amongst women exposed to group education [86, 87, 89]. Second, group health sessions have resulted in an increase in gynaecological and breast cancer screening amongst minority women in the United States [69, 72, 322] – an encouraging indicator given the intervention focus on hysterectomy. Third, CHWs have been shown to be uniquely positioned to influence behaviour change, through their use of both indigenous knowledge and their ability to communicate with empathy and locally appropriate language[323].

The delivery mechanism was aligned with two established characteristics of effective CHW programs: SEWA CHWs were embedded in their communities and were supported through continuous training and management inputs[50]. Implementation of the targeted number of intervention sessions occurred as planned, with a range of communication tools. CHWs were able to recruit an adequate number of women, capitalising on their established rapport in the community to provide education in a group setting. Information was also disseminated through one-to-one visits and print pamphlets, and may have spread through women's interactions with each other socially and through SEWA. However, the film– expected to be a critical component of the intervention–was only shown in 42% of education sessions. In the household survey, the overall proportion who reported attendance was considerably lower (13%) than reflected in monitoring reports (25%), suggesting that monitoring data overestimated coverage due to repeat attendance or that the survey produced an underestimate of intervention coverage due to recall error. If a woman did not recall attending a session, however, she was unlikely to have retained its messages. Accordingly, the survey estimates may reflect effective programme coverage in intervention areas. An estimated 10.5 percent of women in the population would have seen the film, which is closer to the proportion who reported attendance in the survey.

Evaluation

Assuming that the (i) intervention with film reached 10 percent of the population at risk of hysterectomy and (ii) the intervention effect was limited to women who attended sessions (iii) the intervention, if effective, would not have prevented more than 50% of hysterectomies, there would have been, at most, a 5% reduction in an annual incidence of 21/1,000 woman years, which corresponds to approximately three cases over the study period. The evaluation was powered to detect a 40% reduction in hospitalisation for three conditions (diarrhoea, fever, and hysterectomy). At baseline, hysterectomy comprised 65% of hospitalisations for the three conditions. Given the actual coverage of the intervention, had it been effective, the evaluation was not powered to detect the reduction in hysterectomy which might reasonably be expected.

Further, about five percent of women in control clusters reported attending hysterectomy sessions, which could reflect contamination – and thus further reason why the intervention could not detect an intervention effect. Contamination through sessions conducted by control area CHWs was unlikely, as only intervention CHWs were provided with media tools and training on hysterectomies. Women in control areas may have attended sessions in intervention areas, either while visiting or due to geographic proximity. In rural areas, distances between villages would likely have prevented geographic contamination, as reflected in the difference in attendance reported across intervention and control villages. However in urban areas, where slum pockets covered by CHWs are often contiguous, contamination was more likely; the similarity in reported attendance across arms in urban areas supports this possibility.

Some reporting by women in control areas may have also been due to recall error, such as confusing attendance at hysterectomy sessions with routine health education programs. If this type of recall error was similar across intervention and control areas, we may have overestimated coverage in the intervention clusters. It is also possible that the nature of recall error differed between control and intervention areas. For example, women in control areas may not have been aware of hysterectomy sessions and therefore more likely to confuse them with other education programs, whereas women in intervention areas were aware of hysterectomy sessions and less likely to misreport attendance if they did not attend. The difference in urban and rural reporting patterns appears more consistent with the explanation that control area attendance was due to contamination, although some degree of recall error cannot be ruled out. Further, insured women in intervention areas reported higher attendance in intervention areas compared to uninsured women, which suggests that they may have been more receptive to education sessions, had greater contact with SEWA CHWs, or reported differently than uninsured women.

Barriers from knowledge to behaviour change

The intervention pathway expected women, equipped with knowledge of hysterectomy and supported by the local CHW, would: (i) seek early care for gynaecological ailments; (ii) seek at least two medical opinions before undergoing hysterectomy; or (iii) re-consider their own demand for their procedure in the light of the potential adverse side effects. Although knowledge of hysterectomy was observed amongst participants, the process evaluation indicated breakdowns in its translation into behaviour change (Figure 9.2). The low intensity of the intervention may have limited its effectiveness in changing care-seeking. CHW-led group education efforts in other settings, such as interventions to promote breast cancer and cervical cancer screening in the United States, relied on two group sessions – suggesting that low number of meetings could trigger changes in behaviour [69, 73]. However, the intervention outcome was receipt of either a pap test or mammography–one time, preventive actions with logistical support by a CHW and availability of health services—as compared to this attempt to change treatment of gynaecological morbidity and attitudes towards hysterectomy in a setting with limited treatment options. A lifestyle intervention to reduce cardiovascular risk which reported evidence of behavioural and clinical changes was premised on eight sessions and targeted individual follow up, an approach which may have been more relevant to this setting[74]. Similarly, there is a moderate body of evidence that supports the effect of home visits by CHWs as a tool to change behaviour[42, 324]. Although CHWs' existing responsibilities and limited resources prevented a more intensive intervention, more structured individual follow-up and home visits could have potentially been included.

Health system factors and social attitudes may have impeded the translation of knowledge into changes in treatment-seeking behaviour or attitudes towards hysterectomy. Findings from qualitative research, detailed in Chapter VIII, conducted with women who had undergone hysterectomy identified several barriers. For example, the local health system offered limited choices outside of hysterectomy to treat gynaecological ailments in low-income women. Interviews with providers, as well as earlier research by

SEWA, had identified a lack of skills and equipment to conduct less invasive procedures [236]. Further, providers expressed a preference towards hysterectomy as a one-time solution for rural, low-income women with gynaecological ailments, attributed to a systemic focus on maternal health services and beliefs that low-income women would not attend follow-up visits required for other procedures. Thus, even if increased knowledge had led to demand for less invasive procedures, women were unlikely to be offered such treatment within the existing health system. Interviewed women related that providers' opinions were paramount in the decision to undergo hysterectomy. Although women typically sought two to three opinions, most providers in the area regularly advised hysterectomy as first or second-line treatment for a range of gynaecological ailments, effectively leaving women with limited options.

Qualitative interviews also suggested that women's demand for hysterectomy appeared to be linked to attitudes towards the uterus and the desire to treat painful, often untreated ailments. In-depth interviews with women who had undergone hysterectomy revealed that most believed the uterus was dispensable after childbirth. Providers' views and advice to women encouraged and supported this view, contributing to the normalisation of hysterectomy as treatment for common gynaecological ailments. Moreover, quantitative analysis indicated that low-income women underwent hysterectomy at higher rates. Most women in this area were low-income, daily wage labourers who explained that they chose to undergo the procedure to preserve their own health and productivity, which had suffered due to ailments marked by excessive bleeding and pain. In light of limited treatment options, hysterectomy emerged as an inevitable, pragmatic decision driven both by women's economic and health circumstances.

Implications for practice

In a setting with limited knowledge of hysterectomy, CHWs played a natural, sustainable role in disseminating information. CHW-delivered education was not limited to group meetings; discussions continued through casual conversation, road-side meetings and individual follow ups in women's homes. Education also spilled over into other activities such as referral to services and accompanying women through the treatment-seeking process. Coverage of the intervention was low, however, which may have contributed to our failure to detect evidence of an effect. Stronger logistical coordination to ensure film viewings and a greater number of sessions may have reached more women. Implementation realities of community-based work, however, presented challenges. For example, intermittent electricity or lack of space for meetings in urban slums required creative solutions or different intervention delivery mechanisms. The intervention only included one session per month on hysterectomy because SEWA CHWs were already fully tasked with existing responsibilities and potentially overburdened – a common challenge to CHW programs – which prevented further outreach [50]. In-person monitoring of sessions by supervisors would likely have improved delivery quality. However, financial limitations prevented the recruitment of additional supervisors, and SEWA was committed to a fully scalable intervention in which existing human resources would be employed.

Our findings also suggest the need to reconsider the intervention focus on individual behaviour change regarding hysterectomy. Unlike an intervention aimed at handwashing or breastfeeding, wherein individual action can directly affect health outcomes, treatment-seeking related to hysterectomy is dependent on health system options, provider practices and women's socioeconomic circumstances. Breakdowns in the intervention pathway suggest that, even with improved coverage, an approach premised on individual action alone would have been insufficient. Recognising the broader determinants of hysterectomy, this intervention could have utilised CHWs' positions and group education processes to address the normalisation of hysterectomy or instigate collective action for improved gynaecological services. For example, CHWs supported women through treatment-seeking processes and linked them to other women who have undergone the procedure – creating an informal network of knowledge and resources. Led by CHWs such as Ranjanben, these networks could have coalesced eventually into a local movement to demand better health services for women. However, one session is unlikely to be a sufficient catalyst; the intervention would have required an explicit focus on CHW-led community action. However, variation in CHW engagement and skills may limit the effectiveness of an approach dependent on CHWs alone.

Diarrhoea and fever

Although the focus of this process evaluation was hysterectomy, I briefly consider how the intervention may have had an effect on behaviour related to diarrhoea and fever. Unlike hysterectomy, prevention of these conditions has been demonstrated to be amenable to individual behaviour change, such as through handwashing with soap or use of mosquito repellent[325-327]. The baseline survey suggested that there was potential for health education to address preventive behaviour. While almost all households reported having soap in their homes, only half (47% rural, 57% urban) of women at baseline reported washing their hands with soap after using the toilet. Close to one-quarter of rural and urban households reported not taking any precautions against mosquitoes. Qualitative observations of diarrhoea and malaria sessions, conducted by a SEWA colleague, suggested that message delivery was adequate but varied by CHW, as found for hysterectomy. Government and television media also delivered messages on these conditions, albeit sporadically.

At endline, there was no observed difference in reported behaviour regarding handwashing and use of mosquito repellent, neither between intervention and control areas nor as compared to baseline. Interventions that have demonstrated evidence of an effect on both handwashing and mosquito repellent were considerably more intensive campaigns that included distribution of soap or repellent. A handwashing campaign in Karachi, Pakistan that included weekly education as well as soap distribution reported a sustained effect on handwashing with soap, while a rural Indian education-only intervention did not detect evidence of improved behaviours[325, 326, 328]. Further, reviews of interventions to promote handwashing suggest that knowledge transfer may not be sufficient; emotional messaging or creation of new social norms, for example, may be more effective[329]. Regarding mosquito repellents, evidence is limited, though an intervention in Pakistan that distributed DEET mosquito repellent reported a decrease in infection with *p.falciparum*, but not *p.vivax*, malaria[327]. The intervention did not evaluate health education without distribution of repellent, however. Based on these findings, it appears that SEWA’s education sessions without distribution of soap or malaria prevention tools may not have been intensive or innovative enough to trigger a change in behaviour.

CHWs identified several barriers to an intervention effect. Interviews with CHWs revealed that women did not want to waste soap on handwashing; it was expensive and reserved for bathing. Distribution of soap, therefore, was suggested for future interventions in addition to continued handwashing education. Further, CHWs felt that contaminated water supply due to poor sewage systems presented an intractable challenge to diarrhoea prevention, as women could not afford to boil drinking water. Regarding malaria-related fevers, CHWs reported that uptake of repellents was patchy and irregular, also due to perceived expense. As with diarrhoea, they pointed to lack of implementation of government-led initiatives such as spraying and cleaning. The intervention design would have benefitted from formative research amongst women on causes of diarrhoea and fever, potentially innovative methods to change behaviour, barriers to translation of knowledge into behaviour, as well as a stronger advocacy component to address structural determinants such as water supply and anti-mosquito measures with the government.

Alternative approaches to health education

An alternative approach that departs from CHW-led health education has been illustrated by interventions with women's groups in South Asia and Malawi to improve neonatal and maternal health outcomes. Premised on promotion of critical consciousness rather than one-way health education, the interventions involved facilitated learning cycles with women's groups, using interactive tools and joint action to address both demand for and supply of health services [330]. The trials in Nepal and India reported reductions in neonatal mortality of 30% and 45%, respectively and a reduction in moderate maternal depression in India compared to control groups[330, 331]. Both evaluations cited the design focus on the participatory learning process and community action as key factors in reducing neonatal mortality. The Nepal team also identified provision and dissemination of health information as important in changing women's behaviour[80]. Although the authors explicitly distinguished between this participatory model and a CHW-led approach, they also questioned, as the Nepal intervention was implemented in conjunction with government CHWs, if a similar impact would have been found in CHWs' absence[330]. An effort to scale-up this intervention model to a larger population in Bangladesh, however, did not report an intervention effect. The project team identified lack of an intense focus on community participation and wide geographic coverage of women's groups as gaps that precluded an impact[332]. Learning from these experiences, SEWA could have utilised group sessions to examine hysterectomy in the community and considered an approach that facilitated collective action towards improved services and financing mechanisms, for example. As members of India's largest organisation of women workers, CHWs and local SEWA leaders were well-positioned to facilitate advocacy at the local and state level, had that emerged as a demand from group meetings. However, this approach would have entailed more time from CHWs and frequent meetings between women, which was not feasible within their current task loads.

Another approach to CHW-led group health education is interventions that integrate health education with microfinance groups. These interventions are relevant in this case for two reasons. One, most of SEWA's members are also microfinance clients; health education could feasibly be delivered in tandem with financial services on a regular basis. Second, women who underwent hysterectomy cited the insecurity of daily wage earnings as a reason to pursue a quicker, permanent solution to gynaecological ailments rather than longer-term treatment. Thus financial security to the extent provided by microfinance could potentially support women in negotiating, or financing, different treatment options. A recent review of studies using a variety of designs suggests a generally positive effect of health education on knowledge and some improvement in service utilisation and health outcomes amongst microfinance clients, while noting that more rigorous research is required in this field[82]. In South Africa, a randomised evaluation of a microfinance and group health education intervention reported a 55% reduction in reported intimate partner violence, with no effect on the two other primary outcomes, unprotected sexual intercourse or HIV incidence[83]. The higher reported attendance of insured women suggested that CHWs may have had greater traction amongst women linked to SEWA through other services, or that insured women were more receptive to group education. In either case, this finding supports approaches that capitalise upon inter-linkages between existing programs. However, while an integrated microfinance-health education intervention would build on SEWA's existing activities to reduce the economic vulnerability that may promote permanent interventions, it could not address the lack of treatment options available to women.

Although these two approaches could address structural and health systems determinants of hysterectomy, the lack of knowledge about hysterectomy suggests that health education remains a necessary, though not sufficient, intervention in this setting. Our findings suggest that CHWs may not be the most effective medium, however, in light of time constraints and variation in communication skills. Mobile technology could potentially standardise and support CHW-led health education efforts [333], although benefits would have to be considered against financial investment required. Mass media interventions are one alternative that does not depend on CHWs. Evaluations have reported moderate evidence for an effect of mass media on health behaviours when situated within multifaceted interventions [334]. Further, a systematic review suggested that mass media tools can have an effect on reproductive health behaviours in low-income settings, most commonly contraceptive use[335]. Most specific to this intervention, a 1984 mass media campaign to reduce hysterectomy rates in Italy observed a 26% decrease in hysterectomy rates, compared to a 1% increase in a control area with no education intervention[336].

Aside from the delivery mechanism, a theoretical basis for interventions has been identified as critical for effective health education programs. This health education intervention would have benefited from an explicit model for behaviour change, as well as an ecological, rather than individual-centric, approach to reducing hysterectomy. Accordingly, SEWA CHWs' position as bearers of both technical knowledge and indigenous experience could have been better capitalised upon through a role as educator-advocates in the community.

Strengths and limitations

Strengths of this process evaluation included the use of a theoretical framework to examine assumptions in the causal pathway and the use of multiple sources of data. In-depth qualitative research provided critical insight into the context and barriers to the intervention, while process data allowed for assessment of whether and to what extent implementation was achieved.   One limitation to the data was the lack of baseline information on knowledge of hysterectomy; participants' knowledge in post-session interviews may not have been attributable to the intervention. Further, verification of attendance data with names of survey participants may have improved estimates of intervention coverage. Lastly, my role in designing and implementing the initial stages of the intervention may have biased interpretation of observations, although insider status may have also allowed for greater understanding of implementation processes. Interviews with CHWs, similarly, may have presented a desired picture of the intervention due to previous working relationships.

Approaches to process evaluation

This process evaluation drew from the principles of "theory-based impact evaluation" to identify and evaluate each step in the causal chain using quantitative and qualitative methods[209]. A 2013 review of process evaluations of cluster randomised trials, noting that there is no single approach to process evaluations, suggests that more structure is required in their design and reporting[337]. A proposed framework includes (i) evaluation of both individual and cluster-level processes (ii) documenting context pre-intervention and (iii) evaluating the theoretical model of an intervention and its implementation, with clear rationale provided for specific processes and methods chosen by researchers. In another approach, Pawson and Tilley's theory of realist evaluation provides a framework that highlights the importance of mechanisms and context in understanding intervention outcomes[338]. Realist evaluation—based on the configuration "Outcomes=Mechanism + Context"—explains what components, for whom and how an intervention may generate change, by focussing on the actors targeted in the intervention, within their specific conditions and social reality. Based in a realist evaluation approach, Wight and Obasi suggest four key areas of data collection and analysis to structure a process evaluation: (i) extent and quality of programme delivery (ii) intervention mechanisms (iii) context and (iv) differential responses of target groups[339]. Focusing on these four aspects allows for consideration of how design and implementation could have been improved, while calling attention to how interventions are linked to their cultural social, economic and cultural context.

This process evaluation focused on the extent and quality of implementation at the individual level, with some analysis of CHW-level variation and differential responses of insured and uninsured women. Intervention context, although provided retrospectively by qualitative research on hysterectomy, should have been considered for all three conditions as part of the intervention design as well as during the process evaluation. Further, more focus on intervention mechanisms, both theoretically and empirically, would have provided important insight into this intervention, as well as informing future programmes. Lastly, the use of both quantitative and qualitative methods specific to the process evaluation could have been strengthened by considering the sequence, such as conducting qualitative analysis before the intervention outcomes were evaluated[340].

Conclusion

A cluster randomised trial and this process evaluation indicated that SEWA’s CHW-led intervention did not result in a detectable change in hysterectomy incidence. Observations suggested that the intervention at best supported women in making informed decisions, albeit strongly constrained by limited health system options. Future interventions can capitalise on the potential of CHWs as social catalysts to address demand and supply of health services, in addition to or in place of information dissemination. The lack of knowledge amongst women about hysterectomy calls for continuation of community-based health education efforts, although not necessarily through CHWs. Along with information, a comprehensive approach that addresses provider practices and health system priorities is required to expand options available to women for gynaecological treatment.

Chapter X. Conclusion

I. Summary of findings

This thesis examined three interrelated questions: (i) the effect of a CHW-led group health education intervention on treatment-seeking behaviour and morbidity related to diarrhoea, fever and hysterectomy (ii) the influences on, and predictors of, the decision to undergo hysterectomy and (iii) how hysterectomy could be affected by a health education intervention. Since hysterectomy was the leading reason for hospitalisation, understanding why women undergo the procedure was critical to assessing whether and how a health education intervention could be effective in this low-income setting in Gujarat, India.

CHW-led health education intervention

SEWA implemented a CHW-led group health education intervention for 18 months in rural and urban Gujarat, amongst VimoSEWA-insured and uninsured women. The primary intended outcome of the intervention was a reduction in insurance claims amongst VimoSEWA-insured women related to diarrhoea, fever and hysterectomy. Secondary outcomes were reduced hospitalisation and morbidity amongst insured and uninsured women for the three conditions. The VimoSEWA claims database tracked claims amongst insured women, and four rounds of a household survey collected self-reported morbidity and treatment-seeking history amongst a sample of insured and uninsured women over two years. At baseline, both data sources confirmed that hysterectomy, diarrhoea and fever comprised the majority of claims and reported hospitalisation events in the six months preceding the intervention.

The intervention was evaluated by a cluster randomised trial in 28 clusters, in which 14 CHWs were randomised to implement the intervention. They implemented group education sessions on the three conditions, using communication tools that included a film and participatory games. The evaluation did not detect evidence of an intervention effect on claims, hospitalisation or morbidity related to fever, diarrhoea and hysterectomy, although the results do not rule out the possibility of a smaller effect than expected. There was no evidence of effect modification by insurance status or urban/rural location.

A process evaluation focussed on hysterectomy, the leading cause of hospitalisation, indicated that the coverage and quality of the education sessions was lower than expected, and varied by CHW. Qualitative research suggested that health education had the potential to improve women's knowledge and reduce demand for hysterectomy. Their treatment-seeking decisions, however, were limited in practice by a lack of treatment options for gynaecological ailments. The intervention focused on individual behaviour change, but did not address the health system and social factors that normalised hysterectomy. SEWA's intervention could have been strengthened by capitalising on CHWs' potential to influence community action, as well as by considering long-term interventions focussed on providers' behaviour and advocacy for comprehensive women's health services.

Insured and uninsured women

The household surveys provided important insights into women's treatment-seeking behaviour and enabled comparisons between insured and uninsured women. At baseline, Vimo-SEWA insured women were slightly older, more likely to be employed, and widowed, and in rural areas, less educated that uninsured women. Insured women were more likely to perceive their own health as average, compared to uninsured women who tended to report higher levels of very good health. However, reported recent morbidity, type of illness and outpatient treatment were similar among insured and uninsured women. There was strong evidence of higher odds of hospitalisation amongst insured women, for all causes. These findings suggest that insured women behave differently when making health care decisions, as seen in higher utilisation of trust hospitals, for example. Since VimoSEWA only covers hospitalisation events, adverse selection and/or provider moral hazard cannot be ruled out as explanation for these patterns.

Findings over the intervention period suggest further differences between insured and uninsured women. Over the four survey rounds, a notably higher decrease in reported hospitalisation amongst insured women, but not in the claims database, suggested that insured women recalled or reported treatment differently than uninsured women. Also, insured women reported higher attendance at intervention education sessions than uninsured women. They may have been more receptive to CHW activities as a result of active SEWA linkages through VImoSEWA's programs. Alternatively, insured women may have been more inclined towards preventive health education, due to different characteristics that led them to enrol in VimoSEWA in the first place. Insurance status, however, was not static or continuous: the majority of women insured at baseline did not renew their insurance the next year. This research points to the need for further investigation of associations between insurance coverage and women's health care decision-making processes.

Hysterectomy

Hysterectomy was the leading cause of hospitalisation for uninsured and insured women. Analysis of the study cohort over two years provided the first estimate of hysterectomy incidence in India– 20.7/1,000 woman-years – which is considerably higher than that reported in high-income settings. Qualiative research amongst women, providers and other key informants suggested that women decided to undergo hysterectomy to preserve their productivity as workers and caregivers, in a bid to achieve freedom from future risk. The health system and providers offered few options for low-income women to treat gynaecological ailments. Combined with a common view that the uterus was dispensable post-childbearing, hysterectomy was a normalised treatment option for menstrual irregularities, fibroids and cysts for women in their mid-thirties. Women sought two to three opinions, typically in both public and private hospitals, before undergoing hysterectomy. Approximately two-thirds of women reported utilising private services for hysterectomy. The remainder utilised government hospitals, while a small proportion opted for non-profit trust hospitals. Average reported out-of-pocket expenditure for hysterectomy was considerably higher than a household's monthly income; almost all women who utilised private or trust hospitals reported borrowing funds to finance treatment.

A mixed methods analysis identified predictors and determinants of hysterectomy in this setting. There was strong evidence that incidence of hysterectomy was higher amongst lower income women and women who had completed childbearing, with no evidence of a difference between insured and uninsured women. Women's financial insecurity and provider attitudes towards low-income women converged to favour hysterectomy as a one-time permanent solution, rather than longer term, less-invasive options for gynaecological ailments. Women who had previously undergone tubal ligation reported higher rates of hysterectomy, which could reflect higher biological vulnerability to gynaecological morbidity associated with sterilisation, as well as women's own predisposition towards one-time surgical interventions.

A relatively low mean age at the procedure (36 years), along with the health implications of early menopause, supports the case for interventions in this setting to reduce medically unindicated hysterectomy. Education on hysterectomy remains an important need for women to make informed decisions, provided options are available to them. Improvement in the availability and quality of women's health services, including family planning options beyond sterilisation is critically required – as well as efforts to address attitudes towards dispensability of the uterus – to reverse the normalisation of hysterectomy

II. Strengths and limitations

This research study, on the whole, benefited from being embedded within a grassroots women's health program. The intervention, had the evaluation detected evidence of an effect, would have been scalable and sustainable within SEWA. In light of a relatively low budget, the intervention and evaluation were designed to test effectiveness within an existing program, rather than efficacy of an intervention that would have required higher investments in human resources for dedicated implementation support and supervision[321]. While leaning towards effectiveness may have limited the quality of implementation or monitoring – which may have resulted in lower coverage of film viewings or limited data on participants – the intervention was implemented in 'real-life' conditions relevant for CHW programs in low-income settings outside of Gujarat. Implementation lessons, such as the difficulty of tracking addresses in informal settlements, are likely to be widely applicable to community-based organisations in similar environments.

Another strength of this study was its mixed methods approach to understanding where the intervention had succeeded and failed. The combination of a cluster randomised trial and quantitative and qualitative process data collection enabled rigorous evaluation along the intervention causal pathway. Findings at each point of the causal chain, such as the extent of coverage, effectiveness of health education on recall and effect on treatment-seeking behaviour, were individually relevant for the implementation of CHW-led health education in other settings. The synthesis of findings allowed for a comprehensive understanding of whether, how and why the intervention could have an effect on women's health and treatment-seeking behaviour in this setting. Similarly, the use of a mixed-methods approach to hysterectomy enabled examination of incidence, predictors and determinants within their social and cultural context.

The findings on hysterectomy also provided in-depth insight into drivers of women's behaviour regarding the procedure. It identified roots of women's actions and intention and the role of their social and cultural environment in shaping behaviour, as well as the processes by which they sought health care. These findings provide critical information required for a comprehensive, theory-based behaviour change intervention to reduce hysterectomy. For example, an intervention rooted in social cognitive theory may be developed to address the multiple layers of influence on women's behaviour regarding hysterectomy, particularly the social and health systems factors that drive individual behaviour. The findings from this study also underscore challenges when designing theory-based behaviour change interventions, such as acknowledging the competing interests in women's lives who work in the informal economy and the importance of deep-seated, religious notions such as menstrual pollution in shaping individual decisions.

Limitations of the study related both to the design process and the evaluation. The lack of an explicit theory of behaviour change and for the intervention limited both the quality of the intervention as well as process assessment of its outcomes. Applying a behaviour change model from the outset may have strengthened the quality of the intervention, as well as flagging the need for more qualitative/formative research before the intervention was implemented. Further, the interventions would have benefitted from more in-depth consideration of the available evidence. Although some evidence supported the promotion of handwashing and insect repellent, feasibility in this context may have called for a different approach, such as distributing soap through social marketing or linking with government promotion of bed-nets. The evaluation design could have been strengthened by accounting for attrition and survey fatigue when estimating sample size. The evaluation utilised self-reported data in the household survey, which may have been subject to recall error. Specific steps that could have been taken to improve the intervention and evaluation design are discussed in the next section.

Lastly, my role in the study was both an advantage and a potential source of bias. Several years' experience working with SEWA strengthened my ability to understand the context of the intervention. Insider knowledge and comfort with CHWs allowed me to ask questions and observe situations in a manner that an outsider may not have been able to. Understanding nuances of the implementation in this setting helped me to identify potential intervention breakdowns and elicit in-depth responses from CHWs. However, my position as a former supervisor may have biased observations and interpretation of some findings. CHWs may have not felt comfortable sharing weaknesses or interacting with me as a researcher rather than colleague. My interpretation of results may also have been biased as a result of my own closeness to the intervention and organisation. I aimed to limit bias by employing reflexivity, resigning from an implementation role, and limiting my engagement thereafter to that of a researcher, rather than manager. Moreover, the analysis utilised multiple sources of data, in an attempt to reduce bias and strengthen interpretation.

III. Reflections

I was in the fortunate position of identifying research questions and pursuing a PhD after being involved in grassroots implementation of women's health programs. By conducting a range of analyses – a cluster randomised trial, cross-sectional survey, cohort study, qualitative research and intervention process evaluation – I was able to synthesise findings from multiple perspectives, while gaining rigorous research training. Stepping back, however, I also recognise there were several aspects of the intervention design and research that I would approach differently in the future.

Intervention design

The health education interventions were designed to address three leading causes of hospitalisation claims using SEWA's existing resources. This approach ensured that the interventions, if effective, could be sustained and expanded to a larger population. Given resource constraints, however, focussing the interventions on one condition may have improved coverage and quality, as well as allowed for a more in-depth intervention. For example, had only hysterectomy (as the leading reason for hospitalisation) been addressed, CHWs could have organised more sessions and reached more women. Further, in-depth research on the determinants of hysterectomy should have been conducted *before* the intervention design, to provide perspective on required interventions, causal pathways and potential barriers. Addressing only one condition would also have allowed for a wider range of interventions within existing resources. Multiple forms of health education could have been developed, for example, which may have mitigated the dependence on inconsistent film viewings. This approach, however, would have required a larger sample size – and potentially higher budget – to detect an effect on the incidence of hysterectomy

A more rigorous, evidence-based approach to the intervention was required to identify intervention content and feasible delivery mechanisms. Adoption of an explicit theoretical framework for behaviour change from the outset, such as a social cognitive or health belief model, would have strengthened both the design and evaluation of the intervention, even within limited resources. Although the pressures of implementation often favour a heuristic approach to interventions (in my experience), this project should have taken better account of the evidence base, albeit limited, on CHW-led group education. We could have considered a combination of home visits and group education, more intensive contacts, or alternative forms of non CHW-led health education. Lessons learnt from participatory women's groups could have been applied in this setting, to capitalise on CHWs' potential to catalyse community action or affect women's attitudes towards hysterectomy, although this would have required a much more intensive intervention. A targeted approach to hysterectomy to women outside of CHW-led sessions could have also been considered, such as outreach with women attending health clinics for gynaecological ailments.

Evaluation approach

A cluster randomised trial represents the most rigorous approach to evaluate the causal effects of an intervention, provided design and number of clusters are appropriate. The project budget – approximately USD 200,000 over three years – was considerably lower than most evaluation studies; the evaluation is testament to the capacity of community organisations to conduct rigorous trials. However, the project could have managed data resources differently. Use of the VimoSEWA claims database was a cost-effective opportunity to address limitations of survey data, but its potential was not maximised. A data analyst should have been allocated to cross-verification of reported hospitalisation amongst insured women between the VimoSEWA database and household survey. Linked analyses between the database and survey could have also provided insight into recall errors and women's selective use of insurance benefits. Similarly, improved monitoring data on participants could have estimated double-counting, provided demographic information and helped limit contamination. While contamination is a potential factor for any study with a concurrent control group, careful monitoring and follow-up with participants in this case may have identified whether women in control areas attended education sessions.

A baseline survey conducted earlier in the design process would have provided baseline hospitalisation rates and a better estimation of k – both of which could have improved power through a higher sample size per cluster, to the extent budgetary limitations would have allowed. Relevance of the findings was assured, as the intervention and studies emerged from concrete needs articulated by women, CHWs and VimoSEWA. However, although VimoSEWA identified a 30-40% reduction in claims as worthwhile for an intervention, the baseline survey reported a small number of hospitalisation events per cluster, suggesting that this level of reduction was likely unrealistic. Further, the evaluation may have been too ambitious in its aspiration to address three ailments, across both urban and rural populations and amongst both insured and uninsured women. Focus on one condition may have allowed for stronger interventions, better implementation monitoring and improved analyses. Evaluation of the effect on one condition would have enabled cross-verification and triangulation of several data sources such as hospital records, resulting in in-depth findings that could inform both women's health policy and practice. Limiting the intervention to either a rural or urban setting may have limited contamination and improved monitoring, but would have decreased the number of clusters for the evaluation.

In conclusion, while recognising the myriad issues raised by the initial claims analysis, in the future I would adopt a comparably narrow topic focus for the intervention and research studies. This research demonstrated to me that adopting a 'feminist epidemiology' approach in practice – one that (i) determined intervention priorities through examining women's overall hospitalisation patterns (ii) reported on morbidity, treatment and expenditure (iii) identified predictors and underlying social, political and cultural determinants and (iv) focussed on women at each stage– required not only a mix of methods but also a commitment to understanding one issue in-depth in this study. In light of the budget, a focussed approach may have improved quality and feasibility of the intervention and evaluation, without compromising on the mix of methodological approaches utilised to understand and address women's health.

IV. Contributions to research, policy and practice

CHW-led health education

This study contributes to the evidence base on CHW-led group education in low-income settings. The lack of evidence of an effect and the process findings highlight important factors to consider when implementing such interventions. Given the variation of CHW definitions across settings, description of their roles should be part of design and evaluations, ideally through observation. By following CHWs on daily rounds, I observed their potential to address women's attitudes towards hysterectomy and treatment-seeking decisions, for example – a finding that would not have emerged from managerial descriptions of their tasks. Further, observations during the process evaluation suggested that CHWs were not the most effective mechanism for health education in this setting. Design of CHW-led interventions should consider (i) CHW skill levels (ii) available time and (iii) what aspect of health behaviour or outcomes they can address. SEWA CHWs were only able to conduct one hysterectomy session per month, which did not translate into realistic potential to reduce the population incidence of hysterectomy. The wide variety and range of CHW roles – from social activism to direct service delivery – requires a strong theoretical basis to identify the type of intervention CHWs can deliver. In this case, SEWA CHWs appeared to be more suited to a social activist role, whereas CHWs in service delivery settings may be more adept at health education. Similarly, health education interventions require both a theoretical framework and assessment of which, and what combination, of delivery mechanism is most feasible for CHWs.

Hysterectomy

The findings of this study strongly support the need for more research on the epidemiology of hysterectomy, its determinants and health systems factors through both community-based and nationally representative surveys in India. The baseline findings helped initiate a national advocacy meeting, held in New Delhi in August 2013, to discuss hysterectomy trends with researchers, policymakers and activists. Most significantly, the meeting resulted in commitment from the Ministry of Health to include three questions on hysterectomy, taken directly from those used in this baseline survey, in the next round of the National Family Health Survey. The estimated incidence, mean age and determinants of hysterectomy in rural Gujarat highlight the need for interventions to address (i) the normalisation of hysterectomy (ii) available options for treating gynaecological ailments and (iii) provider attitudes towards intervention in women's bodies. In addition, health policymakers should consider systematic monitoring of hysterectomy at the population and facility level that includes medical audits, provider training and monitoring and expansion of sexual and reproductive health services. Lastly, the findings also underscore the importance of a mixed methods approach to contextualise women's treatment-seeking decisions and to explain how predictors such low-income status increase the likelihood of hysterectomy. Incorporating women's voices resulted in a different, more complicated narrative than the unilateral application of medical authority–one of pragmatic agency and multiple negotiations—and called attention to the broader circumstances that define women's choices. Future research on hysterectomy requires similar approaches to examining both population data and individual experiences, in order to identify wider trends as well as localised risk factors.

SEWA Health and VimoSEWA

Research findings were shared with VimoSEWA, SEWA CHWs and local stakeholders in Gujarat in June 2014. VimoSEWA management expressed the need for more research to explore adverse selection and moral hazard in its population. Health education has presented a longstanding, almost divisive, challenge to SEWA Health. While it is promoted based on a principle, to fulfil women's needs for health information, the lack of perceived effect through practice and now, as observed through this evaluation, have suggested other approaches should be tried. CHWs and managers have also grappled with the balance between developing evidence-based interventions to address specific issues and a holistic approach to health that works in tandem with microfinance and livelihoods interventions. Notably, donors have increasingly encouraged the former approach. CHWs continue to utilise the communication materials for diarrhoea, fever and hysterectomy in both intervention and control areas, but not through a targeted or planned group approach at the moment. The health team is considering design of an advocacy and provider monitoring intervention for hysterectomy.

The findings suggest that SEWA could adopt a more focussed approach to CHW-led interventions, reconsider methods of health education and maximise the potential of CHWs to catalyse community action. SEWA CHWs span components of service delivery and social activism, a combination which allowed for a wide range of interactions with women in the community but may have also limited measurable change. In addition, this experience demonstrated the importance of regular analysis of claims patterns and collection of population-based data to track women's treatment-seeking patterns. The value of VimoSEWA's claims database must be capitalised upon further, through regular analysis and dissemination. As a grassroots movement with wide reach and diverse activities, SEWA can implement health interventions, experiment with financing mechanisms as well as sustain advocacy campaigns. A final recommendation, therefore, is that SEWA promote an evidence-based, comprehensive women's health approach to hysterectomy through a combination of direct intervention and long term efforts. Building on the findings of this research, SEWA can demonstrate in practice why and how health interventions must integrate the social, economic and political realities of women's lives.

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List of Annexes

Annex 1 Literature search on women's morbidity patterns in India

This literature search was conducted in May 2011 in the process of developing my dissertation proposal.

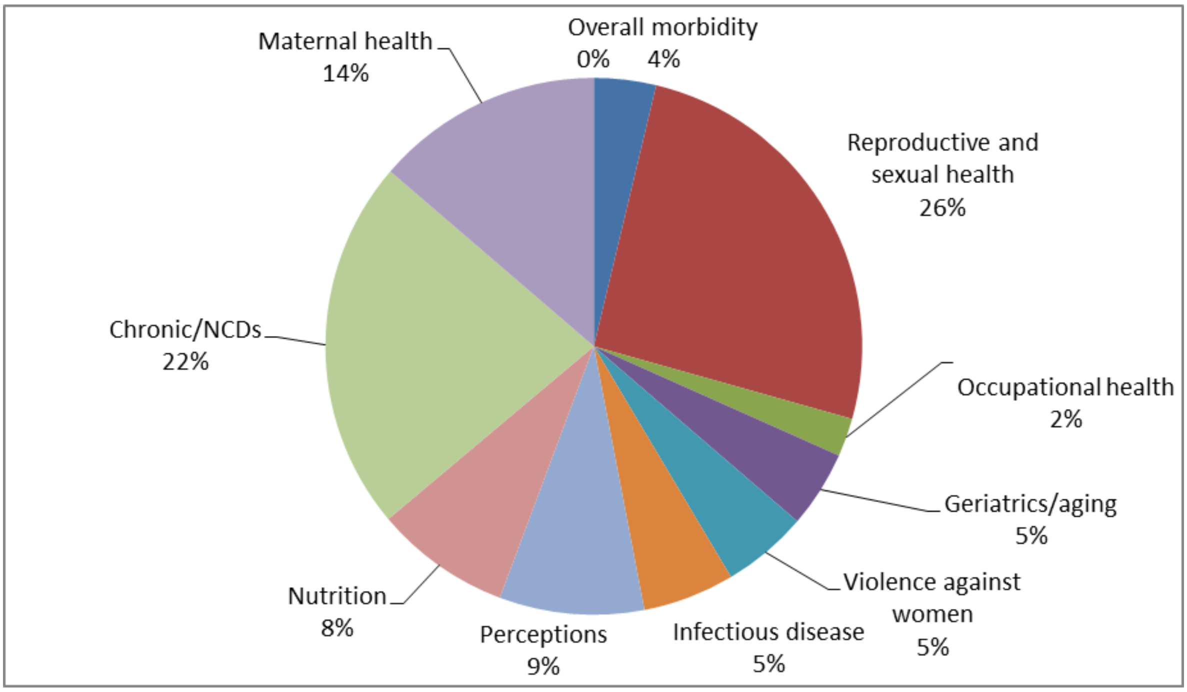
Studies on women's overall morbidity patterns in India were searched for using six databases: Medline, EmBase, IMSEAR, PubMed, Popline and Web of Science.   MeSH search terms included women/female + India + health status/morbidity, with slight variations by database and without the term women as well, for studies published between 1991 and 2011.

The initial search yielded over 2,600 studies. Three filters were used to hone in on specific studies of interest. In the first step, all studies on illness patterns in India that involved, but were not necessarily specific to, women were retained, while studies on Indian women who have emigrated or specific clinical procedures were excluded. Second, articles on the theory or methodology of addressing women's health were excluded.   Of the 938 studies that remained, a final filter excluded facility-based studies and categorised the remaining studies into two types of population-based survey: (i) community-based studies (556 articles) and (ii) analyses of national sample surveys such as the National Family Health Survey and National Sample Survey (148 articles).

1.1 Research on women's health

A large proportion of the community-based studies focuses on a specific aspect of women's health, such as reproductive health, perceptions of illness or chronic disease, rather than women's overall morbidity patterns. A topical overview, based on 556 community-based studies, reflects the range of priorities in women's health research in the past twenty years.

Figure 1   Distribution of community-based women's health research, 1991-2011



Reproductive and sexual health (including HIV/AIDS), chronic/non-communicable disease and maternal health comprise over one-half of all published community-based research. While the number of studies on chronic disease and its risk factors have increased in the past decade, research on maternal health, women's gynaecological morbidities and HIV/AIDS has been conducted consistently since the early 1990s. In addition to community-based research, two government commissioned surveys provide a national picture of women's health. The 60th round of the National Sample Survey in 2004 included morbidity and hospitalisation for all individuals, and the National Family Health Survey conducted every 10 years surveys households practices and knowledge related to maternal and child health, contraception and as of the most recent round, violence against women.

1.2 Women's morbidity patterns

The purpose of this review is to synthesise previous research on women's overall morbidity patterns at a population level, and to the extent possible, identify common threads in evidence and analyses. Given the low number of studies that provide information on overall morbidity, as compared to the research on specific conditions, an 'ailment-wise' synthesis was considered. However, the diversity of regions and socioeconomic conditions covered in the studies – as well as the significant gaps in illness groups – would render such a synthesis incomplete. Accordingly, this review covers findings from the National Sample Survey 60th round and fourteen community-based studies that estimate incidence of illness amongst women or, at a minimum, consider the role of gender in a population-based analysis. .

1.21 Methodological considerations

A brief summary of some methodological issues in morbidity studies is useful to provide context before reviewing findings on incidence, type and drivers of illness in women. In particular, the use of self- reported morbidity – by far the most common method in the literature – has been widely questioned. According to 2002 analysis of self-reported morbidity in a large-scale Indian survey, illness was highest in Kerala, India's socially best performing state, and considerably lower in Bihar, one of its poorest – a finding which suggests that self-reporting results in inaccurate estimations of morbidity[1] . Further, reviews of community-based studies on gynaecological morbidity in India have found both underreporting and dissonance between self-reports and laboratory investigations [2] [3]. This difference has been attributed to variations in perceptions of illness linked to the socioeconomic conditions of respondents, such as education level, access to health care and localised notions of illness [1]. However, in direct response to this hypothesis, a 2008 analysis of two national sample surveys in India found that individuals with no education reported the highest levels of morbidity and poorest perception of their own health, resulting in a call for a less pessimistic view of self-reports of perceived health status [4].

The validity and comparability of self-reports may be strengthened by a combination of survey techniques, such as narrative vignettes[5, 6] or the use of concurrent self-report techniques that include probes, checklists and focus groups [7-10]. Furthermore, a shortened recall period has been found to increase morbidity estimates substantially[8, 11]. While much of the debate has focused on validity of self-reports in light of the perception of morbidity, less analysis considers how accurate reporting of illness episodes may be when asked in conjunction with treatment and expenditure. Lastly, a study comparing different methods of survey instruments in the same population of women contends that, outside of debates on the validity for morbidity estimates, self-reports are a valuable source of information on women's own perceptions of morbidity and well-being [10].

1.22 Findings

The National Sample Survey (NSS) 60th round conducted in 2004 surveyed 47,302 rural and 26,566 urban households across all of India's states and union territories. A module on morbidity inquired about short term illness in the past 15 days and hospitalisation over the past one year for every individual in a household, with a sampling frame that included households categorised into twelve income groups, based on monthly expenditure. The overall proportion of women who reported an ailment was found to be 93/1,000 women in rural areas and 108/1,000 women in urban areas. Outside of the 0-14 age (and above 60 in rural India), a higher proportion of women reported illness than men. Sex and age-specific proportions are presented in Table 1.

Table 1 Proportion reported illness in last 15 days (per 1000 women)

Age group	**Rural**		**Urban**	
	Male	Female	Male	Female
0-14	76	68	84	74
15-29	41	57	44	56
30-44	64	93	64	95
45-59	107	132	127	173
60+	285	282	352	383
All	83	93	91	108

Source: NSS 60th round

The proportion of individuals hospitalised, regardless of duration of stay, for women were 22/1,000 in rural areas and 31/1,000 in urban areas. Hospitalisation rates are largely the same for men and women, with slight differences in age-specific strata. The leading reasons for hospitalisation were: i) accidents/injury (10%) ii) fevers of unknown origin (8%) iii) diarrhoea/dysentery (7%) heart disease (5 %) and gynaecological disorders (5%). A more detailed illness classification with sex-disaggregated data is not available in the NSS report.

While the NSS offers a valuable national and state-level picture, community-based studies have put forth differing estimates and patterns in morbidity. Fourteen population-based studies were reviewed, twelve of which were cross-sectional. They span seven urban and twelve rural locations, covering eight of India's 28 states and one of the seven union territories (Delhi). Each study presents findings from self-reported morbidity, although three also include a physical examination or laboratory investigations.

The reported incidence of illness amongst women in low-income settings, both rural and urban, varies considerably across studies. For example, in four rural studies with samples of at least 2,000 women, the illness incidence ranged from 793/1,000 women over a one-month reference period in Maharashtra to [9] to approximately 188/1,000 over a three month reference period in Karnataka and 273/1,000 individuals over a five month period – both of which crudely translate to less than one-tenth of the incidence found in the former study over a similar reference period [12] [13]. Results from smaller studies are also variable: while a cohort study of 321 women reported an incidence of 2.9 episodes per woman over one year based on one-month recall [14], a cross-sectional study of 348 households with fourteen-day recall reported 80/1,000 women ill [15].

This range also emerges in urban studies: a cross-sectional study amongst slum dwellers in Mumbai found 571/1,000 women ill in the past month, compared to a cohort study in Delhi that found 750/1,000 persons (sex breakdown not available) reported an illness in the same time period, albeit with weekly reporting [11]. While a cross-sectional study found 166/1,000 illnesses over a five month recall period [13], a large study of urban slums reported 104/1,000 women ill in Delhi and 83/1,000 in Chennai over a one-month period [16]. Overall, the findings, even if crudely standardised to a one-month reference period, are vastly different from one another as well as the NSS. Regional diversity may be one explanation: two multi-site studies found that illness incidence varied considerably by geographic location in similar socioeconomic groups [16, 17].

The pattern of illnesses reported were largely similar: fever, respiratory illness and gynaecological morbidities emerged as the most common reported illnesses amongst self-reports [9, 16, 18,19]. In a study that utilised medical examinations for depression, anaemia and reproductive tract infections amongst women, the latter comprised the largest proportion of illness episodes of the three[20]. A similar ranking exercise conducted with self-reported illness amongst a cohort of married women under 35 years found that circulatory/respiratory illnesses were the most prominent, followed by reproductive and infective/parasitic illnesses [14]. Notably, two health utilisation studies did not find gynaecological ailments to be amongst the top illness episodes, perhaps because the survey focused on expenditure [11, 16]. Some studies – particularly those focused on economic impact of illness or health service utilisation – did not report sex-disaggregated illness patterns or link treatment behaviour to of type of illness.

Both the NSS and community-based studies largely converge on basic patterns: reported morbidity is consistently higher amongst adult women than men, with a few exceptions. Living conditions and socioeconomic status emerged as indicators of illness, although it is useful to note that the reporting of morbidity itself may be linked to socioeconomic or geographic context. While the patterns of reported are also similar – mainly primary and gynaecological illness –the NSS data only concerns hospitalisation while the community-based studies largely do not differentiate by treatment patterns.

1.3 Analysis

The primary strength of this combination of one national and several community-based studies is a nuanced perspective of overall morbidity amongst women, with a wide range of estimates and insight into different aspects of women's health. Despite the considerable variation, the existing research offers the evidence that reported morbidity is higher amongst women in most settings. The predominant burden of respiratory illness, reproductive –related disorders and fevers point to the need for further understanding to inform public health interventions, particularly for preventable and primary illness.

This diversity in findings underscores the critical role of methodology in measuring morbidity. Each study utilised different definitions and classification methods for illness and treatment, thus limiting comparability, while the low number of studies prevents any assessment of relative accuracy. In consideration of the ongoing debates, this review notes that (i) validity checks or a combination of survey techniques is a desirable complement to self-reported morbidity (ii) there is a need for further research on methodological issues, including standard variables for comparability.

A broader methodological limitation of the existing studies is that most of the studies are either epidemiological or economic in nature, but rarely both. A lack of illness information in health utilisation studies prevents analysis of implications for resource allocation, rationing of care and prevention. Similarly, epidemiological studies that do not track treatment and expenditure rely largely on self-reporting of symptoms or episodes to understand the severity, perception and economic impact of illness. A combined economic-epidemiological approach, as adopted by the NSS and three of the reviewed studies, offers a potentially powerful assessment of women's health from multiple perspectives. Moreover, only four of the studies analysed correlates of illness in a multivariate setting – one of which found gender to be insignificant explanation for illness patterns [17].

Most critically, the combined information of fourteen community studies over twenty years and one national survey is not sufficient to set priorities at a local or national level for women's health. The sheer lack of studies on women's overall morbidity patterns – a limitation in of itself – also raises questions about the production of research knowledge and determinants of research agendas. There is also limited insight at present on potentially important associations to explain morbidity patterns amongst women. While it could be argued that the National Sample Survey provides sufficient information on women's overall morbidity, it is clear that community-based studies may capture nuances that a large-scale survey may not, potentially improve validity of self-reports through the use of different methods, as well as serve as a localised evidence base to inform policy and programs. A need for more systematic and analytical research on women's morbidity patterns emerges, as does the importance of using a combination of methods to enhance current understanding of women's health needs in India.

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Annex 2 Overview of articles reviewed on CHW-led group education

Authors	Year	Setting and Population	Intervention	Control	Outcomes measured
Eriksen et al[77]	2010	Tanzania Rural women	Training of women leaders in malaria case management in children <5	Usual government care	Prevalence of anaemia, fever, malaria and weight
Kroeger et al[78]	1996	Ecuador, Colombia, Nicaragua Rural men and women	Malaria education through CHW sessions and health promoters	No intervention	Knowledge about malaria symptoms and treatment
Mock et al[69] Lam et al[70]	2007 2003	United States Vietnamese-American women	Media education with 2 CHW sessions on cervical cancer	Media education	Awareness, knowledge and receipt of pap test
O'Brien et al[72]	2010	United States Hispanic women	2 cervical cancer workshops conducted by CHWs	Usual care by promotoras	Knowledge, self-efficacy and receipt of pap test
Nguyen et al[73]	2009	United States Vietnamese-American women	Media education on breast cancer with 2 CHW education sessions + phone calls	Media education	Receipt of mammography and clinical breast exam
Balcazar et al[74]	2010	United States Hispanic men and women	8 CHW group sessions with 2 months of follow-up on reducing CVD risk factors	Given basic educational materials on CVD	Awareness, dietary habits and cholesterol levels
Koniak-Griffin et al[75]	2014	United States Hispanic women	8 CHW group sessions and 4 months of individual follow-up on healthy lifestyles	Comparable educational program and follow-up on different topics	Dietary habits, physical activity and clinical outcomes (eg BP, weight)

Authors	Year	Setting and Population	Intervention	Control	Outcomes measured
Baqui et al[79]	2008	Bangladesh Rural women/households	Community arm: Promotion of safe delivery and newborn care practices through group sessions Home visit arm: Antenatal and postnatal visits and treatment	Usual government care	Neonatal mortality Care-seeking practices
Bhutta et al[47]	2011	Pakistan Rural women/households	Village health committees Group sessions to promote safe delivery and postnatal care Linkages between CHWs and dais Home visits and postnatal care	Usual CHW care	Neonatal mortality Care-seeking practices

Annex 3 Survey Instruments

Baseline Survey, followed by Rounds 2-4

VIMO SEWA AROGYA SANSHODHAN

Baseline Survey (January – February 2010)

Identification details:

Interview Number--------

Date: -----------------

Start time: _____

End time: _____

Researcher's Name_________________ Supervisor's Name__________________

Location (Chali/Area/Village) --

Sevikaben's Name __________________________

Section 1: BACKGROUND INFORMATION

(Note: Please place a ✓mark in the appropriate box provided with options wherever applicable).

A. PERSONAL DETAILS

1. Respondent's Full Name: ____

2. Address: ____

3. Are you a member of SEWA? (1) Yes ☐ (2) No ☐

4. If yes, for how many years have you been a member? _ _ ._ _ (YY.MM)

5. Do you have any of SEWA's insurance products? (1) Yes ☐ (2) No ☐

6. Mother tongue: (1) Gujarati ☐ (3) Marwari ☐ (5) Other (specify) ______
(2) Hindi ☐ (4) Marathi ☐

7. Religion:

1. Hindu ☐	4. Christian ☐
2. Muslim ☐	5. Other, specify _______
3. Sikh ☐	

8. For how many years have you been staying at the present house? _ _ . _ _ (YY.MM)

(If the respondent is residing for less than one year, then skip to section B. Do not ask questions 9 and 10).

9. Where did you stay one year ago? ___________________________________

10. How long do you plan to stay in this house? _ _ . _ _ (YY.MM)

B. HOUSEHOLD INFORMATION

(Definition of Family: Those members of the household who cook and have meals from the same kitchen).

Complete the following table for each person living in the house, starting with the respondent first as well as any household persons who have died in the past 6 months preceding the survey. Fill in the name first then fill the details horizontally from 3rd column. Put an * after the names of the expired members.

11. Total Family Members: _ _ (1) Joint family ☐ (2) Nuclear family ☐

1 Sr. No	**2 Name**	**3 Age**	**4 Sex [code]**	**5 Relation with Respondent [code]**	**6 Marital Status [code]**	**7 Education [code]**	**8 Still Studying? [code]**	**9 Any other source of earning per month? (rent, pension,**	**10 Do you work/help in work in the present year? [code]**
1.									
2.									
3.									
4.									
5.									
6.									
7.									

Coding categories:

4 Sex	***5 Relation with the respondents***	***6 Marital Status***	***7 Education***	***8 Still studying***
1 Male	*1. Self*	*1. Married*	*0 illiterate (Not gone in school)*	*1. Yes*
2 Female	*2. Husband*	*2. Un married*	*K kinder garden*	*2. No*
	3. Son/ Daughter	*3. Divorcee*	*1-12 Classes (write actual class)*	*99. 0-3 years*
	4. Mother/ Father	*4. Widow/ Widower*	*13 Graduate (1,2,3 years)*	
	5. Parents in law	*5. Separated*	*14 Post Graduate (1, 2 years)*	**9 Any other source of earning per month?**
	6. Son/ Daughter in law		*15 Technical Education (diploma course)*	*1. Government help*
	7. Brother/ Sister		*16. Vocational training*	*2. Scholarship*
	8.Grandson/ Grand Daughter		*17. Any other*	*3. Pension*
	9. Niece/ Nephew		*77. Can read and write*	*4. Rent*
	10. Uncle/ Aunt		*88. Don't know*	*5. Money sent by employed*

				children
	11. Grand Parents		*99. Below 3 years*	*6. Life insurance*
	12. Brother in law/ Sister in law			
	13. Others			***10*. Do you work/help in work in the present year?**
				1. Yes
				2. No

C. EMPLOYMENT DETAILS [Starting with the respondent first, if applicable]

12. Total Working members of the family: ______________

Instructions: For all the working members / those who help in work please complete the following table.

1 Name	**2 Type of work (Code)**	**3 Details of work**	**4 Number of working days in a month**	**5 Number of working months in a year**	**6 Place of work (Code)**	**7 Income from work (Rs.)**		
						Daily	Monthly	Yearly
1.	A.							
	B.							
	C.							
2.	A.							
	B.							
	C.							
3.	A.							
	B.							
	C.							

Coding categories

2. Type of Work	**6 Place of Work**
1. Salaried	*1. One's own home*
2. Daily wage earner	*2. Out of home (e.g., shop, factory, door-to-door seller)*
3. Self employed	
4. Piece-rate worker	
5. Trainee	
6. Helper without income	
7. Any other	

1	Total annual income of the household	
2	Total annual income of the household through other	

	sources of earning	
3	**Final Total annual income**	

D. EXPENDITURE AND ASSETS:

13. Expenditure: Please consider expenditure in the past 1 year.

Kind of Expenditure	**Amount (Rs.)**		
	Daily	**Monthly**	**Yearly**
1 Food (Oil, vegetables, grocery etc)			
2 Fuel (Wood, oil, kerosene, cooking gas etc)			
3 Clothing			
4 Education (Uniform, Fees, Books etc.)			
5 Rent (House)			
6 House tax			
7 Electricity bill			
8 Medical Expenses			
9 Transport			
10 Telephone (Cellular phone) expenses			
11 Addiction (Gutkha, Bidi, Alcohol etc.)			
12 Social (marriage, festivals, death, birth etc)			
13 Expenses for one's hobby			
14 Other Expenditure			
Total			

14. Assets: Fill up by observation and/or interviewing.

No.	**Name of Assets**	**A.** If "YES" , then mark (✓)	**B.** Number of items
1	Radio / Tape recorder / DVD player		
2	TV		
3	Cellular phone		
4	Refrigerator		
5	Big vehicle (Tractor, Shuttle-rickshaw etc.)		
6	Two Wheeler		
7	Sewing Machine		
8	Land (Ownership -Self)		
9	Live stock : Cow/ Buffalo / Sheep/ Goat /Poultry		
10	Cart (lari) or Table		
11	Water Tank, Water Motor		
12	Other (specify below) 1.		
	2.		

Section 2: HOUSING INFRASTRUCTURE

Housing

15. Ownership of the house
    (1) Female member's (Respondent's) ownership ☐ (2) Husband's ownership ☐
    (3) Other family member's ownership ☐____________ (4) Don't know ☐
    (5) Rented ☐ (6) Any other ___________

16. Type of house (observe)
    (1) Kaccha ☐ (2) Semi pucca ☐ (3) Pucca ☐

17. What is the main source of light in your home ?
    Note: (All respondents should be asked, "Do you use solar light at your home"?)

    (1) Electricity ☐ (2) Solar ☐
    (3) Oil/kerosene ☐ (4) Other specify_______

Water and Sanitation:

18. What is your source for drinking water? (Multiple responses are possible)
    (1) Tap (individual) ☐ (2) Tap (shared) ☐ (3) Neighbour's house ☐
    (4) Well ☐ (5) Hand pump (individual) ☐ (6) Hand pump (shared) ☐
    (7) Pond/ River/ Lank ☐ (8) Canal ☐ (9) Tanker ☐
    (10) Other specify _________

19. How far is this water source from your home?
    (1) 0 - 15 minutes ☐ (2) 16 - 30 minutes ☐ (3) 31 to 45 minutes ☐
    (4) 46 - 60 minutes ☐ (5) Other specify _________

20. Do you do anything to make your water safe to drink ?
    (1) Boil ☐ (2) Filter ☐ (cotton cloth, plastic filter etc)
    (3) Nothing ☐ (4) Other____________________________________

21. Do you use chlorine tablets to make your water safe to drink? (1)Yes ☐ (2) No ☐
(1) If yes than why ____
(2) If no than why ____

22. How do you take drinking water from holder?
(1) Through hands ☐ (2) Through *Doyo* ☐
(3) Holder/Pot with tap ☐ (4) Other __________________________________

23. Do you have toilet at your home? Yes ☐ No ☐

23.1 If no then where do you go for toilet?
(1) Outside home in open fields/space ☐ (2) Public toilets ☐
(3) Pay and use toilets ☐ (4) Other.____________________

24. Do you keep soap at home? Yes ☐ No ☐
If yes, when do you wash your hands?
(1) Prior to cooking ☐ (2) After using the toilet ☐
(3) When children's hands get dirty ☐ (4) Before eating____________

If no, then why don't you wash your hands with soap?
____

25. What kind of precautions do you use for mosquitoes?
(1) Mosquito Net ☐ (2) Neem leaves ☐
(3) All Out/Good Knight mat ☐ (4) Jadi butti of SEWA ☐
(5) Odomos/any other ointment ☐ (6) Nothing is used ☐
(7) Any other____

26. What kind of fuel is used for cooking?
(1) Wood ☐ (2) Coal ☐ (3) Kerosene (primas) Stove ☐
(4) Gas cylinder ☐ (5) Gobar gas ☐

27. Where is your stove situated?
(1) In the Kitchen ☐ (2) Outside ☐ (3) At both the places ☐

28. If, it is in the kitchen then is there any ventilation facility available?
(1) Yes ☐ (2) No ☐
If yes, please indicate the
same____

Section 3 – SERVICES MAPPING

Government services

29 Do you have rationing card? (1)Yes ☐ (2)No ☐

29.1 If yes then please specify which type do you have.

(1) APL ☐ (2) BPL ☐ (3) Poorest of the poor ☐

29.2 What benefits do you get with this rationing card?

No.	**Items**	**Yes/No**
1	Food grains	**Yes/No**
2	Sugar	**Yes/No**
3	Fuel (kerosene)	**Yes/No**
4	Oil	**Yes/No**

30. Do you get benefit of NREGS (employment for 100 days)? (Applicable only to villages)

(1)Yes ☐ (2) No ☐

Health Facilities

31. A : Closest health facilities for Urban area (Please encircle the correct answer)
(For coding of B and C please refer the table at the end of the question).

Facility	**Know Location**	**Distance (time) (Code)**	**Type of transport (Code)**	**Doctor available**	**Medicines available**	**Tests available**	**Admission available**	**Have you or anyone in HH used it in the last year**
UHC (Municipality)	Y / N			Y / N	Y / N	Y / N	Y / N	Y / N
Government Hospital	Y / N			Y / N	Y / N	Y / N	Y / N	Y / N
Private Consulting room	Y / N			Y / N	Y / N	Y / N	Y / N	Y / N
Private Hospital	Y / N			Y / N	Y / N	Y / N	Y / N	Y / N
Trust	Y / N			Y / N	Y / N	Y / N	Y / N	Y / N
Traditional healer	Y / N			Y / N	Y / N	Y / N	Y / N	Y / N
Chemist	Y / N			Y / N	Y / N	Y / N	Y / N	Y / N
Any other	Y / N			Y / N	Y / N	Y / N	Y / N	Y / N

32 B: Closest health facilities for Rural area (Please encircle the correct answer)

Facility	**Know Location** **A**	**Distance (time) (Code)** **B**	**Type of transport (Code)** **C**	**Doctor available** **D**	**Medicines available** **E**	**Tests available** **F**	**Admission available** **G**	**Have you or anyone in HH used it in the last year** **H**
Sub centre	Y / N			Y / N	Y / N	Y / N	Y / N	Y / N
PHC	Y / N			Y / N	Y / N	Y / N	Y / N	Y / N
Community Health centre (Sanand – Civil & Dholka - Menaben Tower)	Y / N			Y / N	Y / N	Y / N	Y / N	Y / N
Government Hospital	Y / N			Y / N	Y / N	Y / N	Y / N	Y / N
Private consulting room	Y / N			Y / N	Y / N	Y / N	Y / N	Y / N
Trust	Y / N			Y / N	Y / N	Y / N	Y / N	Y / N
Traditional healer	Y / N			Y / N	Y / N	Y / N	Y / N	Y / N
Chemist	Y / N			Y / N	Y / N	Y / N	Y / N	Y / N
Any other	Y / N			Y / N	Y / N	Y / N	Y / N	Y / N

B Distance	***C Type of transport***
1 1-15 minutes	*1 Walking*
2 16- 30 minutes	*2 Cycle*
3 31-45 minutes	*3 Scooter*
4 46-60 minutes	*4 Rickshaw-Shuttle*
5 more than 60 minutes	*5 Bus (Private/Public)*
	6 Bullock Cart
	7 Other (Specify)

33. Are you aware of the 108 facility?

(1)Yes ☐ (2) No ☐

34. If yes, have you ever used it?

(1)Yes ☐ (2) No ☐

Local health workers

For Rural Area

35. ANM worker (Nurse Ben) (1) Yes ☐ (2) No ☐

35.1 Does ANM worker visit your village?

---•------------------------------•------------------------------•--------------------------•-----

Always	**Often**	**Seldom**	**Rarely**
(6 ≥ per month)	(4-5 times/month)	(2-3 times / month)	(once in a month)

35.2 Do you get benefit from her? (1)Yes ☐ (2) No ☐

36. ASHA worker

36.1 Does ASHA worker visit your village? (1)Yes ☐ (2) No ☐

---•------------------------------•------------------------------•--------------------------•-----

Always	**Often**	**Seldom**	**Rarely**
(6 ≥ per month)	(4-5 times/month)	(2-3 times / month)	(once in a month)

36.2 Do you get benefit from her? (1)Yes ☐ (2) No ☐

37. SEWA worker (Sevikaben)

37.1 Does SEWA worker visit your village? (1)Yes ☐ (2) No ☐

---•------------------------------•------------------------------•--------------------------•-----

Always	**Often**	**Seldom**	**Rarely**
(6 ≥ per month)	(4-5 times/month)	(2-3 times / month)	(once in a month)

37.2 Do you get benefit from her? (1)Yes ☐ (2) No ☐

38. Is there Anganvadi in your village? (1)Yes ☐ (2) No ☐

***For Urban Area*:**

39. Link worker (1)Yes ☐ (2) No ☐

39.1 Does a Link worker visit your village?

---•------------------------------•------------------------------•--------------------------•-----

Always	**Often**	**Seldom**	**Rarely**
(6 ≥ per month)	(4-5 times/month)	(2-3 times / month)	(once in a month)

39.2 Do you get benefit from her? (1)Yes ☐ (2) No ☐

40. SEWA worker (Sevikaben)

40.1 Does SEWA worker visit your village? (1)Yes ☐ (2) No ☐

---•------------------------------•------------------------------•---------------------------•-----

Always	Often	Seldom	Rarely
(6 ≥ per month)	(4-5 times/month)	(2-3 times / month)	(once in a month)

40.2 Do you get benefit from her? (1)Yes ☐ (2) No ☐

Section 4 – HEALTH CARE UTILIZATION

41. Have you or any of your family members been consuming medicines without any consulting a doctor or without any illness (e.g., diabetes, cholesterol, asthma, blood pressure)? If yes, how many individuals are such? ______________

41.1 Have you or any of your family members been ill in the past 1 month?

(1)Yes ☐ (2) No ☐

If yes, then, One person ☐ More than one person ☐__________(Number)

42. Healthcare Utilization Table

(Include people who have been ill according to question 41.1)

42.1 In the following table please fill up information on healthcare utilization in the last one month.

Name:___________________________

Illness: ___________________________

Symptoms: _______________________

Diagnosis was made by : Self ☐ Doctor ☐

A		**B**	**C**		**D**	**E**
Treatment	**Code**	**When did you start treatment?**	**Advice**	**What did you do?**	**Duration of treatment (Days/Month)**	**Result of treatment (Code)**
1st						
2nd						
3rd						
4th						

A. Treatments *1. Home based* *2. Bought medicine from chemist* *3. Traditional healer* *4. Government Health Worker* *5. SEWA Health worker*	*6. Consulted Doctor* *6.1 Private Clinic* *6.2 Government Clinic in the area* *6.3 Trust* *6.4 Government Hospital* *6.5 Private hospital* *6.6 Ayurvedic doctor* *6.7. None* *6.8 Any other*	*7.Hhospital* *7.1 PHC* *7.2 Government hospital* *7.3 Private* *7.4 Trust*
***E.* Result of treatment** 1. Cured 2. Not cured 3. Treatment continued		

Important Note: Please note that all questions starting from the "Healthcare expenditure table" up to "Did anyone miss school?" are to be asked separately for each person listed in the Healthcare utilization table**. <u>All these questions, moreover, are for the 30-day (one month) reference period only.</u>**

43. Healthcare Expenditure Table:

A. Description	**B. OP D Doctor**	**C. Hospitalization**	**D. All Other Sources of Care**	
			Code	**Expenses**
Consultation				
Tests				
Surgery / Operation				
Transport				
Tips/Bribes				
TOTAL				

D. Coding

1 Home-based treatment *2. Bought medicines from outside without prescription*
3. Traditional healer *4. Health worker*
5. Aarogya karyakarta *6. Bought medicines from a chemist's shop*

44. Excluding the expenditures indicated in Q. 43, did the household incur any other expenses on the treatment of this individual in the last 30 days?

(1)Yes ☐ (2) No ☐

45. If Yes to 44, please indicate the amount and purpose

Amount: _________ (Rupees)

Reason: ____

46. How did you pay for costs incurred? (Last month)

1. Own Savings/ Income ☐
2. Sell Assets ☐
3. Pawn Jewelry ☐
4. Help from family/friends ☐
5. Borrow from moneylender ☐
6. Borrow from others ☐
7. Vimo SEWA Cashless Payment ☐
8. Any other ________________________

47. Were or will any expenses be reimbursed? (1)Yes ☐ (2) No ☐
(1) Employer ☐ (2) Vimo SEWA ☐
(3) Other insurance ☐ (4) Any other ___________________

48. Roughly what percentage of expenses will be reimbursed? _________________

49. Did anyone accompany and/or provide care to the person who was ill? If yes, did they miss work?

Care giver	Did he/she miss work	Duration (Days)
1. Family member	Yes / No	
2. Non-household caregiver	Yes / No	

50. Provide an estimate of total income lost. (Both ill person and caregiver together):
____

51. Did anyone miss school? (1)Yes ☐ (2) No ☐
If yes, for how many days? ____________

52. Have you (or any member of your household) been hospitalized in the *last six (6) months*, excluding any hospitalization that we have already discussed?

1. Yes ☐ 2. No ☐

52.1 If Yes, then please answer the following questions:

A	B	C	D	E	F	G	H
Name	**Days spent in hospital**	**Illness**	**Hospital (code)**	**Total expenditure**	**Sources of payment (Code)**	**Did you get reimbursed**	**Did you get reimbursed from Vimo Sewa**
						Y / N	Y / N
						Y / N	Y / N

Code: D: Hospital
1. Public hospital *2. Private hospital* *3. Trust* *4. Any other type of hospital*

F: Sources of payment

1. Own Savings/ Income ☐

2. Sell Assets ☐

3. Pawn Jewelry ☐

4. Help from family/friends ☐

5. Borrow from moneylender ☐

6. Borrow from others ☐

7. Vimo SEWA Cashless Payment ☐

8. Any other ________________________

53. Hospitalization Expenditure Table

A. Description	**B. Hospitalization**
Medicines	
Doctors' fee and operation expenses	
Tests	
Hospital charges	
Transport	
Tips/Bribes	
TOTAL	

Has the family incurred any other expense for the treatment of the ill member in the past 6 months excluding the ones mentioned in Question 53?

53.1 If yes, then please specify the amount: _________________(Rupees)
Reason:____

What percentage of these expenses will be reimbursed? ___________________________

54. Had anyone accompanied the patient for care giving?

Care giver	**Did he/she miss work**	**Duration (Days)**
1. Family member	Yes / No	
2. Non-household caregiver	Yes / No	

55. Provide an estimate of total income lost. (Both ill person and caregiver together):
____

56. Did anyone miss school? (1)Yes ☐ (2) No ☐
If yes, how many days? ____________

Section 5: PREGNANCY AND IMMUNIZATION

57. Has anyone in your family been pregnant in the past year?
1. Yes ☐
2. No ☐
3. Miscarriage/Medical termination of Pregnancy ☐

58. Where was the delivery conducted?
1. Home ☐
2. Government Hospital ☐
3. Private hospital ☐
4. Trust hospital ☐
5. Any other specify____

59. Did you get benefit of JSY or Cheerajanjivi (Government) schemes?
(1) Yes ☐ (2) No ☐
(Write a narrative report if applicable)
____
____
____

60. Do you immunize your children? (Age group 0-6 years)
(1) Yes ☐ (2) No ☐ (3) Not applicable ☐

61. Do children in your household attend the balwadi / anganwadi?
(All children in the age group 0-6)
(1) Yes ☐ (2) No ☐ (3) Not applicable ☐

62. If yes than how many children from your family do attend the same? _________.

63. Has anyone in your family ever undergone a hysterectomy?
(1) Yes ☐ (2) No ☐

If No, then skip to Section 6.

If yes,
64. What was her age when she underwent the surgery? --------

65. What was the reason given by the doctor for the necessity of the operation?

66. In which hospital the operation was performed? (1) Public ☐ (2) Private ☐

Section 6: SEWA SERVICES

SEWA Bank

67. Do you have an account with SEWA Bank? (1) Yes ☐ (2) No ☐

Aarogya SEWA

68. What does SEWA health worker (NAME) provide to you?

1. Medicines ☐ 2. Jadi-buti ☐
3. Education: i) Gives information informally ☐
ii) Conducts formal training sessions ☐
iii) Conducts camp ☐
iv) Referral services ☐

Vimo SEWA

69. Currently, do you (or any member of your household) have SEWA insurance?
(1) Yes ☐ (2) No ☐

If Yes to 69 then ask questions 69.1 to 69. 4. If No, then skip to 70.

69.1 How long have you been a Vimo SEWA member?

(1) 0 - 2 years ☐ (2) 2 to 4 years ☐ (3) 4 to 6 years ☐ (4) more than 6 years -------

69.2 If yes, then which scheme?

(1) Individual ☐ (2) Husband-Wife ☐ (3) Individual + Kids ☐ (4) Full family ☐

69.3 If yes, what is the nature of premium payment?

(1) Fixed Deposit ☐ (2)Yearly Premium ☐

69.4 What is the nature of the scheme?

(1) Life insurance ☐ (2) Health ☐

(3) Assets ☐ (4) All combined ☐

(5) Don't know ☐

69.5. Do you plan to renew the insurance?
(1) Yes ☐ (2) No ☐

70. If no, were you ever a member of Vimo Sewa? (1) Yes ☐ (2) No ☐
71. If yes then for how many years were you a member? ____________

72. If yes, then which scheme did you have?

(1) Life insurance ☐ (2) Health ☐

(3) Assets ☐ (4) All combined ☐

(5) Don’t know ☐

73. Why did you discontinue Vimo Sewa insurance?

(1) Claims were not getting processed ☐

(2). We were not getting any benefit ☐

(3) Any other ____

74. What is the main reason for not taking Vimo SEWA’s **health** insurance for you and your family? (Applicable to non-insured participants and those having unbundled Life insurance and asset insurance)

(1) I cannot afford it ☐
(2) I do not need it ☐
(3) It is not useful ☐
(4) I do not know whom to contact & where ☐
(5) I have other health insurance ☐
(6) Sewa workers did not come to meet us ☐
(7) Any other ____

75. Have you submitted a claim to Vimo SEWA in the last 12 months? --------------

If yes, then specify:

(1) Natural death ☐ (2) Asset ☐

(3) Hospitalization ☐ (4) Accidental death ☐

76. Rate the following dimensions of services provided by Vimo SEWA

No	**Particular**	**Poor**	**Average**	**Good**	**Very good**	**Excellent**
1	Speed with which claims were approved					
2	Politeness of staff					
3	Ease of access to Vimo SEWA staff					

77. Do you have insurance from any source other than SEWA?

(1) Yes ☐ (2) No ☐

If Yes, please specify____

78. Overall how would you rate your own health?

Very Poor	**Poor**	**Average**	**Good**	**Very good**	**Excellent**

VIMO SEWA AROGYA SANSHODHAN

2nd, 3rd and 4th round surveys

Identification details:

Interview Number--------

Date: ----------------

Start time: _____

End time: _____

Researcher's Name_________________ Supervisor's Name_________________

Location (Chali/Area/Village) ---

Sevikaben's Name __________________________

1. Respondent's Full Name: ____

1a. Was husband present during survey?

2. Address: ____

HEALTH CARE UTILIZATION

1. Do you or any of your family members consume any medicines regularly for a chronic condition (where you do not have to consult a doctor each time e.g., diabetes, cholesterol, asthma, blood pressure)? If yes, how many individuals are such? ______________

2. Have you or any of your family members been ill in the past 1 month?

(1)Yes ☐ (2) No ☐

3.1 If yes, then, One person ☐ More than one person ☐__________(Number)

4. Healthcare Utilization Table

(Include people who have been ill according to question 2)

4.1 In the following table please fill up information on healthcare utilization in the last one month.

4.2 When in the last month did this person fall ill?

a) In the past week?

b) In the last two weeks?

c) In the last month (2-4 weeks)?

Name: ___________________________

Person number

Sex

Relationship to respondent

Illness: ___________________________

Symptoms: _______________________

Diagnosis was made by: Self ☐ Doctor ☐

A		**B**	**C**		**D**	**E**
Treatment	**Code**	**When did you start treatment?**	**Advice**	**What did you do?**	**Duration of treatment (Days/Month)**	**Result of treatment (Code)**
1st						
2nd						
3rd						
4th						

A. Treatments *1. Home based* *2. Bought medicine from chemist* *3. Traditional healer* *4. Government Health Worker* *5. SEWA Health worker*	*6. Consulted Doctor* *6.1 Private Clinic* *6.2 Government Clinic in the area* *6.3 Trust* *6.4 Government Hospital* *6.5 Private hospital* *6.6 Ayurvedic doctor* *6.7. None* *6.8 Any other*	*7.Hospital* *7.1 PHC* *7.2 Government hospital* *7.3 Private* *7.4 Trust*
***E.* Result of treatment** 1. Cured		

2. Not cured 3. Treatment continued		

Important Note: Please note that all questions starting from the “Healthcare expenditure table” up to “Did anyone miss school?” are to be asked separately for each person listed in the Healthcare utilization table**. <u>All these questions, moreover, are for the 30-day (one month) reference period only.</u>**

5. Healthcare Expenditure Table:

A. Description	**B. OP D Doctor**	**C. Hospitalization**	**D. All Other Sources of Care**	
			Code	**Expenses**
Consultation				
Tests				
Surgery / Operation				
Transport				
Tips/Bribes				
TOTAL				

D. Coding

1 Home-based treatment *2. Bought medicines from outside without prescription*
3. Traditional healer *4. Health worker*
5. Aarogya karyakarta *6. Bought medicines from a chemist’s shop*

6. Excluding the expenditures indicated in Q. 4, did the household incur any other expenses on the treatment of this individual in the last 30 days?

(1)Yes ☐ (2) No ☐

7. If Yes to 5, please indicate the amount and purpose

Amount: _________ (Rupees)

Reason: ____

8. How did you pay for costs incurred? (Last month) Multiple answers allowed

1. Own Savings/ Income ☐ 5. Borrow from moneylender ☐

2. Sell Assets ☐ 6. Borrow from others ☐

3. Pawn Jewelry ☐ 7. Vimo SEWA Cashless Payment ☐

4. Help from family/friends ☐ 8. Any other ______________________

9. Were or will any expenses be reimbursed? (1)Yes ☐ (2) No ☐
(1) Employer ☐ (2) Vimo SEWA ☐
(3) Other insurance ☐ (4) Any other __________________

10. Roughly what percentage of expenses will be reimbursed? ________________

11. Did anyone accompany and/or provide care to the person who was ill? If yes, did they miss work?

Care giver	Did he/she miss work	Duration (Days)
1. Family member	Yes / No	
2. Non-household caregiver	Yes / No	

12. Provide an estimate of total income lost. (Both ill person and caregiver together):
____

13. Did anyone miss school due to this person's illness?
(1)Yes ☐ (2) No ☐
If yes, for how many days? ___________

14. Have you (or any member of your household) been **hospitalized** in the *last six (6) months*, excluding any hospitalization that we have already discussed?

1. Yes ☐ 2. No ☐

14.1 If Yes, then please answer the following questions:

A	**B**	**C**	**D**	**E**	**F**	**G**	**H**
Name	**Days spent in hospital**	**Illness**	**Hospital (code)**	**Total expenditure**	**Sources of payment (Code)**	**Did you get reimbursed**	**Did you get reimbursed from Vimo Sewa**
						Y / N	Y / N
						Y / N	Y / N

Code: D: Hospital
1. Public hospital *2. Private hospital* *3. Trust* *4. Any other type of hospital*

F: Sources of payment

1. Own Savings/ Income	☐	*5. Borrow from moneylender*	☐
2. Sell Assets	☐	*6. Borrow from others*	☐
3. Pawn Jewelry	☐	*7. Vimo SEWA Cashless Payment*	☐
4. Help from family/friends	☐	*8. RSBY*	☐

9. Any other ________________________

15. Hospitalization Expenditure Table

A. Description	**B. Hospitalization**
Medicines	
Doctors' fee and operation expenses	
Tests	
Hospital charges	
Transport	
Tips/Bribes	
TOTAL	

16. Has the family incurred any other expense for the treatment of the ill member in the past 6 months excluding the ones mentioned in Question 14?

17.1 If yes, then please specify the amount: _________________(Rupees)
Reason:____

18. Were or will any expenses be reimbursed? (1)Yes ☐ (2) No ☐
(1) Employer ☐ (2) Vimo SEWA ☐
(3) Other insurance ☐ (4) Any other ___________________

19.. What percentage of these expenses will be reimbursed? ___________________________

20. Had anyone accompanied the patient for care giving?

Care giver	**Did he/she miss work**	**Duration (Days)**
1. Family member	Yes / No	
2. Non-household caregiver	Yes / No	

21. Provide an estimate of total income lost. (Both ill person and caregiver together):
____

22. Did anyone miss school? (1)Yes ☐ (2) No ☐
If yes, how many days? ____________

Annex 4 Hysterectomy Interview Guides

Woman name	
Village and Area	
How met	

Background

Age, occupation and education

SEWA member/Vimo holder

Family structure/members

Observed socio-economic status

Hysterectomy, if had

When was the operation?

What symptoms did you have? (chronology)

What did you think the symptoms were? How did you explain it to others?

Treatment process – home based, any other providers (and compare with other illness)

Who else did you consult along the way?

Experience with gynaecologists and interaction. Did you ask questions?

How did you decide to have an operation? Whom did you consult?

What did your family think? Your mother, mother in law? Other women in the village?

Where was the operation?

What body parts were removed?

Experience in hospital

Recovery period

Impact on work

Cost and payment method.

Insurance (if yes, experience)

Health status now? Any side effects? (personal, emotional, financial, family, husband)

How would you characterise the entire experience – positive, difficult, etc? *Not sure if appropriate*

What would you suggest to other women in the village with symptoms like yours?

General health care

Health care - where, who, and why for regular illness

Recent illness and/or hospitalisation events and treatment sought

Generally, what health care for gynaecological or menstrual difficulty? Childbirth?

Menstruation in home - rules, what it means, any difficulty?

Gynaecological morbidity – Past experience with morbidity, its treatment and with gynaecologists.

Interview guide – Providers

Provider name	
Location	
Training & years of practice	
How identified	

Frequency of hysterectomy operations (per week/month) and thoughts

Primary causes

Treatment procedures and protocol (what done first for symptoms)

Thoughts on prevalence and determinants of gynaecological morbidity and of hysterectomy

Women’s response to prescription of hysterectomy

Women’s ability to pay and effect on treatment choice

Need for interventions?

Annex 5 Process Evaluation Guides

Observation guide for health education sessions

Setting

CHW Name	
Village and Area	
Time and Length	
Setting	
# of women	
Occupation categories	
Approx age group	

Notes on session attendance

How session began

Session Delivery and Content

CHW communication style (discussion, classroom etc)

How hysterectomy introduced and defined

Causes explained

Side effects

Treatment options

Types of questions asked/discussion points

Nature of participation in discussion

Other topics covered

General observations

Potential women to meet later

Interview guide – education session participants

Woman name	
Village and Area	
How met	

Background

Age, occupation and education

SEWA member/Vimo holder

Family structure/members

Observed socio-economic status

Her thoughts on and/or previous experience regarding:

Menstruation – what does it mean to you? Rules or restrictions in household, any difficulty, beliefs on links to illness? Probe if menstruation comes up later.

Health care - where, who, and why for regular illness

Recent illness and/or hospitalisation events

Generally, what health care for gynaecological or menstrual difficulty? Childbirth?

Gynaecological morbidity – Past experience with morbidity, its treatment and with gynaecologists. Ever had an exam? Why?

Health insurance

Influences on health care decisions – family, others?

Session

Why attended health education session

Thoughts on session, the CHW and information provided

Main points she recalls

What points were new? What do you think of the information – is it relevant to you?

What do you think you would do if doctor ever prescribed hysterectomy? *Not sure about this question*

Whom would you speak to for further information or questions?

Short interview guides to test recall

(Conducted separately by topic)

Malaria

1. Where can you get free medicine for **malaria**?

Govt/PHC/ASHA

2. If you start **malaria** medicine, when should you stop taking it?

After completing the full course of medicine

3. What should you do to prevent being bitten by **mosquitoes**?

Fumigation

All-Out

Diarrhoea

4. What is the best way to prevent **diarrhoea**?

Washing hands with soap

6. When are the two times/occasions when it is essential to wash hands with **soap**?

Before eating

After using the toilet

7. What is the first course of treatment when someone has **diarrhoea?**

Give them ORS made with boiled water

8. This is an **ORS** packet. How will you make the solution?

Boil water

Measure water

Shows measuring cup Yes/No

Hysterectomy

9. Is a **hysterectomy** always necessary?

10. For what reasons do women have a **hysterectomy**?

11. What should you do after the doctor says you should have a **hysterectomy**?

Annex 6 Information Sheet (Survey) and Study Protocol

Information Sheet (Read to Participants)

Round 1

Namaste. My name is ______________________. I have come from SEWA Academy's research team. We are conducting a survey on health and health care utilization so that we can make SEWA health and insurance services better in the future. In this context, we would like to ask you questions about your household and health. We will come back once every six months to understand health care patterns.

If you give your consent, I will start by asking some background information about you and your family, such as where you live, your work, education and income. We will then ask you about local health facilities, any illness in your family in the past six months and treatment sought, and your experience with SEWA's services. You and your household members can answer questions together if you prefer. You can stop the interview at any time.

We want to assure you that the information you share with us will be kept completely confidential. Your name and personal details will not be kept or shared. The overall results and patterns we learn from this study will be shared with you, your village/area and local SEWA leader at the end of the study. Do you have any questions? Do you consent to taking part in this survey?

Rounds 2, 3 and 4

Namaste. My name is ______________________. I have come from SEWA Academy's research team. As you know, we are conducting a survey on health and health care utilization so that we can make SEWA health and insurance services better in the future. We have returned after six months, to ask you about any illness in your family in the past six months and treatment sought.

We want to assure you that the information you share with us will be kept completely confidential. Your name and personal details will not be kept or shared. The overall results and patterns we learn from this study will be shared with you, your village/area and local SEWA leader at the end of the study. You can stop the interview at any time. Do you have any questions? Do you consent to taking part in this survey?

Study Protocol: Measuring the Impact of a Community-Based Health Education Intervention

This protocol was submitted to the International Labor Organisation in May 2009 as part of the grant proposal, submitted by SEWA with study design by Professor Ajay Mahal.

1. Background

VimoSEWA has been implementing an integrated insurance program (life, hospitalization, accident and asset) for poor women workers and their families since 1992. Health insurance has proved to be a primary need of the poor: over 90% of all claims are for illness expenditure. SEWA's hospitalisation claims data indicate that at least one-third of claims are for preventable illness such as diarrhoea and fever. SEWA's experience indicates that these diseases, if treated early in a primary health setting, often do not require hospitalization. Further, hysterectomy is a leading cause of hospitalisation amongst women, at an average age of 36 years.

Allowing primary illnesses to reach hospitalization translates into unnecessary loss of income and assets for the poor, and impedes viability of health insurance. The main problems are: 1) high hospitalization rates that lead to unsustainably high claims ratios for health insurance; and 2) unnecessary financial burden on the poor. Direct causes, as we hypothesise them to be, are low awareness on preventive measures and a lack of community-based referral services to outpatient or home-based care.

2. Action Research Design

SEWA hypothesizes that the bulk of primary illnesses, if treated early in a primary health setting, may not require hospitalization. In the case of hysterectomy, a trend in unnecessary operations, driven largely by providers, may be at play. Unnecessary hospitalization translates into unnecessary loss of income and assets for the poor, and impedes the use of health insurance for other catastrophic illness. These claims may be prevented through community health interventions.

The interventions will focus on reducing unnecessary hospitalization and decreasing expenditure on commonly claimed conditions. An analysis of claims over the past five years found that 1) gastroenteritis and water-borne disease 2) fever and 3) malaria are most commonly claimed in Ahmedabad city. The same pattern applies to rural Ahmedabad district, with the addition of hysterectomy as the highest reimbursed reason for hospitalization. (Note: while fever itself is not an illness, it is commonly cited as the reason for hospitalization and fair claim reimbursement amongst physicians in India.)

3. Research Questions

1. Does the community health intervention impact on VimoSEWA hospitalization claim patterns?

2. Does the health intervention impact on a) health outcomes b) health care use c) expenditure and d) knowledge – for those insured by VimoSEWA – for commonly claimed conditions?

3. Does the health intervention impact on a) health outcomes b) health care use and c) expenditure – for those uninsured by VimoSEWA - for commonly claimed conditions?

4. Health Interventions

The health intervention will include:

a) In-depth group health education sessions on waterborne disease, malaria and hysterectomy. Each session uses a range of new media tools like participatory games, film and stories. Hand soap will be provided to all participants in group education, after a session on the benefits of handwashing. Community media on these three illnesses (wall paintings, posters etc)will be utilised in treatment areas alone,
b) Individual referrals to outpatient facilities for these three illnesses (treatment of gynaec ailments in the case of hysterectomy) and one-to-one education.
c) Monthly capacity building CHWs on health education. During the course of the 2 year project, only the 14 selected CHWs will participate in additional training sessions.

5. Methodology

The study is a cluster randomized trial, in which each community health worker (CHW) area of work is defined as a discrete "cluster". 28 CHWs from Ahmedabad city and Ahmedabad district will participate in the study. Of these, 14 will be randomly selected to deliver the added health interventions. The other 14 will continue their regular activities.

5.1 Sampling

In each of the 28 clusters, 70 households will be surveyed 5 times over 2 years. The study begins with a baseline study, followed by six-monthly surveys that will track health-seeking behaviour, i.e. illness in the household over one month, treatment and costs for each illness, and hospitalization over the past 6 months.

Basic Assumptions (Set I)

a. Number of clusters = 28
b. Significance level of tests = 0.05 and 0.10
c. Minimum Effect sizes: 0.20 and 0.25

Number of Clusters

The number of clusters is 28, which refers to the number of SEWA health workers. The intervention will be at the level of CHWs, that is, it will be directed towards all SEWA members, insured and uninsured, who live her ‘area of activity.’ In the urban areas, this refers to a collection of ‘chalis’ (a locality/set of streets) and in the rural areas, this usually refers to a set of villages, on average about five (5) per CHW.

Minimum Effect Size

We will work with a minimum effect size (ME) of around 10-20% of ***all* claims** made for hospitalizations under the SEWA insurance plan. The main point is that an effect size of less than 10-20 percent (or about 25-50 percent of the “unnecessary” hospitalizations as perceived by SEWA) is probably is not cost-effective. The unnecessary hospitalizations relate to diarrhea and malaria that are either treatable at home, or hysterectomies in younger age groups that are actually unneeded and probably supplier driven.

Basic Assumptions (Set II)

To get at the appropriate sample sizes, we need to clarify a number of issues. The first set of issues has to do with assignment of SEVIKAs into treatment and control groups. One way to do this is to undertake a simple random assignment into treatment and control CHWs. The main problem with such an approach is that it is possible that in any single random draw, the assignment may result, purely by chance, in very ‘unbalanced’ (or unequal) baseline values of key explanatory variables among treatment and control CHWs. This is so even if, in an *expectation* sense, random assignment leads to balanced values of the variables in question

There are several ways to address the concern of the previous paragraph. The first is to use what are referred to as “re-randomization” strategies – that is, to redo the random assignment if the initial assignment results in unbalanced baseline values. Bruhn and McKenzie (2008) argue against this approach because it is likely to lead to substantial losses in degrees of freedom in the estimation of the treatment effect. This approach is not suitable for our work given the small number of CHWs. Another is to adopt a ‘blocking strategy’ – that is, to stratify CHWs into groups and randomize *within* groups. An extreme version of this approach is ‘pair-wise’ matching where we randomize among SEVIKA-pairs matched according to a number of pre-set criteria.

We adopt a strategy whereby we undertake randomization separately in two main blocks, rural and urban. The main reason for doing so is simplicity and also because the rural-urban differential explains about 30% of the variation in claim-rate use. We decided against pair-wise matching simply because the marginal gains of adopting that strategy were unclear.

Because the intervention is being undertaken at the cluster level, we could think of the statistical model we are working with as a hierarchical set up where the individual outcome Y_{ij} (for individual 'i' located in cluster 'j') is a function of a cluster-level parameter (mean) β_j and an individual-level random error term e_{ij}, distributed independently and identically as $(0, \sigma^2)$.

(1) $$Y_{ij} = \beta_j + e_{ij}$$

Moreover, the cluster-level mean is distributed as

(2) $$\beta_j = \beta_0 + \beta_1 T_j + \beta_2 R_j + v_j$$

Here, T_j is the value of dummy variable that takes the value 1 if the SEVIKA is assigned to treatment and 0, otherwise; and R_j is the dummy for rural location (0 if urban). It is easy enough to include interaction terms in this specification. The term v_j is a cluster-level error term, independently distributed across clusters as $(0, \tau)$.

In our first set of basic assumptions, we have outlined the minimum treatment effect we wish to identify and our level of significance. Does this mean that there is no other way we can increase the 'power' of a test? Actually there is – via increasing sample size. Increasing sample sizes collapses sampling distributions for 'consistent' statistics around their mean. Thus, for a *sufficiently large sample* we can always make sure that the power is very high, for any given minimum treatment effect. Usually, sample sizes of 200-300 can achieve this state of affairs.

Unfortunately, we cannot increase sample sizes without limit in our study. ***Because the intervention is at the level of the CHW***, there are ***at most*** **28** cluster-level observations that we can have. This raises the question whether increasing the number of observations (households) within clusters (CHW areas) can help expand the power of the tests that we propose to estimate the effect of the intervention. In general, this is not guaranteed. The answer depends on whether the variation in observed outcomes is primarily the result of individual-level variation σ^2, or cluster-level variation τ. For instance, if there is no cluster level variation (that is, $\tau = 0$), any difference in outcomes in treatment and control clusters would be the result of individual outcomes (plus random shocks). Increasing cluster-level sample sizes would collapse the resulting sampling distributions and increase the power of the test. On the other hand, if individual level variation were relatively small compared to variation at the cluster level, we would not be able to do so and would need to increase the number of clusters.

The key parameter for this purpose, *intra-class correlation parameter* ρ , where

(3) $$\rho = \frac{\tau}{\tau + \sigma^2}$$

Thus, the greater ρ is, the ***lower*** the possibility of enhancing power by increasing the number of households sampled per cluster (for a given minimum treatment effect and level of significance) (Spybrook et al. 2008).

Power Calculations

For the purpose of this exercise, in addition to information on 'minimum effect size', the number of clusters and the size of the test of significance, we also need to know (a) the magnitude of ρ and (b) the proportion of variation in health care utilization and claim rates that could be explained by location in rural and urban areas. Moreover, we need to know ρ not only for SEWA claim rates but potentially for other variables that we are interested in – outpatient care use, overall hospitalizations and so forth.

Estimating the intra-class correlation ρ

There are three ways to calculate the intra-class correlation parameterρ. The ***first*** method is to rely on data on SEWA claim rates. The main advantage here is that data are available for each SEVIKA area. The main disadvantage is that are data are available only for hospitalization claim rates, and do not include any hospitalizations for which claims were not submitted to SEWA (this includes all uninsured by SEWA as well) and any outpatient visits. The ***second*** method is to rely on National Sample Survey (NSS) household survey data (for 2004) for rural and urban areas by district in Gujarat. The main advantage is that now the data are available both for outpatient and for inpatient care for the sample of individuals, separately for rural and urban areas. The main disadvantage is that NSS data are not representative of the population at the district level, and are certainly not reflective of the distribution across SEVIKAs in Ahmedabad district, the area of the planned study. While the NSS data contain no information about household insurance status, it is safe to presume that they reflect on average the situation in uninsured households, given the vast majority are uninsured. The ***third method*** is to revisit the whole issue of household sample size after undertaking a baseline survey to collect information on outpatient and inpatient care, separately by insurance status and for rural and urban SEVIKA areas. The main drawback is that reliance on the baseline to devise sample sizes for each cluster is limited by the sample size for the baseline itself. On the other hand, it can help in deciding upon the type of stratification adopted for this study (and in principle for future sample sizes).

We adopted a mix of approaches. First, we used the hospital claims rate data for different SEVIKA areas (clusters) to arrive at our estimates of population means for each of the clusters for the SEWA insured. This helped us to obtain a sample-based estimate for the cluster-level variance, namely τ for hospitalization among the SEWA insured. On a per-insured person basis, we had an inter-cluster mean (weighted by the number of claims) claim rate of 0.071 and a 'weighted' inter-cluster variance of 0.00126. We took the latter number to be our estimate of τ used for power calculations.

Next, we estimated the variance in claims at the level of the cluster. Because, the number of hospitalizations per person in any given year tends not to exceed 1, we proceeded by assuming that the likelihood of hospitalization for any one insured person (per year) is given by a Bernoulli distribution, with a probability "p" of incurring a claim, and a probability "1-p" of not incurring a claim. Then defining the estimated claims rate for any cluster as its *observed* value of 'p', we infer the variance of a single observation to be simply $p(1-p)$. We take the weighted mean of the variance across clusters to be our estimate of σ^2 - 0.06427. Combining the estimates of τ and σ^2 yielded an estimate of *intra-class correlation parameter* ρ of roughly 0.02 (at least for the claims rate variable for the SEWA insured.) We sought to obtain an estimate of ρ for hospitalization in Gujarat as a whole, using district-level rural and urban data on hospitalization rates from NSS data. This yielded a mean hospitalization rate of 0.0303 and a weighted variance of 0.00021 (the estimate of τ). Similarly, we obtained an estimate of σ^2 of 0.01350. Thus, using NSS data, we obtained an *intra-class* correlation parameter ρ of 0.0154 (or roughly 0.02).

Finally, we estimated the *intra-class* correlation parameter ρ for outpatient visits in a period of 30 days preceding the survey. The district-level average (separately for urban and rural areas) number of outpatient visits was *approximately* 0.1437 in the month preceding the survey; and the variance (our measure of inter-cluster variation τ) was 0.00386. Because the Bernoulli distribution is no longer useful for describing outpatient visits (there can be multiple visits during a reference period), we adopted a slightly different procedure for capturing the number of visits per person – by assuming a Poisson distribution. Because the mean and variance of a Poisson random variable are the same, we took the variance to be the (unweighted) mean across rural and urban areas in the various districts of Gujarat, yielding an estimate of σ^2 of 0.07186. This yields an *intra-class* correlation parameter ρ of 0.051. We worked with intra-class correlation parameters of between 0.02 and 0.05.

Assessing the benefits from Stratification: Rural and Urban

The main benefit from stratification occurs in the form of a better balancing of important covariates that likely explain outcomes. Stratification by specific variables, however, is useful only if those specific variables explain a non-negligible level of variation in outcomes.

The natural covariate for stratification is the rural-urban characteristic of a cluster. Using NSS data we found that rural-urban differences explained only 1% - 5 % of the variation in outpatient visits and inpatient stays across districts. However, rural-urban differences explained 30% of the inter-SEVIKA claim-rate variation. We went by the SEVIKA claims rate data for justifying stratification both because the data refer to the clusters that we plan to intervene in, and also because the NSS district-level samples are small. Thus, **we will randomize among Sevikas in rural and urban areas *separately***.

Power Calculations and Sample Sizes per Cluster

Table 1 below shows for the given number of clusters (28), one values of the intra-class correlation parameter (0.02) and the proportion of variation in cluster outcomes explained by rural-urban stratification (0.30), the **statistical power** attained by our research design for different cluster sizes (number of households) for (a) minimum effect size of 25% and levels of significance of 5% and 10%, respectively (b) minimum effect size of 50% and levels of significance of 5% and 10%, respectively. In the calculations, we assume throughout that the number of insured individuals per household is about 2 (two).

Table 1: Minimum effect size 25%; levels of significance (5% and 10%), $R^2 = 0.30$

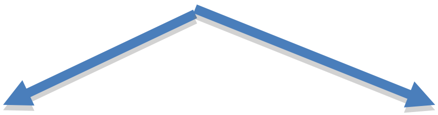
Number of households	α = 5 percent		α = 10 percent	
	Power (ME = 25%)	Power (ME = 40%)	Power (ME = 25%)	Power (ME = 40%)
15	0.22	0.47	0.33	0.61
20	0.25	0.55	0.37	0.68
25	0.28	0.60	0.41	0.73
30	0.31	0.65	0.44	0.77
35	0.33	0.68	0.46	0.79
40	0.35	0.71	0.48	0.82
45	0.37	0.73	0.49	0.84
50	0.38	0.75	0.51	0.85

Note: A minimum effect size of 25% refers to 25% of the 40% of hospitalizations that are deemed “unnecessary” or about 10% of all hospitalizations. Similarly, 40% refers to 40% of 40%, namely 16% of all hospitalizations.

The calculations in Table 1 show that under the parameters that we have, it would be difficult to achieve reasonable power to detect a minimum effect size of 10% of all hospitalizations (or 25% of all ‘unnecessary’ hospitalizations). **On the other hand, if we relaxed our requirement to an effect size of 16% of all hospitalizations, then we can achieve reasonable power with insured households of between 35 and 40 for the 28 clusters, with either of the levels of significance.** Our guess that is controlling for additional covariates may increase power further (including introducing a cross-term with the treatment indicator and the rural dummy).

These results are for an intra-class correlation parameter value of 0.02. If the intra-class correlation parameter were to take a value of 0.05, we would achieve a power of 60 percent with a sample of 35 insured households, even with a level of significance of 10% and an effect size of 40 percent of ‘unnecessary’ hospitalizations. Thus we arrive at a sample size of 35 insured and 35 uninsured households per cluster.

28 CHWs



14 intervention

70 HH per sevika surveyed

(35 insured, 35 uninsured)

14 control

70 HH per sevika surveyed

(35 insured, 35 uninsured)

70 HH per * 28 sevika = 1960 households surveyed

Breakdown of households that will be surveyed:

	Insured	Uninsured
Intervention (14 sevika)	490 HH	490 HH
Control (14 sevika)	490 HH	490 HH

5.2 Randomisation and Allocation

Treatment Allocation: Allocation of treatment groups will be conducted separately for urban and rural areas, through a computer generated numbering system by Ajay Mahal, off-site. Fourteen CHWs – 6 urban and 8 rural – will be allocated to the treatment group. The selected numbers will be matched to CHW names in the presence of the entire CHW team and in the presence of the local health team managers.

Household selection : Households with health insurance will be randomly selected from VimoSEWA's membership database through computer-generated numbering within each cluster. An equal number of households from the uninsured population will be selected in the same cluster in a two-step process. First, the research team will list all uninsured households in a cluster by following a community health worker on her rounds, so that no household was excluded, particularly as many slum settlements are not listed in government rosters. Next, 35 households will be randomly selected through a computer-generated numbering process for each cluster. In total, 1,960 households in 28 clusters will be sampled.

6. Evaluation

Five rounds of household surveys will be evaluated for effects on insured women, uninsured and a comparison of the two groups. Qualitative analysis of the intervention process and women's health seeking behaviour will be conducted, with methodology determined after the baseline findings are available. Cost-effectiveness of the intervention will be assessed through analysis of claim ratios as well as overall health benefits measured by hospitalisation and average out-of-pocket expenditure.

7. Data collection

Data will be collected by SEWA Academy's research team and entered into a Microsoft Access database by dedicated data operators. Field surveyors will be monitored by SEWA Academy supervisors. All forms will be checked on-site, and then reviewed after entry independently by supervisors. Inconsistencies will be raised with the PI.

8. Replicability

Results from this project will inform VimoSEWA's approach in all of its program areas in Gujarat and six other states of India. SEWA's national federation, SEWA Bharat, already implements health programs in Bihar, Rajasthan, Delhi and West Bengal – and thus are natural sites for replication of this converged approach. In India, the National Health Insurance Scheme, Rashtriya Swasthya Bima Yojna (RSBY), is being rolled out for families below the poverty line. In some states, government community health workers are the focal point for promotion and claim servicing. Thus if these results indicate the specific community health activities that impact on health seeking behaviour and claim ratios, there is clear potential for national replication. Further, findings will have far-reaching effects on the implementation of health insurance amongst the poor at a global level. A high incidence of primary illness likely impedes the viability of health insurance, regardless of region.

Based on VimoSEWA's experience, governments, insurance companies and implementing agencies can integrate community health with health insurance. Where VimoSEWA works directly, replication will be achieved through program implementation. At the national level, VimoSEWA can serve as a technical advisor to RSBY implementation teams, including insurance companies, on how to integrate health education into health insurance services. We can also share lessons learned through our partners in Indian microfinance networks such as CLASS and Sadhan. Globally, VimoSEWA will share findings and technical expertise through our partnerships in organisations such as ICMIF, HomeNet and WIEGO.

9. Innovation

Providing community health services with health insurance, as a means to prevent unnecessary hospitalization, is an innovation that has not been systematically implemented in any microinsurance programs in India or most of the developing world. Thus our innovation has the potential to transform the delivery of health insurance services. Moreover, there is virtually no data on the “health” component of health insurance, i.e. the illness pattern of health insurance claims by the poor. This project will create the foundation for an evidence base on why and how health services can be integrated with health insurance.

Secondly, this project can serve as a model for how a microinsurance program can partner with the public health system and government schemes, such as the National Rural Health Mission (NRHM) and RSBY in India. Since our approach is based on a local grassroots woman worker – akin to the village-based community health worker (ASHA) of the NRHM – who provides both health and insurance services, this innovation can be a model for an integrated, government-led scale up of health and insurance. The action research component is an innovation in of itself. Literature reviews indicate that virtually no research has been conducted on the impact of health services on health insurance in a community-based setting. Given that health insurance is increasingly promoted as a key intervention for poverty alleviation, research and evidence are critical. Further, an experiment of this kind can catalyse similar efforts to create a solid evidence base.

10. Lessons

This project will create both an implementation model and evidence base for integrating health activities with health insurance. We will learn if health education and referrals truly can reduce avoidable hospitalization, which in turn will reduce claim ratios and improve viability of health insurance. This initiative will provide specific evidence on what components, and how, health activities are effective – thus it will contribute to the “implementation science” of health insurance. We will also learn the cost-benefit of health with health insurance, i.e. how much an investment in health can reduce both claims and illness expenditure. Through qualitative research, this project will also provide insight into health seeking behaviour, on why people choose specific care at a point in time. For example, we will learn for whom, and for what illness insurance is used, and importantly, why. Overall, this project will allow us to determine 1) if health programs do have an impact on reducing claims for primary illness; 2) how this approach can be implemented in a viable model; and 3) the direct, insurance-related cost benefit of investing in health.

11. Potential Benefits

Potential benefits will include: 1) 1,960 women and their family members will have obtained health services that can reduce illness expenditure. 2) Decrease in claim ratio by 19% points in Ahmedabad city and 14% points in Ahmedabad district. 3) Decrease in cost to customer (reduction in work days lost and expenditure on illness) by 4% points, based on total cost to patient. 4) Decrease in hospitalization for preventable primary illness. We anticipate a 30% reduction in hospitalization for leading illnesses. As this is a new approach, we will closely monitor claims to estimate the quantitative impact of the interventions. 5) Decrease in cost of health care due to referral linkages, cashless linkages, increase in utilization of public hospitals and preventive health information. 6) Decrease in selling of assets or borrowing for illness. 7) Increase in women seeking health care services. Being the policyholders, women will be encouraged to seek health care, including preventive health information, to promote a higher priority for their health.

12. Risks

Health insurance itself may be an incentive for hospitalization, as care can be purchased at a lower cost. Thus despite health education and referrals, there is a possibility that hospitalization rates will not decrease significantly. Mitigating factors include: 1) Out of pocket expenditure may still decrease due to VimoSEWA's focus on linkages with government and trust hospitals 2) A focus on disease prevention, early identification, and outpatient services, so that hospitalization is not required.

Further, implementing the intervention study without spillover effects will be a risk for action research results. We will ensure that control and intervention wards in Ahmedabad city, and villages in Ahmedabad district, are far enough from each other to avoid spillover. For this reason, we have chosen to employ a grassroots research team, rather than have local insurance promoters implement the simple survey, to avoid bias.

Annex 7 Information sheet (Qualitative research)

1. Information and consent forms (Used in Gujarati)

Information sheet and consent form for women who have undergone hysterectomy (n=30)

Hello. My name is Sapna Desai. I have worked here with SEWA for several years. VimoSEWA has found that hysterectomy is common in Ahmedabad and this research aims to understand women's experiences and the reasons why they undergo the operation.

I hope to speak with around 30 women in this area and I have come to speak to you because 1) you submitted a claim to VimoSEWA for a hysterectomy *OR* (2) ______ (SEWA community health worker) suggested I speak with you.

If you agree to take part, I would like to spend about 45 minutes to one hour discussing your experience and opinions. During the interview some written notes will be taken, and with your permission, the session will be tape-recorded. Taking part in the research is entirely voluntary and you can stop the interview without having to give a reason.

Anything we discuss will be confidential, and I will not use your name to identify anything you share. After I speak to women and local providers, I will write up the overall findings in Gujarati and English. A SEWA health worker and I will come back to share what we have learned.

Do you have any questions you would like to ask me about this research? Would you be willing to speak with me about your experience? If yes, could you sign here to indicate that you agree to this conversation and for me to write up the findings? May I tape record our conversation? Or would you prefer I take notes?

Consent by participant

1. "I have read the information sheet concerning this study and I understand what will be required of me and what will happen if I participate in this interview."

2. "My questions concerning this study have been answered by Sapna Desai."

3. “I understand that at any time I may withdraw from this study without giving a reason.”

4. “I do/do not agree to the interview being recorded.” (please delete as appropriate)

5. “I agree to take part in this study.”

6. “I do/do not agree to be quoted anonymously in any publications arising from this study” (please delete as appropriate)

Name of participant ………………………………..………………………

Signed ………………………………………… Date …...

Information sheet and consent form for women who have not undergone hysterectomy (n=10)

Hello. My name is Sapna Desai. I have worked here with SEWA for several years. VimoSEWA has found that hysterectomy is common in Ahmedabad and this research aims to understand women's experiences and the reasons why they undergo the operation. I have already spoken to 30 women in this area who have undergone a hysterectomy.

I hope to speak with around 10 women in this area who have not had the operation to understand my findings further. ______ (SEWA community health worker) *OR* __________ suggested I speak with you.

If you agree to take part, I would like to spend about 45 minutes to one hour finding out about your experience and opinions. During the interview some written notes will be taken, and with your permission, the session will be tape-recorded. Taking part in the research is entirely voluntary and you can stop the interview without having to give a reason.

Anything we discuss will be confidential, and I will not use your name to identify anything you share. After I speak to women and local providers, I will write up the overall findings in Gujarati and English. A SEWA health worker and I will come back to share what we have learned.

Do you have any questions you would like to ask me about this research? Would you be willing to speak with me about your experience? If yes, could you sign here to indicate that you agree to this conversation and for me to write up the findings? May I tape record our conversation? Or would you prefer I take notes?

Consent by participant

1. "I have read the information sheet concerning this study and I understand what will be required of me and what will happen if I participate in this interview."

2. "My questions concerning this study have been answered by Sapna Desai."

3. "I understand that at any time I may withdraw from this study without giving a reason."

4. "I do/do not agree to the interview being recorded." (please delete as appropriate)

5. “I agree to take part in this study.”

6. “I do/do not agree to be quoted anonymously in any publications arising from this study” (please delete as appropriate)

Name of participant ……………………………………..………………………

Signed ….. Date …..

Information sheet and consent form for health care providers (n=5)

Hello. My name is Sapna Desai. I have worked here with SEWA for several years and am also pursuing a PhD at the London School of Hygiene and Tropical Medicine. We are conducting a trial to test the effectiveness of health education with women, in particular if it changes the way they seek care.

VimoSEWA has found that hysterectomy is common in Ahmedabad and this research aims to understand women's experiences and the reasons why they undergo the operation. I am also speaking to 30 women in this area who have undergone a hysterectomy and 10 who have not.

If you agree to take part, I would like to spend about 30 minutes to ask you about your experience and opinions. During the interview some written notes will be taken, and with your permission, the session will be tape-recorded. Taking part in the research is entirely voluntary and you can stop the interview without having to give a reason.

Anything we discuss will be confidential, and I will not use your name to identify anything you share. After I speak to women and local providers, I will write up the overall findings in Gujarati and English. I will come back to share what we have learned.

Do you have any questions you would like to ask me about this research? Would you be willing to speak with me about your experience? If yes, could you sign here to indicate that you agree to this conversation and for me to write up the findings? May I tape record our conversation? Or would you prefer I take notes? May I quote you anonymously in any publications that arise from this study?

Consent by participant

1. "I have read the information sheet concerning this study and I understand what will be required of me and what will happen if I participate in this interview."

2. "My questions concerning this study have been answered by Sapna Desai."

3. "I understand that at any time I may withdraw from this study without giving a reason."

4. "I do/do not agree to the interview being recorded." (please delete as appropriate)

5. “I agree to take part in this study.”

6. “I do/do not agree to be quoted anonymously in any publications arising from this study”
(please delete as appropriate)

Name of participant ………………………………………..……………………….

Signed …….. Date …..

Information sheet and consent form for women who participated in SEWA education sessions (n=10)

Hello. My name is Sapna Desai. I have worked here with SEWA for several years. We met at the health education session on ______ conducted by _______ in your village *OR* ____ suggested I speak with you.

VimoSEWA has found that hysterectomy is common in Ahmedabad and this research aims to understand more about women's opinions on hysterectomy and SEWA's education sessions on the topic. I hope to speak with around 10 women in this area who have participated in the sessions.

If you agree to take part, I would like to spend about 45 minutes to an hour to discuss your experience and opinions. During the interview some written notes will be taken, and with your permission, the session will be tape-recorded. Taking part in the research is entirely voluntary and you can stop the interview without having to give a reason.

Anything we discuss will be confidential, and I will not use your name to identify anything you share. I will write up the overall findings in Gujarati and English. I will share them with you, and SEWA will also use your thoughts to improve their education sessions.

Do you have any questions you would like to ask me about this research? Would you be willing to speak with me about your experience? If yes, could you sign here to indicate that you agree to this conversation and for me to write up the findings? May I tape record our conversation? Or would you prefer I take notes?

Consent by participant

1. "I have read the information sheet concerning this study and I understand what will be required of me and what will happen if I participate in this interview."

2. "My questions concerning this study have been answered by Sapna Desai."

3. "I understand that at any time I may withdraw from this study without giving a reason."

4. "I do/do not agree to the interview being recorded." (please delete as appropriate)

5. “I agree to take part in this study.”

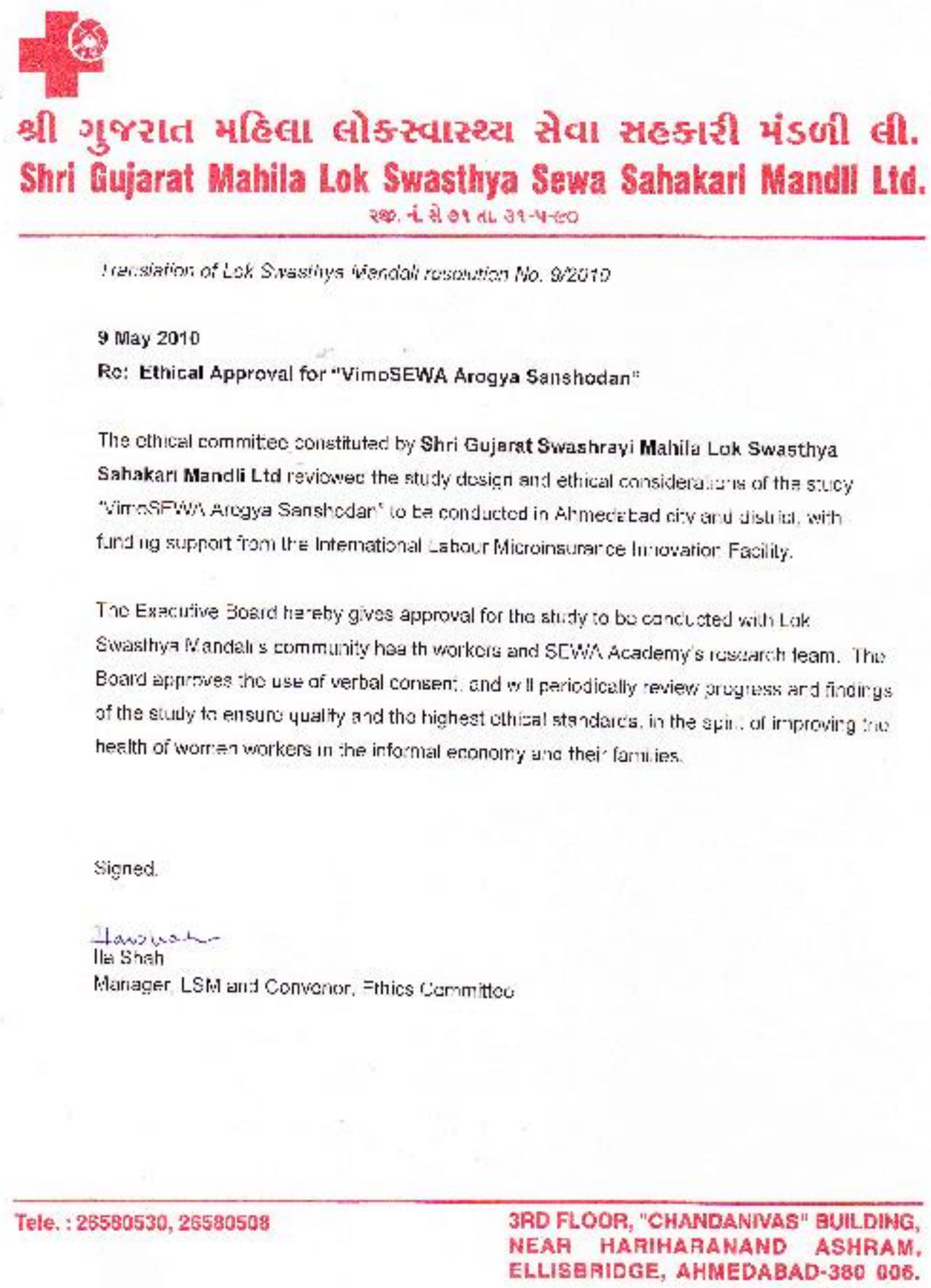
6. “I do/do not agree to be quoted anonymously in any publications arising from this study” (please delete as appropriate)

Name of participant ……………………………………..………………………

Signed ………………………………………… Date ….………………………………………

Annex 8 Ethical Approvals

Ethical approvals from SEWA Health Cooperative and London School of Hygiene and Tropical Medicine are attached.



શ્રી ગુજરાત મહિલા લોકસ્વાસ્થ્ય સેવા સહકારી મંડળી લી.
Shri Gujarat Mahila Lok Swasthya Sewa Sahakari Mandli Ltd.
રજી. નં. સે ૭૧ તા. ૩૧-૫-૯૦

Translation of Lok Swasthya Mandali resolution No. 9/2010

9 May 2010

Re: **Ethical Approval for "VimoSEWA Arogya Sanshodan"**

The ethical committee constituted by **Shri Gujarat Swashrayi Mahila Lok Swasthya Sahakari Mandli Ltd** reviewed the study design and ethical considerations of the study "VimoSEWA Arogya Sanshodan" to be conducted in Ahmedabad city and district, with funding support from the International Labour Microinsurance Innovation Facility.

The Executive Board hereby gives approval for the study to be conducted with Lok Swasthya Mandali's community health workers and SEWA Academy's research team. The Board approves the use of verbal consent, and will periodically review progress and findings of the study to ensure quality and the highest ethical standards, in the spirit of improving the health of women workers in the informal economy and their families.

Signed,

Ila Shah
Manager, LSM and Convenor, Ethics Committee

Tele. : 26580530, 26580508

3RD FLOOR, "CHANDANIVAS" BUILDING,
NEAR HARIHARANAND ASHRAM,
ELLISBRIDGE, AHMEDABAD-380 006.

LONDON SCHOOL OF HYGIENE
& TROPICAL MEDICINE

ETHICS COMMITTEE

APPROVAL FORM
Application number: **A273 5974**

Name of Principal Investigator **Sapna Desai**

Faculty **Epidemiology and Population Health**

Head of Faculty **Professor Laura Rodrigues**

Title: **The evaluation of a health education intervention on women's health, insurance utilisation and health-seeking in Gujarat, India**

Amendments to this application have been approved by the Ethics Committee.

Chair of the Committee

Date ....18 August 2011..

Approval is dependent on local ethical approval having been received.

Any subsequent changes to the application must be re-submitted to the Committee.

Annex 9 Baseline claims rates in 28 clusters

Table 1a Baseline claims, intervention clusters

Intervention clusters (14)									
Cluster	**All claims**	**Claims - 3 conditions**	**Feve**	**Diarrhoeal**	**Hysterectomy**	**% of claims, 3 conditions**	**p-years**	**All claims rate**	**3 conditions claims rate**
Urban									
1	19	7	5	1	1	36.8	128.7	14.8	5.4
2	14	4	0	1	3	28.6	123.8	11.3	3.2
3	13	3	1	1	1	23.1	114.0	11.4	2.6
4	1	4	1	3	0	400.0	77.2	1.3	5.2
5	55	25	9	6	10	45.5	261.0	21.1	9.6
6	6	2	0	0	2	33.3	65.2	9.2	3.1
Total	*108*	*45*	*16*	*12*	*17*	*41.7*	*769.8*	*14.0*	*5.8*
Rural									
7	24	10	8	2	0	41.7	136.0	17.6	7.4
8	6	4	1	2	1	66.7	66.0	9.1	6.1
9	9	5	0	2	3	55.6	73.3	12.3	6.8
10	5	3	1	0	2	60.0	45.5	11.0	6.6
11	14	7	2	2	3	50.0	203.2	6.9	3.4
12	7	2	1	1	0	28.6	70.5	9.9	2.8
13	9	3	1	0	2	33.3	23.8	37.9	12.6
14	4	3	0	2	1	75.0	51.1	7.8	5.9
Total	*78*	*37*	*14*	*11*	*12*	*47.4*	*669.3*	*11.7*	*5.5*
Overall	**186**	**82**	**30**	**23**	**29**	**44.1**	**1439.2**	**12.9**	***5.7***

Table 1b Baseline claims, control clusters

Control clusters (14)									
Cluster	**All claims**	**Claims - 3 conditions**	**Fever/ Malaria**	**Diarrhoeal**	**Hysterectomy**	**% of claims, 3 conditions**	**p-years**	**All claims rate**	**3 conditions claims rate**
Urban									
15	5	2	0	2	0	40.0	47.5	10.5	4.2
16	12	4	0	2	2	33.3	74.7	16.1	5.4
17	13	8	1	5	2	61.5	109.2	11.9	7.3
18	7	1	0	1	0	14.3	50.4	13.9	2.0
19	24	5	0	1	4	20.8	101.4	23.7	4.9
20	42	6	1	1	4	14.3	302.6	13.9	2.0
Total	*103*	*26*	*2*	*12*	*12*	*25.2*	*685.8*	*15.0*	*3.8*
Rural									
21	1	0	0	0	0	0.0	35.6	2.8	0.0
22	21	7	1	4	2	33.3	79.2	26.5	8.8
23	21	11	3	4	4	52.4	97.9	21.4	11.2
24	7	3	0	3	0	42.9	47.1	14.9	6.4
25	4	2	0	0	2	50.0	54.5	7.3	3.7
26	20	11	3	2	6	55.0	142.8	14.0	7.7
27	4	0	0	0	0	0.0	23.6	17.0	0.0
28	8	3	0	0	3	37.5	88.5	9.0	3.4
Total	*86*	*37*	*7*	*13*	*17*	*43.0*	*569.2*	*15.1*	*6.5*
Overall	**189**	**63**	**9**	**25**	**29**	**33.3**	**1254.95**	**15.1**	***5.0***

Annex 10 Baseline hospitalisation rates in 28 clusters

Table 1a Baseline hospitalisation amongst uninsured women, intervention clusters

Intervention clusters, uninsured women c_{1}=14									
Cluster	**All hosp**	**3 conditions**	**Fever/Malaria**	**Diarrhoeal**	**Hysterectomy**	**% of hosp, 3 conditions**	**p-years**	**All hosp rate**	**3 condition hosp rate**
Urban									
1	1	1	0	1	0	100.0	17.5	5.7	5.7
2	2	1	1	0	0	50.0	17.5	11.4	5.7
3	1	0	0	0	0	0.0	17.5	5.7	0.0
4	1	1	0	1	0	100.0	17.5	5.7	5.7
5	1	0	0	0	0	0.0	17.5	5.7	0.0
6	2	0	0	0	1	0.0	17.5	11.4	0.0
Total	*8*	*3*	*1*	*2*	*1*	*37.5*	*105.0*	*7.6*	*2.9*
Rural									
7	1	0	0	0	0	0.0	17.5	5.7	0.0
8	1	1	1	0	0	100.0	17.5	5.7	5.7
9	1	1	0	1	0	100.0	17.5	5.7	5.7
10	1	0	0	0	0	0.0	17.5	5.7	0.0
11	0	0	0	0	0	0.0	17.5	0.0	0.0
12	0	0	0	0	0	0.0	17.5	0.0	0.0
13	2	1	0	0	1	50.0	17.5	11.4	5.7
14	1	1	0	0	1	100.0	17.5	5.7	5.7
Total	*7*	*4*	*1*	*1*	*2*	*57.1*	*140.0*	*5.0*	*2.9*
Overall	**15**	**7**	**2**	**3**	**3**	**46.7**	**245.0**	**6.1**	**2.9**

Table 1b Baseline hospitalisation amongst uninsured women, control clusters

Control clusters, uninsured $c_{0=}14$									
Cluster	**All hosp**	**3 conditions**	**Fever/Malaria**	**Diarrhoeal**	**Hysterectomy**	**% of hosp, 3 conditions**	**p-years**	**All hosp rate**	**3 condition hosp rate**
Urban									
15	1	1	0	0	1	100.0	17.5	5.7	5.7
16	0	0	0	0	0	0.0	17.5	0.0	0.0
17	1	0	0	0	0	0.0	17.5	5.7	0.0
18	1	0	0	0	0	0.0	17.5	5.7	0.0
19	0	0	0	0	0	0.0	17.5	0.0	0.0
20	0	0	0	0	0	0.0	17.5	0.0	0.0
Total	*3*	*1*	*0*	*0*	*1*	*33.3*	*105.0*	*2.9*	*1.0*
Rural									
21	2	2	0	0	2	100.0	17.5	11.4	11.4
22	1	1	0	0	1	100.0	17.5	5.7	5.7
23	0	0	0	0		0.0	17.5	0.0	0.0
24	2	2	0	0	2	100.0	17.5	11.4	11.4
25	2	1	0	0	1	50.0	17.5	11.4	5.7
26	3	1	0	0	1	33.3	17.5	17.1	5.7
27	0	0	0	0	0	0.0	17.5	0.0	0.0
28	1	0	0	0	0	0.0	17.5	5.7	0.0
Total	*11*	*7*	*0*	*0*	*7*	*63.6*	*140.0*	*7.9*	*5.0*
Overall	**14**	**8**	**0**	**0**	**8**	**57.1**	**245.0**	**5.7**	**3.3**

Table 2a Baseline hospitalisation amongst insured women, intervention clusters

Intervention clusters, insured $c_{1=}14$									
Cluster	**All hosp**	**3 conditions**	**Fever/Malaria**	**Diarrhoeal**	**Hysterectomy**	**% of hosp, 3 conditions**	**p-years**	**All hosp rate**	**3 condition hosp rate**
Urban									
1	2	1	0	0	1	50.0	17.0	11.8	5.9
2	0	0	0	0	0	0.0	17.5	0.0	0.0
3	4	1	1	0	0	25.0	16.5	24.2	6.1
4	0	0	0	0	0	0.0	17.0	0.0	0.0
5	4	2	0	1	1	50.0	17.5	22.9	11.4
6	1	0	0	0	0	0.0	17.5	5.7	0.0
Total	*11*	*4*	*1*	*1*	*2*	*36.4*	*103.0*	*10.7*	*3.9*
Rural									
7	1	0	0	0	0	0.0	17.5	5.7	0.0
8	9	6	1	2	3	66.7	17.5	51.4	34.3
9	2	2	0	2	0	100.0	17.5	11.4	11.4
10	4	2	1	0	1	0.0	17.5	22.9	11.4
11	2	0	0	0	0	0.0	17.5	11.4	0.0
12	1	0	0	0	0	0.0	17.5	5.7	0.0
13	2	0	0	0	0	0.0	17.0	11.8	0.0
14	2	1	0	0	1	50.0	17.5	11.4	5.7
Total	*23*	*11*	*2*	*4*	*5*	*47.8*	*139.5*	*16.5*	*7.9*
Overall	**34**	**15**	**3**	**5**	**7**	**44.1**	**242.5**	**14.0**	**6.2**

Table 2b Baseline hospitalisation amongst insured women, control clusters

Control clusters, insured $c_{1=}$14									
Cluster	**All hosp**	**3 conditions**	**Fever/Malaria**	**Diarrhoeal**	**Hysterectomy**	**% of hosp, 3 conditions**	**p-years**	**All hosp rate**	**3 condition hosp rate**
Urban									
15	3	2	2	0	0	66.7	15.0	20.0	13.3
16	1	1	1	0	0	100.0	16.5	6.1	6.1
17	1	0	0	0	0	0.0	17.0	5.9	0.0
18	0	0	0	0	0	0.0	11.5	0.0	0.0
19	6	4	3	0	1	0.0	17.5	34.3	22.9
20	2	0	0	0	0	0.0	17.5	11.4	0.0
Total	*13*	*7*	*6*	*0*	*1*	*53.8*	*95.0*	*13.7*	*7.4*
Rural									
21	1	1	0	1	0	100.0	17.5	5.7	5.7
22	5	2	0	0	2	40.0	17.5	28.6	11.4
23	1	0	0	0	0	0.0	17.0	5.9	0.0
24	3	1	1	0	0	33.3	17.5	17.1	5.7
25	2	1	0	0	1	50.0	17.5	11.4	5.7
26	3	3	0	1	2	100.0	17.5	17.1	17.1
27	3	1	0	0	1	33.3	17.5	17.1	5.7
28	5	2	0	0	2	40.0	17.5	28.6	11.4
Total	*23*	*11*	*1*	*2*	*8*	*47.8*	*139.5*	*16.5*	*7.9*
Overall	**36**	**18**	**7**	**2**	**9**	**50.0**	**234.5**	**15.4**	**7.7**

Annex 11 Baseline morbidity rates in 28 clusters, by intervention and insurance status

Table 1a Baseline morbidity amongst uninsured women, intervention clusters

Intervention clusters, uninsured($c_{1=}$14)									
Cluster	**All morbidity episodes**	**3 conditions**	**Fever/Malaria**	**Diarrhoeal**	**Gynaec**	**% of morbidity, 3 conditions**	**p-months**	**Overall morbidity rate**	**3 condition morbidity rate (/100 p-months)**
Urban									
1	6	3	2	0	1	50.0	35.0	17.1	8.6
2	3	3	3	0	0	100.0	35.0	8.6	8.6
3	11	4	3	1	0	36.4	35.0	31.4	11.4
4	6	3	3	0	0	50.0	35.0	17.1	8.6
5	5	1	1	0	0	20.0	35.0	14.3	2.9
6	8	1	1	0	0	12.5	34.0	23.5	2.9
Total	*39*	*15*	*13*	*1*	*1*	*38.5*	*209.0*	*18.7*	*7.2*
Rural									
7	7	3	2	1	0	42.9	35.0	20.0	8.6
8	5	1	1	0	0	20.0	35.0	14.3	2.9
9	1	0	0	0	0	0.0	35.0	2.9	0.0
10	3	1	1	0	0	33.3	35.0	8.6	2.9
11	5	2	2	0	0	0.0	35.0	14.3	5.7
12	4	1	1	0	0	0.0	35.0	11.4	2.9
13	1	0	0	0	0	0.0	35.0	2.9	0.0
14	1	0	0	0	0	0.0	35.0	2.9	0.0
Total	*27*	*8*	*7*	*1*	*0*	*29.6*	*280.0*	*9.6*	*2.9*
Overall	**66**	**23**	**20**	**2**	**1**	**34.8**	**489.0**	**13.5**	**4.7**

Table 1b Baseline morbidity amongst uninsured women, control clusters

Control clusters, uninsured ($c_{0=}14$)									
Cluster	**All morbidity episodes**	**3 conditions**	**Fever/Malaria**	**Diarrhoeal**	**Gynaec**	**% of morbidity, 3 conditions**	**p-months**	**Overall morbidity rate**	**3 condition morbidity rate (/100 p-months)**
Urban									
15	5	3	2	0	1	60.0	35.0	14.3	8.6
16	10	7	5	2	0	70.0	35.0	28.6	20.0
17	6	1	1	0	0	16.7	35.0	17.1	2.9
18	8	3	1	2	0	37.5	35.0	22.9	8.6
19	3	1	0	1	0	33.3	35.0	8.6	2.9
20	2	2	1	0	1	100.0	35.0	5.7	5.7
Total	*34*	*17*	*10*	*5*	*2*	*50.0*	*210.0*	*16.2*	*8.1*
Rural									
21	1	1	1	0	0	100.0	35.0	2.9	2.9
22	3	2	2	0	0	66.7	35.0	8.6	5.7
23	6	3	2	0	1	50.0	35.0	17.1	8.6
24	3	2	2	0	0	66.7	35.0	8.6	5.7
25	2	2	2	0	0	100.0	35.0	5.7	5.7
26	3	2	2	0	0	66.7	35.0	8.6	5.7
27	2	2	2	0	0	100.0	35.0	5.7	5.7
28	5	2	0	1	1	40.0	35.0	14.3	5.7
Total	*25*	*16*	*13*	*1*	*2*	*64.0*	*280.0*	*8.9*	*5.7*
Overall	**59**	**33**	**23**	**6**	**4**	**55.9**	**490.0**	**12.0**	**6.7**

Table 2a Baseline morbidity amongst insured women, intervention clusters

Intervention clusters, insured ($c_{1=}14$)									
Cluster	**All morbidity episodes**	**3 conditions**	**Fever/Malaria**	**Diarrhoeal**	**Gynaec**	**% of morbidity, 3 conditions**	**p-months**	**Overall morbidity rate**	**3 condition morbidity rate (/100 p-months)**
Urban									
1	3	2	2	0	0	66.7	34.0	8.8	5.9
2	13	3	3	0	0	0.0	35.0	37.1	8.6
3	10	6	5	1	0	60.0	33.0	30.3	18.2
4	6	3	3	0	0	0.0	34.0	17.6	8.8
5	3	1	1	0	0	33.3	35.0	8.6	2.9
6	8	2	0	2	0	25.0	35.0	22.9	5.7
Total	*43*	*17*	*14*	*3*	*0*	*39.5*	*206.0*	*20.9*	*8.3*
Rural									
7	4	2	2	0	0	50.0	35.0	11.4	5.7
8	8	3	2	0	1	37.5	35.0	22.9	8.6
9	1	1	1	0	0	100.0	35.0	2.9	2.9
10	3	2	1	0	1	66.7	35.0	8.6	5.7
11	7	4	3	0	1	57.1	35.0	20.0	11.4
12	3	2	1	1	0	66.7	35.0	8.6	5.7
13	8	3	0	2	1	37.5	34.0	23.5	8.8
14	0	0	0	0	0	0.0	35.0	0.0	0.0
Total	*34*	*17*	*10*	*3*	*4*	*50.0*	*279.0*	*12.2*	*6.1*
Overall	**77**	**34**	**24**	**6**	**4**	**44.2**	**485.0**	**15.9**	**7.0**

Table 2b Baseline morbidity amongst insured women, control clusters

Control clusters, insured ($c_{0=}14$)									
Cluster	**All morbidity episodes**	**3 conditions**	**Fever/Malaria**	**Diarrhoeal**	**Gynaec**	**% of morbidity, 3 conditions**	**p-months**	**Overall morbidity rate**	**3 condition morbidity rate (/100 p-months)**
Urban									
15	4	2	2	0	0	50.0	30.0	13.3	6.7
16	4	4	3	0	0	100.0	33.0	12.1	12.1
17	8	2	0	1	1	25.0	34.0	23.5	5.9
18	9	4	4	0	0	44.4	23.0	39.1	17.4
19	9	0	0	0	0	0.0	35.0	25.7	0.0
20	10	8	7	1	0	80.0	35.0	28.6	22.9
Total	*44*	*20*	*16*	*2*	*1*	*45.5*	*190.0*	*23.2*	*10.5*
Rural									
21	1	1	1	0	0	100.0	35.0	2.9	2.9
22	6	3	3	0	0	50.0	35.0	17.1	8.6
23	6	3	1	2	0	50.0	34.0	17.6	8.8
24	7	2	2	0	0	28.6	35.0	20.0	5.7
25	5	1	1	0	0	20.0	35.0	14.3	2.9
26	7	1	0	0	1	14.3	35.0	20.0	2.9
27	8	4	4	0	0	50.0	35.0	22.9	11.4
28	6	3	2	1	0	50.0	35.0	17.1	8.6
Total	*46*	*18*	*14*	*3*	*1*	*39.1*	*279.0*	*16.5*	*6.5*
Overall	**90**	**38**	**30**	**5**	**2**	**42.2**	**469.0**	**19.2**	**8.1**

Annex 12 Causes of hospitalisation and morbidity

As referenced in Chapter VII, Table 7.7, p.148:

Table 1 Reported causes of hospitalisation in past six month (n=275)

Reason for hospitalisation	n
Blood pressure	11
Cancer	2
Cataract	11
Cardiovascular	18
Delivery	30
Diarrhoeal	30
Fever	23
Gynaecological	13
Hysterectomy	62
Injury	8
Pain	7
Respiratory	9
Kidney stone	9
Tuberculosis	2
Urinary	6
Other	20
Other surgery	14
Total	275

As referenced in Chapter VII, Table 7.11, p.153:

Table 2 Reported reasons for illness in past one month (n=880)

Illness category	**n**
Fever	320
Other*	146
Cold cough	85
Diarrhoea	74
Body pain	51
Blood Pressure	44
Stomach pain	30
Weakness	24
Injury	24
Gynaecological	16
Acidity	15
Eye problem	13
Stone	12
Respiratory	11
Cardiovascular	8
Diabetes	7
Total	880

*Other comprises all categories with less than 5 cases