Social Interventions for HIV/AIDS
Intervention with Micro-finance for AIDS and Gender Equity

IMAGE Study
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## The IMAGE Study

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<th>South African National Department of Health</th>
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<th>RADAR National Pilot Programme</th>
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<th>RADAR Administration</th>
<th>UCB SA PTY Ltd</th>
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<td>Jackie Hills</td>
</tr>
</tbody>
</table>
# INDEX

**FOREWORD**

**ACKNOWLEDGEMENTS**

**LIST OF ACRONYMS**

**EXECUTIVE SUMMARY**

**CHAPTER 1: INTRODUCTION**

1.1 THE HIV EPIDEMIC IN SOUTH AFRICA
1.2 ENVIRONMENTAL ASPECTS OF THE HIV EPIDEMIC
1.3 APPROACHES TO HIV PREVENTION
1.4 THE INTERVENTION WITH MICRO-FINANCE FOR AIDS AND GENDER EQUITY (IMAGE) STUDY

**CHAPTER 2: THE IMAGE INTERVENTION**

2.1 MICRO-FINANCE PROGRAMMES
2.2 THE SMALL ENTERPRISE FOUNDATION (SEF) AND TŠHOMIŠANO CREDIT PROGRAMME (TCP)
2.3 SISTERS FOR LIFE
2.4 INTERVENTION WITH MICRO-FINANCE FOR AIDS AND GENDER EQUITY (IMAGE)

**CHAPTER 3: CONCEPTUAL FRAMEWORK**

3.1 DISCUSSION OF THEORETICAL FRAMEWORK
3.1.1 ENVIRONMENT
3.1.2 HEALTH-RELATED OUTCOMES
3.2 OPERATIONALISING THE THEORETICAL FRAMEWORK IN THE IMAGE STUDY DESIGN

**CHAPTER 4: THE IMAGE STUDY SETTING: SEKHUKHUNELAND**

4.1 HISTORY
4.2 THE IMAGE STUDY VILLAGES
CHAPTER 5:
RESEARCH DESIGN 32
5.1 STUDY OVERVIEW AND RESEARCH DESIGN 32
5.2 THE EVALUATION OF MICRO-FINANCE AND HIV PREVENTION PROGRAMMES 35
5.2.1 EVALUATIONS OF MICRO-FINANCE PROGRAMMES 35
5.2.2 EVALUATIONS OF HIV PREVENTION INTERVENTIONS 38

CHAPTER 6:
DATA COLLECTION 41
6.1 PARTICIPATORY WEALTH RANKING (PWR) 41
6.1.1 MAIN OBJECTIVES 41
6.1.2 METHODS 41
6.1.3 ANALYSIS 43
6.2 COHORT STUDY I : THE IMPACT OF IMAGE ON LOAN RECIPIENTS 43
6.2.1 MAIN OBJECTIVES 43
6.2.2 METHODS 44
6.3 COHORT STUDY II : THE IMPACT OF IMAGE ON YOUNG PEOPLE LIVING IN THE HOUSEHOLDS OF LOAN RECIPIENTS 48
6.3.1 MAIN OBJECTIVES 48
6.3.2 METHODS 48
6.4 COHORT STUDY III : THE IMPACT OF IMAGE ON COMMUNITIES 52
6.4.1 MAIN OBJECTIVES 52
6.4.2 METHODS 53
6.5 ROUTINE DATA COLLECTION SYSTEMS 56
6.5.1 SEF MONITORING INFORMATION 56
6.5.2 CLINIC AND HEALTH SERVICE UTILISATION RECORDS 56

CHAPTER 7:
DISCUSSION 57
7.1 ENVIRONMENTAL INTERVENTIONS 57
7.2 CAN IMAGE PREVENT HIV INFECTIONS? 59
7.3 STRENGTHS AND LIMITATIONS OF THE IMAGE STUDY 59
7.4 WHO DOES THE IMAGE STUDY AFFECT? 62
7.5 CONCLUSION 63

APPENDICES 65

REFERENCES 75
Limpopo Province in northern South Africa is home to over 4 million people. The majority face the same challenges as those in any developing country. 60% of households live below the poverty line and only one third of the population has access to employment.

The Small Enterprise Foundation (SEF) is a development NGO committed to the elimination of poverty through encouraging and nurturing self-employment. SEF is achieving this goal by providing micro-credit and savings services to rural, historically disadvantaged communities. It has challenged the industry by its specific focus on identifying the very poor and ensuring that it has a positive impact with this group.

Now SEF and Radar have come together in a three-year pilot to deepen our understanding of the impact of micro-finance on very poor individuals and communities. In particular, we are committed to learn more about the relationship between micro-finance and HIV/AIDS.

The pilot aims to assess the ability of households and communities involved with micro-finance programmes to cope with the effects of HIV/AIDS, as well as their ability to avoid the disease.

We are very excited about this opportunity to work towards improvements in two of the most important issues facing the region today.

Paul M. Pronyk
Managing Director
Rural AIDS & Development
Action Research Programme

John de Wil
Director
Small Enterprise Foundation
ACKNOWLEDGEMENTS

This programme of research is a collaboration between the Rural AIDS & Development Action Research Programme of the School of Public Health, University of the Witwatersrand, and the Small Enterprise Foundation. It brings together three years of planning, alongside the patient and generous contributions of many. Academic support from the London School of Hygiene and Tropical Medicine has been critical to strengthen the scientific rigour of the work, and connect a small research team to the outside world. Input and support from South African-based colleagues and friends has also provided much in the way of richness, relevance and perspective. In this regard, we appreciate the mentorship and guidance provided by Prof. John Gear, Mmatshilo Motsel and Chris Peters.

IMAGE has brought together a diverse array of funders from the health and development fields – all of whose contribution has been critical. The South African National Department of Health, through Dr. H. Hausler, provided substantial support to all aspects of the project. The Anglo American/de Beers Chairman’s Educational Trust, the Henry J. Kaiser Family Foundation, the Ford Foundation, and the Enterprise Development Innovation Fund of the UK Department for International Development have also graciously provide core support to programme activities. The International Alliance (Financial Women’s Association of New York) provided further funds to support TCP. Finally, Orasure Technologies Incorporated provided Orasure collection devices and Omnimed and Organon Teknika provided Vironostika Uniform HIV 11+ O kits for use in the study.
### List of Acronyms

<table>
<thead>
<tr>
<th>Acronym</th>
<th>Description</th>
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<tbody>
<tr>
<td>AIDS</td>
<td>Acquired Immune Deficiency Syndrome</td>
</tr>
<tr>
<td>CBO</td>
<td>Community Based Organisation</td>
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<td>DOH</td>
<td>Department of Health</td>
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<td>GBV</td>
<td>Gender Based Violence</td>
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<tr>
<td>HIV</td>
<td>Human Immunodeficiency Virus</td>
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<td>IMAGE</td>
<td>Intervention with Micro-finance for AIDS and Gender Equity</td>
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<tr>
<td>IPV</td>
<td>Intimate Partner Violence</td>
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<tr>
<td>LSHTM</td>
<td>London School of Hygiene and Tropical Medicine</td>
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<td>MFI</td>
<td>Micro-finance Initiative</td>
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<td>MRC</td>
<td>Medical Research Council</td>
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<td>NGO</td>
<td>Non-Governmental Organisation</td>
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<td>OMT</td>
<td>Oral Mucosal Transudate</td>
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<td>PLA</td>
<td>Participatory Learning and Action</td>
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<td>PRA</td>
<td>Participatory Rural Appraisal</td>
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<tr>
<td>PWA</td>
<td>Person living with HIV/AIDS</td>
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<td>PWR</td>
<td>Participatory Wealth Ranking</td>
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<td>RADAR</td>
<td>Rural AIDS and Development Action Research Programme</td>
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<td>NHLS</td>
<td>National Health Laboratory Service</td>
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<td>SEF</td>
<td>Small Enterprise Foundation</td>
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<td>SFL</td>
<td>Sisters for Life</td>
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<td>STD</td>
<td>Sexually Transmitted Disease</td>
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<td>TCP</td>
<td>Tshomisano Credit Programme</td>
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<td>UNAIDS</td>
<td>United Nations Joint Programme on AIDS</td>
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<td>VCT</td>
<td>Voluntary Counselling and Testing for HIV</td>
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Executive Summary

There are over 4 million people living with HIV in South Africa - more than in any other country in the world. Many communities are just beginning to feel the impact of the epidemic, but it is clear that a humanitarian disaster is approaching. By 2010, over 5 million people are likely to have died of AIDS in South Africa.

HIV prevention efforts in South Africa have been ambitious and rights oriented but have fallen short on implementation, being lost among a wide range of profound and immediate concerns inherited from the apartheid regime. South Africa’s strategic plan for HIV/AIDS/STDs 2000-2005 represents the current policy blueprint. It highlights important health sector led interventions in targeting HIV prevention. It is necessary for the prevention goals outlined in that document to be urgently met, yet it remains unclear if this will be sufficient to combat HIV in South Africa. Despite widespread agreement that the rapid spread of HIV has been facilitated by migrant labour, widespread poverty and entrenched gender inequalities, there have been no attempts to prevent HIV by targeting these environmental level factors. The IMAGE study seeks to fill this gap.

Intervention with Micro-finance for AIDS and Gender Equity (IMAGE) emphasises the importance of the environment in which sexual behaviours, gender-based violence and HIV infections are occurring. IMAGE is targeted at disadvantaged women and their households. It combines the introduction of a poverty-targeted micro-finance programme to rural communities with a participatory learning and action curriculum (Sisters for Life) for clients. The combined intervention aims to be mutually reinforcing, seeking to strengthen individual client agency and to improve household well-being, communication and power relations. IMAGE plans to enrol 10-20% of households within targeted communities and thus aims to have an impact on social norms, social networks and relationships, and community level responses to issues such as poverty, gender-based violence and HIV. Through an impact on these environmental level factors it is hypothesised that IMAGE has the potential to influence levels of gender-based violence and vulnerability to HIV/AIDS.

The IMAGE study is an integrated, prospective, randomised, controlled, community-matched intervention trial being conducted in the Sekhukhuneland region of South Africa’s rural Limpopo province. The evaluation programme
integrates data from participatory, qualitative and quantitative methodologies to investigate the impact of the IMAGE program. The study is built around the prospective follow up of three cohort pairs; IMAGE clients, young people living in the household of IMAGE clients and young people living in communities where the IMAGE programme is operating. Appropriate comparison groups are recruited from villages where the program is not operating. Prospective data will be used to analyse differences in key indicators (including gender-based violence, sexual behaviour and HIV) between groups from Intervention and Comparison communities. Qualitative data will examine processes of change, interrogate and triangulate results of quantitative work and provide a detailed understanding of the IMAGE study context.

The IMAGE study represents an opportunity to explore the potential for developmental programs to have a role in preventing HIV infections and gender-based violence. The study represents a rigorously designed programme of evaluation in which multiple analyses, both qualitative and quantitative, will be used to paint a picture of process and impact.

A retreat was held in early 2002 to discuss progress with the IMAGE study.
In 2002, over 4 million people in South Africa are HIV-positive.
By 2010, at least 5 million people will have died of AIDS in South Africa.
HIV prevention efforts in South Africa have been hampered by widespread social and political restructuring in the post-apartheid era.
South Africa’s policy blueprint highlights HIV prevention activities that are necessary, but may not be sufficient to combat the HIV epidemic.
The rapid spread of HIV in South Africa has been facilitated by an environment characterised by poverty, migrant labour and entrenched gender inequalities.
There have been few attempts to influence environmental level factors as a strategy in preventing new HIV infections.
The IMAGE study is as attempt to implement an environmental level intervention and evaluate its potential impacts in changing sexual behaviour and preventing HIV infections and gender-based violence.

1.1 The HIV epidemic in South Africa

In 1990, South African national antenatal surveillance data documented an HIV prevalence of 0.7% among women attending public antenatal clinics. By 1993, the prevalence figures had already risen to 4%, signalling a dramatic shift in the burden of infection. Over the following years the epidemic began to spiral out of control, with the prevalence doubling every two years (see figure 1). By 2000, South Africa had an antenatal prevalence rate of 24.5%, over 4 million infected individuals, and was host to one of the fastest growing HIV epidemics in the world. In the year 2002, there are more people living with HIV in South Africa than in any other country in the world. Recent Medical Research Council (SA) projections highlight that while many communities are already experiencing increased mortality and morbidity as a result of HIV/AIDS, the worst is yet to come. In 2000 an estimated 20% of all adult deaths were attributable to AIDS, making it already the single largest cause of death in South Africa. In the absence of developments that will prevent HIV infected individuals developing AIDS, the number of deaths can be expected to grow in the next 10 years. 5-7 million cumulative AIDS deaths are predicted to have occurred in South Africa by 2010, and life expectancy at birth will have dropped below 40 years.
Efforts to combat HIV in South Africa have been characterised by an ambitious, rights-oriented policy agenda – but one that has fallen short on implementation\(^5\)\(^6\). The South African National STD&HIV/AIDS Review (1997) found that while there was high commitment to the problem, there was also disarray among those responsible for both policy and implementation. The review found gaps in the response including very little on-the-ground service implementation, crippling stigma and discrimination, a lack of policies at provincial level to guide program implementation and a lack of commitment from governmental departments beyond the DOH\(^1\).

The current "HIV/AIDS & STD Strategic plan for South Africa 2000-2005" identifies a number of aims, including a priority towards prevention in which 6 goals are outlined\(^7\).

These goals are:

- promoting safe sexual behaviour
- improving the management and control of STDs
- reducing mother to child transmission
- addressing blood transfusion safety issues
- providing services for post exposure prophylaxis (PEP)
- improving access to voluntary counselling and testing (VCT).
A vast amount of work lies ahead of those involved in service provision, including government departments, NGOs and the private sector, simply to implement these basic measures. There is no doubt of the necessity for the goals laid out in this strategy to be met with great urgency. However, there remain questions about whether these initiatives will be sufficient to combat HIV in South Africa. A comprehensive response to HIV/AIDS in South Africa is likely to require additional efforts focused on the societal forces that have shaped the course of the epidemic.

1.2 Environmental aspects of the HIV epidemic

The HIV epidemic has lasted more than two decades in sub-Saharan Africa and the bulk of the world’s infections are concentrated in this region. The causes of this massive epidemic are multiple, complex and act at many levels.

Individual behaviours can increase an individual’s risk of HIV infection and the propensity of the virus to spread in a population. Such behaviours include having multiple, concurrent sexual partners, particularly combined with the widespread non-use of condoms. Other individual level factors can also contribute to increased HIV transmission; lack of male circumcision and the presence of other sexually transmitted diseases have been shown to be particularly important.

In recent years there has been an increased awareness of how factors at other levels may contribute to the epidemic spread of HIV. Structural and
environmental factors shape the complex realities in which individual behaviours occur. Such factors include physical, social, cultural, organisational, community, or economic forces that may affect individual efforts to avoid HIV infection. In particular, three key environmental forces have been identified as of importance in providing a context in which HIV epidemics unfold.

- Economic underdevelopment and poverty,
- Mobility, including migration, seasonal work, and social disruption due to war and political instability
- Gender inequalities and gender-based violence

Poverty has been identified as South Africa’s greatest problem. In rural areas, apartheid policies have eroded traditional lifestyles and agricultural livelihood strategies are unable to support most households. However, 34% of the “economically active” population were unemployed at the last census (rising to 46% in the Limpopo Province). Consequently, households in rural South Africa rely on remittances from migrant labour (38%) and secondary labour market employment (often local, poor prospect jobs, e.g. farm workers; 37%) to generate a livelihood. Many are also dependent on state transfers such as pensions (32%)\footnote{14}. In Limpopo province, just 37% of households use electricity for lighting, while only 39% have access to piped water, with the majority collecting water from a public tap\footnote{15}. 75% of the population live in households with income below a subsistence level poverty line\footnote{14}.

There is wide recognition of the potential importance of poverty in the spread of HIV, although the links are complex. Worldwide the bulk of infections have occurred in poor countries, with a greater burden of infection in urban areas\footnote{2}. Within those countries worst affected HIV has spread most quickly among mobile, more affluent groups although this pattern may be changing as epidemics age and populations change their behaviour\footnote{16-19}. Less educated, lower socio-economic status groups may increasingly be at the highest risk of new infection\footnote{18-21}. In South Africa, entrenched migrant labour means families are separated for long periods of time, while migrant men are often may be housed in bleak, socially alienating conditions. Rural families are dependant on remittance, and the education and socialisation of children is disrupted. Migrants themselves may be isolated, badly paid and often work in dangerous jobs. It is not surprising that many adopt families or girlfriends, or that the mines are associated with extensive commercial sex work networks\footnote{20,21,22,23}.  

\textit{INTRODUCTION}
Gender inequalities and gender-based violence in South Africa are intrinsically linked to issues of race and social class. One of the most common forms of violence against women is abuse by their husbands or other intimate male partners. Men's experience of racism and economic deprivation might predispose to reactionary backlash within the family. Frustration engendered in the public domain is expressed more safely in private, with women the most accessible target. Moreover, although intimate partner violence (IPV) occurs in all socio-economic groups, studies have found that women who live in poverty are more likely to experience violence than women of higher status. It is unclear, however, why poverty increases the risks of violence – whether it is due to low income itself or to other factors that may accompany poverty, such as overcrowding, a sense of desperation, or elevated levels of general violence. Poverty may also be a source of marital conflict, while simultaneously making it difficult for women to leave violent partnerships. Indeed, it is likely that low socio-economic status reflects a variety of conditions which, in combination, increase the likelihood of IPV.

IPV is a reality for many women. In nearly 50 population-based surveys from around the world, 10-50% of women report being hit or otherwise physically harmed by an intimate male partner at some point in their lives. In South Africa, a recent population-based study in 3 provinces found that 19-28% of women reported physical violence by a current or ex-partner. In rural South Africa, domestic violence has become normalised, even among health care professionals.

A growing body of research also points to ways in which violence against women may have an impact on women's susceptibility to HIV infection. HIV transmission may be the direct result of an unwanted or forced sexual act, and in South Africa the issue of HIV post-exposure prophylaxis following rape has been the focus of much recent debate. In addition, coercive sex, including young women and girls agreeing to sexual relationships with older men in exchange for material support, has been well described in Southern Africa. The power imbalances inherent in such relations may affect the ability of such women to protect themselves from HIV infection. Finally, the experience of domestic violence may profoundly impact upon a woman's expectations of her relationship, her ability to negotiate the terms and

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1 Often referred to as “domestic violence” or “wife battering”, intimate partner violence (IPV) is generally part of a pattern of abusive behaviour and control, rather than an isolated act of physical aggression, and can take the form of physical assault, psychological abuse, and/or coercive sex.
conditions of that relationship, the circumstances in which sex takes place, and whether or not she can insist on the use of condoms. Refusing sex, inquiring about other partners, or raising the issue of condoms (often interpreted as an admission or accusation of infidelity) have all been described as “triggers” for such violence, and yet all are intimately connected to the HIV prevention mantra: “Abstain, Be Faithful, Condomize”.

South Africa is a compelling case study in how environmental factors have fuelled a rapidly growing HIV epidemic. Widespread poverty, labour migration and entrenched gender inequalities have not simply provided a backdrop for the spread of the virus. Rather, it is likely that they have directly contributed to the progression of the epidemic in South Africa over the past decade. As such, policies and programmes that attempt to impact these factors may themselves have a role to play in fighting HIV in South Africa.

1.3 Approaches to HIV Prevention

While substantial resources have already been mobilised for research and programme development in efforts to combat HIV/AIDS, there have been calls for significantly greater commitment from governments and donor agencies. Despite this, there have been few controlled studies on interventions that aim to change sexual behaviour in Africa. Still fewer interventions have been shown to have beneficial effects in preventing new infections.

Worldwide, there has long been an emphasis on preventive strategies targeting individual-level risk characteristics. Condom use has been actively promoted as a rational and effective means of protection, alongside education programmes aimed at risk reduction. Enhanced STD treatment services and Voluntary Counselling and Testing for HIV remain two of the only interventions with proven efficacy in preventing STD/HIV infections from randomised, controlled trials in developing countries.

However, such programmes pay little attention to the broader context within which HIV infection occurs. Public health programmes have been challenged to move beyond information campaigns and to engage with environmental factors that are important in facilitating the spread of HIV. It is increasingly clear that providing information alone may not be sufficient to motivate behaviour change. Such environmental interventions will be guided not only by models of psychological process, but also by theories of cultural dissemination and social transformation.
Yet far-reaching dilemmas such as poverty, migration, and gender-based violence are unlikely to be overcome in the short run or through the limited resources available for health-related interventions. Consequently, despite the growing awareness of the underlying environmental factors driving the HIV/AIDS epidemic, the conceptualisation and evaluation of interventions which critically engage issues at this level are rare\(^3\)\(^9\), \(^4\)\(^0\). Indeed, no interventions that directly attempt to influence the environment in which decisions about sexual and reproductive behaviour are taken have been evaluated for their impact on the incidence of HIV or STD in Africa. A key question has thus has been raised; is there a role for focused environmental interventions that address the consequences of factors such as poverty and gender inequality in producing meaningful reductions in behavioural risk, while recognising that such small-scale programs will not eradicate poverty or sexism in the short term?

### 1.4 The Intervention with Micro-finance for AIDS and Gender Equity (IMAGE) Study

In 1999, in response to the escalating AIDS epidemic in South Africa, the National Department of Health established a new initiative to design, implement and evaluate strategies for addressing HIV/AIDS within three pilot sites across the country. All three sites were responsible for implementing a core package of HIV-related services and support, including the provision of voluntary counselling and testing services and the training of health care workers in the implementation of National HIV/AIDS clinical care guidelines. However, in addition to this basic package, the pilot sites were encouraged to test more innovative and multi-sectoral approaches to HIV control, and it is in this context that the IMAGE (Intervention with Micro-finance for AIDS and Gender Equity) study was developed.

The IMAGE study is a programme of intervention research based in the Limpopo Province of South Africa. IMAGE is an environmental level intervention that combines a poverty alleviation programme and participatory learning and action intervention. The IMAGE study is an integrated attempt to evaluate the potential role of this programme in promoting women’s agency, improving household welfare, changing attitudes and behaviour, and preventing new HIV infections and gender-based violence.
Chapter 2: The IMAGE Intervention

- Micro-finance programs provide financial services to the disadvantaged, particularly women, including access to credit to support income generating projects.
- Participation in micro-finance programs can support women’s businesses, and lead to improvements in household welfare, and changes in intra-household decision-making. Health related benefits, including impacts on nutrition, contraceptive use and gender-based violence have also been reported.
- The Small Enterprise Foundation’s Tšomisano Credit Program (TCP) is a poverty-targeted micro-finance programme operating in South Africa’s Limpopo Province.
- Sisters for Life is a two phase participatory learning and action curriculum developed in South Africa, to be implemented with TCP clients during fortnightly centre meetings.
- IMAGE is Intervention with Micro-finance for AIDS and Gender Equity, and comprises participation in TCP and access to Sisters for Life training sessions.
- The IMAGE study seeks to evaluate the impact of IMAGE among clients, their households and their communities.

2.1 Micro-finance Programmes

Micro-finance programmes employing a system of group-based lending were originally developed in India and Bangladesh to assist poor households and expand the resources, opportunities and choices available to rural women. Micro-finance programmes now operate in Africa, Asia, Europe and Latin America and are seen as a key development tool. The Microcredit Summit Campaign aims at reaching 100 million of the world’s poorest with credit by the year 2005.

Regularly reported impacts of micro-finance programmes include improvements in household welfare, enterprise stability and individual control over resources among programme participants. Health benefits have also been reported including beneficial effects on the use of family planning services reported among borrowers. Such benefits may also diffuse beyond participating households to impact the community. Other reports have demonstrated improvements in nutritional intake and in the educational attainment of children from participating households. Programmes may also
have the potential to reduce men’s violence against women\textsuperscript{45}. Benefits often take some time to accrue. Micro-finance programmes may have a role to play in preventing HIV infections through their effect on the social and environmental context in which high rates of transmission occur. To our knowledge no studies have directly investigated this link.

Microcredit programmes aim to facilitate the growth and establishment of small businesses run by women.

2.2 The Small Enterprise Foundation (SEF) and Tšhomíšano Credit Programme (TCP)

SEF is a development micro-finance NGO operating in the South Africa’s Limpopo Province. It started operating in 1992, disbursing small loans for micro-enterprises owned by poor women. Four years later, a review was conducted. The results showed that women who ran microenterprises were participating in large numbers, with the hope of getting bigger loans in future. However, these non-poor participants were acting as an active deterrent to the very poor becoming involved. In response to this finding a parallel project, Tšhomíšano Credit Project (TCP), was established to cater specifically for the very poor. SEF is currently servicing over 13 000 micro-enterprises.

TCP uses Participatory Wealth Ranking (PWR) to identify the poorest households in communities\textsuperscript{46}. Women in these poorest households are then approached by SEF staff and encouraged to participate in TCP. Women organise themselves into groups of five with each member of the group guaranteeing the loans of the other group members. Repayment rates are generally high with group lending. The members are trained to understand the
terms and conditions associated with the loan. At the end of repayment of one loan, a new loan cycle may begin. Loan size increases in line with business value. Women meet once a fortnight, in a centre of approximately 40 borrowers to make repayments, discuss business problems and apply for new loans.

The living conditions of women in TCP households are monitored closely by the staff member in that area and these living conditions build the foundation for TCP Impact Assessment. A recent impact assessment reported benefits to loan recipients similar to those reported for other micro credit programs and found that the real impact of participation among very poor women starts to be more visible in the third loan cycle. No formal evaluation of involvement in SEF programmes on health outcomes has been performed.

2.3 Sisters for Life

TCP centre meetings offer an ideal opportunity to introduce a program of training and skills development relating to Gender and HIV/AIDS. The Sisters for Life program comprises two phases. Phase I is a structured series of 10 training sessions, while phase II is an open-ended program that aims to support participants in developing and implementing responses appropriate to their own communities.

The phase I curriculum is based on participatory learning and action principles and has been developed and piloted specifically for the IMAGE study context. It covers a broad range of issues that have been identified as priorities for rural women. Topics include gender roles, gender inequality and cultural beliefs, sexuality and relationships, and domestic violence, as well as
topics relating to HIV prevention. Sessions are structured to give participants an opportunity to strengthen confidence and skills relating to communication, critical thinking and leadership. Moreover, they are designed to complement TCP values and principles such as mutual respect, personal responsibility, and group solidarity. The curriculum comprises 10 one-hour sessions which are led by a team of four facilitators during regular centre meetings. To build continuity between the fortnightly sessions, "homework" activities are assigned and used to reflect on how the sessions relate to ongoing experiences in the women’s lives.

Throughout phase I, participants are encouraged to identify both obstacles and opportunities for engaging with men and youth in their communities. In phase II, key women who have been identified in the previous phase as natural leaders are brought together for further training on leadership and community mobilization. Taking these skills back to their respective centres, they are encouraged to develop an Action Plan with their centres, with the aim of implementing what they regard as appropriate responses to priority issues. In this phase, the four facilitators continue their relationship with the centres, this time using the one-hour sessions to provide support and guidance for the Action Plan.

Please refer to IMAGE intervention monograph number 2 for a full description of the Sisters for Life Intervention.

Sisters for Life training sessions take place at the beginning of SEF centre meetings
THE IMAGE INTERVENTION

2.4 INTERVENTION WITH MICRO-FINANCE FOR AIDS AND GENDER EQUITY (IMAGE)

IMAGE is a public health and development intervention that comprises both involvement in SEF’s Tshomišano Credit programme and the Sisters for Life training sessions. IMAGE is made available to communities, in which women from the poorest households are identified and then encouraged to join the programme. IMAGE is jointly administered by the Small Enterprise Foundation (SEF) and the Rural AIDS and Development Action Research Programme (RADAR).

The IMAGE study seeks to evaluate the impact of this combined intervention on the communities to which it is made available, and the individuals and their families that participate. The research study outlined in this monograph has been designed explicitly for this purpose. The potential impacts that will be investigated are diverse, including factors relevant to discussions of poverty alleviation, household dynamics and gender-based violence. In addition the study seeks to assess impacts on attitudes, norms and behaviours of relevance to the spread of HIV. The IMAGE study also includes a prospective assessment of the rate of newly occurring HIV infections. The IMAGE study provides an opportunity to examine these complex social processes through the application of multiple data collection and analysis methodologies, in the context of an action-based programme of research and implementation.
IMAGE aims to influence factors that predispose individuals to HIV infection and gender-based violence by influencing the social environment in which they occur. The IMAGE framework describes factors at the individual, household and community level that constitute the environment in which these health related outcomes occur. Individual agency, household well-being, communication and power relations, and the norms, networks, relationships and responses of communities constitute the environment in the IMAGE framework. Processes that lead to health related outcomes, including gender-based violence, sexual behaviours and HIV infection, occur within this environment. The IMAGE study operationalises the framework in a programme of implementation and evaluation.

3.1 The IMAGE theoretical framework

The framework identifies factors at three levels defining a complex environment in which sexual behaviours, HIV infection and gender-based violence occur. The IMAGE work seeks to underscore the importance of this environment in shaping vulnerability to both gender-based violence and HIV.

3.1.1 Environment

The concentric circles in the framework diagram reflect the notion of dynamic systems at the individual, household and community level that together constitute an environment. The use of dotted-lines to indicate boundaries explicitly emphasises their permeability, while dotted two-way arrows are used to imply a constant process of communication and exchange of knowledge, attitudes, and other ‘resources’ between different levels.
**Individual level:** Agency reflects the capacity for free and independent decision making. It may be realized through actual autonomy in decision-making, determined in part by levels of self-esteem, self-confidence, and a perceived control over one's environment. An individual's ability to make choices in relation to their reproductive health and sexual well-being is inextricably linked to their ability to negotiate decisions on a variety of other levels. For the purposes of this framework, agency defines a property attributable to individuals. However, relationships of social, economic and political importance at the levels of households and communities provide the context, opportunities and constraints for its development.

**Household level:** At the household level three factors are emphasised that are influenced by and themselves influence individual agency. Household well-being reflects the absolute and relative availability of resources, the ability of the household to meet basic needs and in turn the standard of living.
enjoyed by household members. Power dynamics in relation to control over resources and household decision making also operate both between sexes and between generations. In addition the level and type of communication between household members, and of household members with their community, contributes to the household environment.

Community level: A number of community level factors are emphasised in the framework that may influence and be influenced by the processes occurring at adjacent levels. Social norms represent an evolving common understanding of significant social issues, such as gender, sexuality or the HIV epidemic. While individuals may constantly challenge norms in their cognitive processes, there remain underlying beliefs and attitudes that shape communities and their responses. Social networks, including community groups and institutions, provide the opportunity for the exchange of resources (material, informational or emotional) within communities. The networks that exist, the strength of their association and the focus of their activities, are important in defining a community environment. Further, relationships that exist between groups and individuals in a community dictate levels of social cohesion and social capital, outlining the extent of connectedness and solidarity in relation to levels of trust, reciprocity, mutual aid and resource flows. Finally, social responses are an indicator of collective action taken by community groups in relation to pervasive social or political circumstances. These responses contribute to, and are themselves the product of, the environment in which they occur.

3.1.2 Health-related outcomes

The IMAGE framework hypothesises that the social environment is important in shaping health related outcomes, specifically to gender-based violence, sexual health and HIV infection.

Gender Based Violence: Outcomes of interest in the IMAGE study include the experience of gender-based violence, the perceptions and attitudes of those in the community, and the responses to its occurrence.

Sexual Health Indicators: Sexual behaviour models suggest that knowledge of HIV and attitudes towards people living with HIV/AIDS and towards certain behaviours influence sexual behaviour. Communication relating to issues of sex, sexuality and HIV risk with peers and household members may be related to the process of sexual socialisation, while accessing VCT may be an
important decision in strengthening sexual health and providing access to information. Finally, sexual behaviour and the use of condoms more directly influence the risk of HIV infection.

**HIV infection:** The IMAGE work aims to strengthen HIV prevention through an impact on the outcomes and environmental factors outlined above. The use of dotted lines to link GBV and sexual health to HIV highlights that these relationships are themselves complex and non-linear.

### 3.2 Operationalising the theoretical framework in the IMAGE study design

IMAGE has been designed to impact the environment in which sexual behaviours and gender-based violence occur. It seeks to encourage actions that promote sexual health and prevent gender-based violence through making the environment in which they occur more enabling. The IMAGE study encompasses both this intervention programme, and a programme of research that seeks to explore the relationships described.

The IMAGE intervention engages individuals, households and communities in different but related ways, and monitors potential impacts on all of these levels (figure 3).

**Individual women** participate directly in IMAGE through involvement in income generating activities, loan centre meetings, and the Sisters for Life training sessions conducted during fortnightly meetings.

**Households** participate in IMAGE since economic activities almost always involve household members beyond the loan recipient. Furthermore, individuals in the household might experience the effects of the training indirectly through communication, role modelling or mentorship.

**Communities** are the central unit at which the intervention operates. Villages where no pre-existing services had been available were randomly selected and offered participation in the programme. Recruitment of a substantial proportion (10-20%) of village households into IMAGE has the potential to generate significant community level effects.

As depicted in figure 3, the IMAGE study operationalises the theoretical framework and the three key levels of engagement of the IMAGE intervention.
in a programme of evaluation. The study is centred around data collection concentrating on three cohort groups that map broadly to the three levels at which the intervention engages; namely loan recipients, young people that live in the households of loan recipients and communities that have access to IMAGE. Data is also collected from comparison groups. Chapters 4-6 of this monograph describe the IMAGE study setting, its structural research design and the multiple data collection nodes that it encompasses.
Chapter 4: The IMAGE study setting: Sekhukhuneland

- The IMAGE study is set in 8 villages of the Sekhukhuneland region of South Africa's Limpopo Province.
- The 20th century in Sekhukhuneland, part of the former homeland of Lebowa, has seen the erosion of traditional leadership structures and farming to support livelihoods. The late 1980's and early 1990's saw widespread social and political upheaval.
- In 2002, the villages are characterised by dense population, high unemployment and a reliance on migrant labour to generate livelihoods.
- HIV prevalence in the region is estimated at 13.2% among antenatal clinic attending women.

The IMAGE study is set in 8 rural villages of Sekhukhuneland, a district of the former homeland region of Lebowa in South Africa's north east. The region sits on the brow of the Drakensberg escarpment approximately 1000m above sea-level on the northern side of the Limpopo/Mpumalanga border, some 500m above the lowveld to the East, and 600m below Gauteng to the west. The rapidly developing town of Burgersfort, which sits just inside the Mpumalanga border, is the major centre of economic activity for residents of all the study villages. Figure 4 shows the location of villages included in the IMAGE study.
4.1 History

Sekhukhuneland is a region steeped in the history of the BaPedi people. In 1879 the BaPedi kingdom was finally overcome by the combined forces of the British and Swazi armies after many decades of resistance. In the 120 years that have followed the region’s history has reflected broad patterns common to much of rural South Africa while also being the site of a number of unique historical events.

As the early decades of the 20th century passed the economic and social order of Sekhukhuneland increasingly rested on migrant labour. While originally many communities continued to plough and herd cattle, the push towards “rural development” encapsulated in the 1936 Native Trust and Land Act left homes with less and less land. Cattle were increasingly culled in the 1930s and 1940s to “preserve” the land. Migrants to the Rand and to local mines maintained important links with their rural homesteads, joined regional organisations based in the cities and provided important remittances to those back at home.

After 1948, the National Party’s election victory meant life for Sekhukhuneland residents and migrants became increasingly strained. The Native Affairs
Department increasingly sought to implement boipušo (self-rule) in the Reserves, which in turn generated increasing levels of political discussion and action among the population. In 1958 tensions erupted in the Sekhukhuneland revolt in which supporters of the imposed Bantu authorities (termed marangera, or Rangers) were attacked and killed by the BaPedi. A small victory was won with the return of the previously deported, but widely respected paramount Morwamotše, and his wife Mankopodi, to the district capital of Mohlaletše.

Yet the 30 years that followed would see the final erosion of rural life in Sekhukhuneland as many had once known it. As the apartheid framework was widely implemented, and residents were increasingly moved out of white farming areas, the population boomed in the reserves. Land and livestock ownership was almost completely eroded. Tribal authorities were rapidly established and the Bantu system took hold. Migrating to work became the main mode of survival for the majority of households, and increasing numbers of women also went in search of domestic work positions in the cities. Children were often left to grow up with their grandparents, and to go through the increasingly accessible but restrictive Bantu education system.

In these increasingly desperate conditions, it is no surprise that as the 1980’s progressed, and levels of political and resistance activity increased across South Africa, tensions once again surfaced in Sekhukhuneland. In 1986 there was widespread youth dissension, including school boycotts and increasing levels of active resistance. This coincided in the region with a spate of witch burnings in Sekhukhuneland communities, highlighting local tensions and frustrations. Further burnings occurred in 1994 around the time of the first free elections in South Africa, and as the dust settled around the ANC’s massive election victory in the region there was much for the new administration to do.

4.2 The IMAGE study villages

The 8 villages involved in the IMAGE study encompass approximately 9500 households with a population of over 50 000 people. Some population details from the 1996 national South Africa census are held in figure 5. Traditional leaderships still maintain a degree of control in some areas, but transitional local councils are now active in many of the study villages. While the political landscape has changed substantially during the past decade, many of the realities of life have steadfastly remained constant. The age structure of the population reflects a classic developing country pattern, with nearly 50% of the population being under 15 years old. The social fabric
remains characterised by very high levels of labour migration (among both sexes) and an unemployment rate in excess of 40%. While ploughing the land remains a survival tactic for many families, few have land or livestock sufficient to completely support their livelihoods. Continued expansion of platinum mining is hoped to bring jobs and investment to the region.

The area is served by one hospital and one health centre, while four of the study villages have primary health care clinics situated inside their borders. Six of the study villages are widely electrified, while the remaining two small, in-accessible villages do not have widespread access to electricity. Water supply remains one of the most problematic issues across the whole study site. 47% of households report that their main source of water collection is a public tap in the village, with even these supplies being irregular in many places.

Data on HIV are obtained from the Department of Health national HIV prevalence survey conducted among antenatal clinic attending women. The prevalence in Southern Region (Limpopo province) among this group was 13.2% in 2000. This figure reflects a greater similarity with the situation across the largely rural Limpopo province, than with that in the more developed Mpumalanga. HIV education is largely limited to campaigns in schools and multi-media campaigns. HIV-related services were strengthened in all the local clinics in advance of the start of the IMAGE study. Available services include free condom distribution, the practise of syndromic STD management and the provision of voluntary counselling and testing (VCT) for HIV.
The IMAGE study is an integrated, prospective, randomised and controlled, community matched, intervention trial. This experimental design lends great strength to the IMAGE evaluation. Evaluations of micro-finance programs have often been retrospective, descriptive and/or small scale. Evaluations of HIV prevention initiatives must ensure accurate collection of sexual behaviour or biological outcome data and be appropriately designed. The IMAGE study design incorporates best practice methodology from the fields of micro-finance and HIV prevention evaluations. The IMAGE study is unique in aiming to understand both micro-finance and sexual health related outcomes.

5.1 Study Overview and Research Design

The IMAGE study is a programme of action research that has been established in the Sekhukhuneland district of South Africa’s Limpopo Province. The work encompasses three years of follow up, centred around eight villages, in which multiple levels of data collection are ongoing.

The IMAGE study is built around a key structural design, termed an integrated, prospective, randomised, controlled, community-matched intervention trial. A discussion of some of these key features of this design is given below.

Integrated: The IMAGE study is an attempt to integrate information collected using different research methodologies. The evaluation recognises that behaviours and attitudes are complex and non-linear, and that the causes of observable change are likely to reflect similar characteristics. Measured changes might be the product of a wide range of causal factors and may be sudden, discontinuous and unpredictable. Within the IMAGE study, quantitative techniques will give representative summaries of changes in indicators and provide an overall inference of the magnitude of changes associated with the
programme’s operation. Such changes may be contextually specific, dynamic and open-ended. Qualitative research aims to document the process, seeking to establish how and why changes might occur. Quantitative evidence will contribute to an evaluation of pre-determined hypotheses, while qualitative research will help understand divergence from initial expectations and support a contextual interpretation of the programme’s research hypothesis. Quantitative techniques will analyse indicator measures generated by survey tools, while qualitative work will be used in triangulation, supporting a critical evaluation of the interpretation of survey data. Finally, quantitative data will be collected through large-scale waves of data collection, while qualitative work adopts continuous review and monitoring, allowing a deeper understanding to be gained of the dynamic complexities within which the IMAGE programme and those affected by it are situated.

The strength of the IMAGE study comes from a commitment to integrate these techniques and perspectives in both the design and analysis of data generated within the programme.

Prospective: The IMAGE study recruits individuals in a “baseline” state, before they have access to IMAGE, and data is collected from these individuals before, during and after the intervention programme. The use of a prospective design minimises the likelihood of distortion of results through recall bias. This phenomenon occurs when individuals questioned retrospectively exhibit a systematically distorted recall of past events. Many evaluations of micro-credit programmes have suffered from this problem whilst it is also a major problem in the interpretation of questionnaire based data on reproductive and sexual health decision-making.

Randomised and Controlled: “Intervention” in this study is assigned at the village level and consists of SEF and RADAR making IMAGE available to a village (as described in section 2.4). In advance of services being made available SEF conduct a participatory wealth ranking procedure to identify the poorest households in the village. The study has made the IMAGE programme available to four intervention villages (I) from late 2001. In four comparison villages (C), IMAGE will be made available three years later (see figure 4). The primary study analyses will compare information from individuals recruited in villages that have access to IMAGE over the next 3 years (I), with individuals from those villages that don’t (C). The decision about which villages would receive IMAGE, and which would not, was made randomly.
This randomised, controlled design lends academic rigor to the work, increasing its potential impact. The use of comparison groups has not been widely adopted in micro-finance evaluations on ethical grounds. In the current study, IMAGE was not previously available to any of the study villages. IMAGE will be extended so that it is available to the population of all eight villages in three years, after the completion of comparative studies. This time period is equivalent to that in which SEF would normally expand to an area of this size. We believe these factors answer ethical concerns.

Community-Matched: The eight villages included in the IMAGE study were paired (matched) according to estimated size and accessibility, leading to four village pairs, as denoted in figure 4. The pairs are:

- small / inaccessible
- small / accessible (1)
- small / accessible (2)
- large / accessible

Matching is used to increase the similarity of communities that are to be directly compared. Within each matched pair of villages, one village was randomly assigned to be an Intervention village, and the other to be a Comparison village.

Intervention trial: This phrase explicitly refers to the fact that the IMAGE research programme centres around an intervention, specifically the introduction of IMAGE to four villages. The provision of this intervention is an intrinsic part of the research process and distinguishes the research from programmes of observational research that typically collect information to observe relationships between individuals or communities, but do not directly control any interventions study participants may have experienced.

These features describe the core structural design of the IMAGE research programme. Around this structural design a number of independent, but linked assessments operate, each with their own research questions, design and processes. A participatory wealth ranking and mapping process has been conducted covering all of the approximately 9,500 households in the study villages. Village profiles will be developed through interviews with leaders, civil society groups, local employers and providers of health care and education. SEF centre meetings and Sisters for Life training sessions will be monitored, while key informant households and loan groups will be followed in depth.
Targeted data collection through the administration of survey questionnaires will enable longitudinal follow up of three pairs of cohorts assembled in the villages to gain evidence of impact of the intervention strategy. A community-based PRA project will provide further information on the lives of young people. Finally, IMAGE will also make use of information from routine data collection systems of both local health services and the Small Enterprise Foundation. We present details of each of these data collection strategies and their primary objectives in Chapter 6 of this monograph. In the remainder of this chapter we discuss technical issues of relevance to the IMAGE study design.

The IMAGE study villages are situated in a mountainous area with low rainfall.

5.2 THE EVALUATION OF MICRO-FINANCE AND HIV PREVENTION PROGRAMMES

Many authors have previously examined the impact of micro-finance services, while many others have examined the impact of HIV prevention initiatives. We are not aware of any other studies that examine both issues together. Reviewing both bodies of literature highlights strengths and weaknesses of these past evaluations. We have designed the IMAGE study with close reference to the literature to maximise strengths and minimise weaknesses wherever possible.

5.2.1 Evaluations of micro-finance programmes

Evaluations of micro-finance programmes fall broadly into two categories. On one hand are those that examine issues such as loan repayment, enterprise strategies, client dropout and MFI sustainability. Such issues are crucial for all micro-finance initiatives. SEF’s routinely collected financial monitoring data will form an important component of the overall picture gained in the IMAGE study.
A second field of studies attempt to examine the impact of being involved in loan programmes on clients and their households. There has been great interest in the potential for such programmes to improve household welfare and expand the resources, opportunities and choices available to rural women. Such studies are difficult to perform, and there a number of conceptual and practical issues associated with their conduct. There have been a number of discussions of methodological challenges in assessing the impact of microfinance programmes. Selected key issues are discussed below.

Retrospective data: Retrospectively collected data come with a number of associated problems. Recall may be inaccurate, but even more problematically it may be biased. Such issues are particularly difficult to deal with when the issues under study may be highly subjective. Put simply, questions of the type "Are you better off now than you were when you started taking part in this programme?" suffer from obvious problems, particularly when posed by program staff, or people perceived to be associated with the program. However, while prospectively collected data are preferable, they are costly and time-consuming to collect. The micro-finance literature suggests that benefits may accrue only slowly (over many years) compounding the difficulties associated with prospective studies.

The IMAGE study is a prospective study, collecting information from clients and their households before, during and after exposure to the programme.

Selection bias and control groups: Clients who join programmes self-select in response to the availability of a programme within a village. This process makes the selection of appropriate comparison groups difficult. A number of comparative strategies have been employed in impact evaluations of micro-finance programmes including:

- purely descriptive assessments in which, no comparison group is used.
- the use of comparison groups assembled from women who live in villages where programmes operate, but who do not join,
- comparison of recent recruits to a micro-finance programme with those who have been involved for some time,
- the use of comparison groups assembled from women who live in villages where a micro-finance programme does not operate.
While the last of these is preferable to the others, it remains problematic identifying which women in those villages should be interviewed. The desire is to interview those who would join the programme if it were to open in their village. Few micro-finance evaluations have adequately addressed such issues at either the design or analysis stages of evaluation.

The IMAGE study attempts to deal with this issue by recruiting, programme-eligible, age and “village type” matched, women from villages where the micro-finance programme is not operational. While this does not fully account for “self selection”, it does improve the likelihood that like will be compared to like, and that longitudinally measured differences may be attributable to participation in the programme. Analysis will utilise multivariate statistical techniques, where appropriate, to examine such issues in detail.

Selective, small scale and primarily qualitative: Evaluations of micro-finance programmes have often conducted small numbers of in-depth interviews with purposefully selected women. The reasons for their selection may include their success in a programme, or focus on women who drop out. Few studies, however, are able to give a full account of the impact, or lack of impact, among all individuals who join the programme, and because of this most have limited generalisability.

Qualitative techniques have often been cited as preferable since “impact” is a complex, quantitatively problematic concept. It is certainly true that qualitative data has been critical in the development and refinement of micro-finance programmes, and in contributing to an understanding of impact among members. Such techniques are crucial in providing information on process, and understanding the complex situations in which people live. Nevertheless, such studies do not completely override the need for quantitative approaches that attempt to describe the pattern and overall magnitude of impacts among all individuals who join micro-finance programmes. Careful, contextual, use of quantitative techniques is crucial in fully understanding the true impact of participation in micro-finance programmes and can help to describe what does happen rather than only describing what can happen.

The IMAGE study comprises both quantitative and qualitative components. Approximately 500 newly recruited IMAGE clients will be interviewed at baseline and after two years, regardless of their level of success in the programme or whether they drop out. The combination of contextual, standardised indicators of progress with a deeper qualitative, process-oriented picture will lend great strength to the evaluation.
5.2.2 Evaluations of HIV prevention interventions

There have been widespread attempts to evaluate the impact of interventions that aim to prevent new HIV infections. Such interventions can be broadly categorised as those that attempt to change sexual behaviour, and those that aim to prevent HIV infections through other means such as improving the treatment of other sexually transmitted infections, thus reducing their co-factor effect on HIV transmission. These types of studies have also led to discussions on methodological issues of particular relevance to this work, and key issues are discussed below\(^{(57-63)}\).

Collecting data on sexual behaviour: The validity of self-reported sexual behaviour as an outcome measure for behavioural change interventions has been questioned. Many investigators have pointed at problems with both recall and falsification in such reports. Such concerns have led to an increased interest in biological markers of impact. However, more recently there have been suggestions that where guidelines are followed, reported sexual behaviour data may not be as problematic as previously suspected. Recall is thought to be most accurate for up to c.3-6 months for many behaviours, depending on the frequency of behaviour and on the format of questioning.

Further, it has been suggested that falsification may be minimised if:

- it is clear to the respondent that data is confidential,
- the importance of honesty is stressed,
- methods that avoid face-to-face interview are employed,
- respondents are asked to sign a statement that they will give honest answers.

While not all of these issues have been directly addressed in the IMAGE study methodology, a number have. Confidentiality is stressed throughout the interview process, and the importance of honesty is discussed with the respondent. Interviews are conducted in a private place, and at a time, chosen by the respondent. Female interviewers will conduct all survey interviews in the IMAGE study, and great care has been taken in the training of interviewers to ensure they are sensitive to the needs and problems of respondents. Questions on sexual behaviour within survey instruments relate both to recent and past occurrence (up to 1 year recall in some cases).
Behavioural and biological markers: The concern in many quarters on the quality of sexual behaviour data has led to a great interest in the use of biological outcomes, specifically laboratory measurements of HIV and other STDs, in HIV prevention studies. Indeed, where the aim of an intervention is to reduce the incidence of HIV infection, sexual behaviour and biological STD outcomes act only as proxy measures for HIV incidence. However, HIV incidence is often a problematic endpoint since it is relatively low among many populations, and thus very large trials are indicated in order to empirically study it. Many other STD infections have higher incidence rates, and gonorrhea and chlamydia have been those most often used as outcome measures. While much interest in recent years has gone into such biological markers, it is now widely accepted that the relationship between STD occurrence and HIV incidence is complex and non-linear. There are limitations to the sensitivity and specificity of assays for many STDs, particularly in separating new sexually acquired infections from recurrent or untreated infection.

Since a core aim of IMAGE is to prevent new HIV infections and since HIV incidence in the population under study is likely to be relatively high (estimated at 2-3% per annum) we have decided to follow HIV incidence as well as extensive behavioural data in this study. Further, data on HIV incidence is likely to be of great utility in its own right. We will compare the incidence of HIV infection and changes in sexual behaviour between intervention and comparison villages.

Participation bias: Many trials related to the study of sexual behaviour and HIV infection have suffered from selective participation that has detrimentally affected the inferences that could be made from collected data. In particular, low response rates in trials that have sought to collect blood specimens or utilise other invasive techniques have been reported. Piloting work in the local IMAGE study area suggested that this would also be a significant barrier in this context. Consequently, the assessment of HIV status has been made using ELISA analysis of a sample collected from inside the mouth, Oral Mucosal Transudate, which is collected in a non-invasive collection device (OraSure). Early work suggests that this significantly improves participation, as well as being an accurate measure of HIV status.

Community randomised trials: An important development in recent years has been the adoption of community-randomised methodology in studies that examine interventions that are most appropriately implemented at this level. Recent trials related to the treatment of sexually transmitted diseases
as an HIV prevention strategy have pioneered the modern use of these methodologies. The IMAGE intervention is implemented as a village, or community, level programme. Consequently, the IMAGE study employs a community-randomised approach.
Chapter 6: Data Collection

- The IMAGE study collects data through the use of participatory, qualitative and quantitative techniques.
- The IMAGE evaluation is built around three prospective cohort studies (figure 6)
  - Cohort Study I: The impact of IMAGE on loan recipients
  - Cohort Study II: The impact of IMAGE on young people living in the households of loan recipients
  - Cohort Study III: The impact of IMAGE on communities
- Qualitative and participatory data collection strategies include,
  - Participatory Wealth Ranking
  - Community profiling
  - Monitoring of Sisters for Life training sessions
  - Key informant, household and loan group monitoring
  - A community-based PRA project

6.1 Participatory Wealth Ranking (PWR)

6.1.1 Main objectives

(i) To identify households eligible for inclusion in IMAGE in both Intervention and Comparison villages.
(ii) To collect information on perceptions of poverty, and on the relative wealth of households in villages.

6.1.2 Methods

Community members are invited to attend an open meeting in the village. Those who attend are sub-divided by neighbourhood and these groups each draw a map of their village section (usually of 50 – 200 households), providing a list of all the households. Following this, groups of 4-6 village section residents who know the community well (known as “reference groups”) hold a discussion on aspects of poverty in their section. Participants are asked to characterise households that are poor, those that are doing a bit better and those that are doing well. Households are then ranked in categories by these residents, from the poorest to the most well off households, according to the poverty definitions provided. Each house is ranked on three occasions by different groups of individuals, providing an aggregate “score”. Consistent agreement between the three reference groups is usually
<table>
<thead>
<tr>
<th>Cohort Study</th>
<th>Target group</th>
<th>Eligibility Criteria</th>
<th>Questionnaires</th>
<th>Approx total sample size</th>
<th>Baseline Data collection</th>
<th>Follow up</th>
<th>Outcomes of Interest</th>
<th>Qualitative Data Collection</th>
</tr>
</thead>
<tbody>
<tr>
<td>I</td>
<td>Loan Recipients</td>
<td>Woman joining IMG</td>
<td>Nearest aged woman from contemporaneously randomly selected &quot;eligible&quot; household</td>
<td>Household Senior Female</td>
<td>1000</td>
<td>At entry to loan group</td>
<td>Year 2 of participation</td>
<td>Individual agency, Household well being, communication and gender relations, Community factors, Gender based violence</td>
</tr>
<tr>
<td>II</td>
<td>Young people in the households of loan recipients</td>
<td>Aged 14-35 yrs., living in household of loan recipient</td>
<td>Aged 14-35 yrs., living in household</td>
<td>Household Young Person</td>
<td>1500</td>
<td>At entry to loan group</td>
<td>Year 2 of participation</td>
<td>Attitudes, Communication, Sexual Behaviour, HIV incidence</td>
</tr>
<tr>
<td>III</td>
<td>Young people in communities where IMG is operating</td>
<td>Aged 14-35 yrs., living in randomly selected household in Intervention village</td>
<td>Aged 14-35 yrs., living in randomly selected household</td>
<td>Household Young Person</td>
<td>3000</td>
<td>Population survey conducted before IMG implemented</td>
<td>End of 3 years</td>
<td>Community profiling, Communication, Sexual Behaviour, HIV incidence</td>
</tr>
</tbody>
</table>

Figure 6: Key characteristics of 3 parallel cohort pair trials in the IMG study.
achieved. The groups must produce results that are consistent in identifying poor households for the results to be accepted. After this process, participants are asked to describe the characteristics of the households in each ranking pile. The number of ranking piles is not set in advance, but at least four ranks must be delineated for the results to be deemed valid. Information is recorded on pre-designed forms at all stages of the process. The discussions are then assessed by a trained SEF staff member, who assigns a cut-off score. Houses below a given "cutoff" are characterised as poor enough to be eligible for loans provided by TCP.  

6.1.3 Analysis

The information collected is constantly used for identification of households eligible to be involved in IMAGE, both for targeting IMAGE and for identifying suitable comparison groups. Additionally, the information collected during PWR will be used to provide a contextual analysis of perceptions of poverty in the study region. It will also provide relative wealth information for individual households which will be compared and correlated with objective markers of poverty collected during other stages of the study.

6.2 Cohort Study 1: The impact of IMAGE on loan recipients

6.2.1 Main objectives

(I) To evaluate changes in individual agency among women who enroll in IMAGE, and compare this with women who do not have access to IMAGE.

(II) To evaluate changes in well-being, levels of communication and gendered power relations within households of women who enroll in IMAGE, and compare this with households that do not have access to IMAGE.

(III) To evaluate changes in social networking and the perceived strength of social cohesion among women who enroll in IMAGE, and compare this with women who do not have access to IMAGE.

(IV) To evaluate changes in attitudes, responses to and experiences of gender-based violence among women who enroll in IMAGE, and compare this with women who do not have access to IMAGE.
6.2.2 Methods

6.2.2.1 Monitoring Sisters For Life training sessions

Sisters for Life (SFL) training sessions adopt a Participatory Learning and Action approach (PLA), consisting of facilitated discussions and activities within a sequential curriculum. Topics are raised for discussion in line with the broad themes of the curriculum, and responses to questions that are raised in discussion by loan recipients are probed.

In-depth qualitative data collection will take place in both phases of the SFL training within four loan centres, one in each of the Intervention villages. Each centre has approximately 40 loan recipients. Key programme indicators will be ‘revisited’ through the course of the training allowing shifts within individual/group perceptions, attitudes or actions to be explored in terms of how and why these may have come about.

Each training session is attended by a team of up to four trainers. Within this team, for each session there is at least one facilitator and one “data recorder”. Data are collected in the form of flipcharts produced within training sessions, pre-designed report forms describing observed discussions, and semi-structured notes taken by the recorder during each session. After each training session a reflection meeting is held with all trainers and a researcher, to analyse and describe information ready for transcription. Additionally, an end-term focus group meeting conducted by an external facilitator will allow IMAGE clients to review and discuss their own feelings about the sessions and possible impacts on perceptions and behaviour.

Many of the IMAGE clients have limited access to facilities such as running water and electricity.
Data is coded under categories and related topics and sub-topics in the form of sequential trees as they arise from each session, with accompanying notes on observations, attitudes, quotes and comments. Special note is taken of linkages and relationships between categories and topics. These categories, topics and sub-topics and their relationships emerge largely from the subjective construction of the participants themselves. Each session provides new data that may confirm, modify or contradict previously collected information. The data collected will suggest a number of focused research questions that will be addressed in order to understand the process of change and its possible attribution.

6.2.2.2 Cohort Outcome Study I

**Study Design**
Contemporaneous, village-type and individual-age matched, prospective cohort study among women eligible to join IMAGE.

**Criteria for inclusion in the study**
Eligible women in villages where IMAGE is operating join the programme through a self-selection process in response to house-to-house visits from SEF staff. All such loan recipients recruited in the first year of program operation will be asked to join the study.

Comparison women ("non-loan recipients") are recruited from randomly selected households that are eligible to be involved in IMAGE (on the basis of PWR), but from a village where IMAGE is not operating. Comparison women will be current residents, and will be matched to a loan recipient both on village type and age (in groups of 18-25, 26-35, 36-45, 46-55, over 55 yrs).

**Sample size**
Approximately 500 new loan recipients will be recruited in Intervention villages. This represents programme penetration such that approximately 10% of households in intervention villages will be likely to have an IMAGE client. The recruitment period will be approximately 12 months. Beyond this, SEF will continue to recruit IMAGE clients in order to increase penetration and replace drop-outs, in line with normal SEF practice. However, these indivi-duals will not be recruited to IMAGE Cohort Outcome Study I.

Each loan recipient will be matched to a single comparison woman. The total sample size will thus be double the number of loan recipients recruited during the recruitment period, i.e. about 1000.
Study procedures: Baseline
Loan recipients are enrolled to this study upon recruitment to IMAGE. They are interviewed after initial SEF orientation and application for full group membership (either as part of a newly forming SEF group, or in joining a previously established group). However, interviews are conducted before the receipt of the first micro-finance loan, and before exposure to any Sisters for Life training sessions. Matched comparison women are recruited contemporaneously. Interviews will be conducted within two months of the interview with the matched loan recipient where possible.

Each loan recipient and non-loan recipient is interviewed at this stage with a standardised questionnaire ("the Senior Female Questionnaire"). Additionally, information on the household is gathered at this point in an interview either with the woman, or with the head of the household (using the "Household Questionnaire").

Study procedures: Follow up
Loan recipients and non-loan recipients will be re-interviewed using an adapted version of the above questionnaires at two years after enrolment of the loan recipient to IMAGE. Follow up interviews will be conducted with all women enrolled at baseline, including those who later drop out of IMAGE. An effort will be made to interview women who have moved out of their home during this two years of follow up, but who are traceable at this point.

Data from the IMAGE study is stored and managed in purpose built databases
Outcome variables and analysis

The primary focus of this evaluation is on the direct impacts of IMAGE involvement on loan recipients and their households. Impacts of interest will include changes in measured indicators relating to individual, household and community factors that define the environment in which health related outcomes occur (see Section 3). In addition, core outcomes relating to gender-based violence will be examined.

The primary study analysis will compare differential changes over time in indicators of interest between loan recipients and non-loan recipients. Indicators will include markers of individual agency, GBV, household well-being, power relations and communication, and community social cohesion. Statistical analysis will take account of matching and the community randomised design of the study. Multivariate statistical techniques will be used to adjust for baseline differentials in indicator distribution and potential confounders where appropriate.

6.2.2.3 Key loan recipients and groups

Identification

Key informants and loan groups are identified from monitored SFL sessions and loan centre meetings during SFL Phase I. Key informant and loan group interviews and focus groups will allow IMAGE involvement to be explored in detail, examining both the loan repayment and centre meeting dynamics as well as training session responses. In order to provide research flexibility and to counter presumed drop-out rates, the identification of potential new key informants and/or loan groups will be ongoing throughout the programme. Monitoring will be ongoing during and after the IMAGE intervention.

Selection

At least one key informant will be purposefully selected from each of the centres followed during intensive Sisters for Life monitoring (at least four in total). Additionally, one key loan group within each centre will be selected within each village (at least four in total).
Data collection
Information will be collected from key informants on age, attendance/non-attendance of SFL sessions, leadership qualities, business types and histories and household situation. Key loan groups will be selected within each village and information collected on relationship dynamics (for example, whether the members are relatives or were friends before IMAGE involvement), levels of competition between individual loan recipients, and coping mechanisms and crisis management.

The financial data of key informants and loan groups is monitored and this data will be combined with interviews and observations drawn from both centre meetings and training sessions. The use of this information is to provide a quantitative framework for the qualitative exploration. Data will be collected as part of SEF’s ongoing monitoring and will include business evaluation and impact monitoring processes.

6.3 Cohort Study II:
The impact of IMAGE on young-people living in the households of loan recipients

6.3.1 Main Objectives

To evaluate:
(i) changes in attitudes, knowledge, VCT access, communication and condom use,
(ii) changes in sexual behaviour,
(iii) HIV incidence

among young people living in households of IMAGE clients, and compare this with young people in similar households in villages where IMAGE is not operating.

6.3.2 Methods

6.3.2.1 Cohort Outcome Study II

Study design
Contemporaneous, village-type and IMAGE-client-matched prospective cohort study among young people in the households of women eligible to join IMAGE.
Criteria for inclusion to the study
All individuals of both sexes aged 14 – 35 years who are currently resident members of households of loan recipients and non-loan recipients enrolled to Cohort Study I are eligible for inclusion to Cohort Study II. IMAGE clients falling in this age group are also recruited to IMAGE Cohort Study II.

Sample size
Demographic data suggest that there will be, on average, three individuals in this age group in every two households recruited to Cohort Study I. The total sample size will thus be approximately 750 in each arm of the study (Total 1500).

Study procedures: Baseline
The baseline state for Cohort Study II is as for Cohort Study I. Young people will be interviewed within two months of loan recipient/non loan recipient interviews being conducted where possible.

Interviews will be conducted using a standardised questionnaire ("Young Person's Questionnaire"). Study recruits will also be asked to provide a sample collected from inside the mouth (Oral Mucosal Transudate, or OMT), using a specially designed collection device (OraSure), which is tested for the presence of antibodies to HIV.
**Study procedures: Follow up**

Follow up interviews with young people will be conducted two years after their enrolment to the study, utilising a modified version of the young persons questionnaire. Repeat OMT samples will also be collected at this time.

**Analysis**

The primary focus of this evaluation is to examine the effects of having a participating IMAGE client in the household on the young people who live there. Young people are the population group most vulnerable to new HIV infection. Outcomes of interest will include longitudinally measured changes in knowledge, attitudes, VCT access, communication, condom use, sexual behaviour and HIV infection.

The primary study analysis will compare differential changes over time in relevant indicators between IMAGE-household young people and non-IMAGE-household young people. As with Cohort Study I, statistical analysis will take account of matching and the community-randomised design of the study and multivariate statistical techniques will be used to adjust for baseline differentials in indicator distribution and potential confounders where appropriate.

**6.3.2.2 Key informant households**

A further objective in utilising key informants lies in their potential ability to link IMAGE inputs, and subsequent negotiation by recipients, directly into the context of the household and other household members, particularly young people and spouses. Perceived change in existing intra-household relations, and their possible attribution will be explored from a number of viewpoints. Further, the complex mechanisms of diffusion of attitudinal ‘change’ and its negotiation, accommodation or resistance by individual household members will be explored, and possible linkages into the wider community identified. The households of key informants thus provide an opportunity to use qualitative techniques to evaluate potential impact processes. Appropriate households of key informants, as outlined in Cohort Study I, will be studied in-depth using qualitative techniques seeking to understand processes of change. Interviews will be conducted with spouses/partners and with young people associated with each of the households.
6.3.2.3 PRA project

The knowledge, attitudes and beliefs related to HIV/AIDS, relationships and communication patterns of young people will be explored through a PRA project. The approach allows for very detailed discussion and data collection, and also allows young people to participate in information-gathering. The project will also provide information to examine processes of potential impact of IMAGE.

Approach
Suitable young people will be identified via key informants or other loan recipients from each of the centres being monitored in the four Intervention villages. Other avenues for meeting young people such as chance meetings and networking will also be pursued within what is envisaged as an evolving young persons’ qualitative programme. Once identified and having agreed to become involved in the PRA project, young people will be asked to recruit his/her friends to become involved in the group. How these groups might be gendered will be left to the initial participant to decide. Young people from IMAGE and non-IMAGE households will be included in the PRA project.

Participatory Rapid Appraisal will be run with each group as a series of workshops over a two month period, meeting once a fortnight (total of four meetings per group per village). After completion, those who wish to remain in contact with the programme will be encouraged to do so.

Content
Workshops will be approximately two hours long and there will be refreshments provided. The workshops will be held on a fortnightly basis and reminders will be sent out to participants in the weeks before a workshop. The workshops will seek to generate an improved understanding of:

- Relationships with partners
- Negotiating sex and condoms.
- Discussing sex with parents/relatives,
- Discovering one's HIV status,
- Dealing with pregnancy.

The techniques to be used will include role-plays (which will be video recorded), body mapping, social resource mapping, cause-effect charts and the generation of time-lines.
Analysis and assessment

PRA sessions will be videotaped and observed. Transcriptions and notes will be organized into categories and topics for analysis and will be triangulated with previous sessions, quantitative data and other PRA data to compare whether attitudes and opinions expressed coincide with data from the other evaluation components.

Follow up focus group discussions will begin with the group being shown a videotape of their role-plays. Discussions will be based on the topics brought up in the workshops and how participants responded to exercises.

Individual interviews and focus group discussions will be conducted periodically after the initial PRA sessions to follow changes over time. Finally, individuals will be followed up to assess their continued involvement in youth groups working on HIV-related issues, and their success and challenges within those activities.

6.4 COHORT STUDY III: THE IMPACT OF IMAGE ON COMMUNITIES

6.4.1 Main Objectives

(I) To describe the changing community context in which IMAGE is occurring.

To evaluate:

(II) changes in attitudes, knowledge, VCT access, communication and condom use,

(III) changes in sexual behaviour,

(IV) HIV incidence

among young people living in villages where IMAGE is operating, and compare this with the progress of young people from villages where IMAGE is not operating.
6.4.2 Methods

6.4.2.1 Community profiling

Main objectives

(I) To provide a description of the contextual framework in which IMAGE is being conducted.

(II) To investigate the possible diffusion of IMAGE impacts into the wider community.

Event time-lines, focus groups and PRA techniques will be conducted with informants in each of the study intervention villages. Data will be gathered from traditional leaders, modern authorities and civil society groups. Topics for discussion will include gendered employment opportunities, local and external initiatives such as community development programmes, service provision and reticulation. Ongoing event time-lines will include identification of collective social action. In addition, more general perceptions of ‘village life’ past, present and future will be explored, including perceptions of the IMAGE programme. Interviews will also be conducted with major employers and those involved in the provision of HIV/AIDS education and/or health services. Data collection will be open-ended and reiterative, adopting a ‘logic in practice’ approach, whereby research questions (and possible concomitant theory) are developed and modified via ongoing data collection and evaluation. Extensive literature review will also be conducted including relevant academic papers, village histories, demographic reports, service provision and past/present, informal/formal, employment profiles.
In addition to the above methodologies, baseline and follow up survey data will be used to describe the HIV epidemic among the general population in this rural area of South Africa, and to examine trends in knowledge, attitudes, norms and behaviours relevant to the spread of HIV. Additionally, the data will be used to examine trends in socio-demographics, and to examine household poverty, livelihood strategies, food security, access to credit and savings, asset accumulation and other related factors in this rural area of South Africa.

6.4.2.2 Cohort Outcome Study III

Study design
Village-matched prospective cohort study among young people in the IMAGE study villages.

Criteria for inclusion to the study
Individuals of both sexes aged 14 – 35 years living in randomly selected households from the study villages. Both young people currently staying in the home (the de facto population), and young people who are recorded as “permanent household members”, but who are not currently staying in the home are eligible for Cohort Outcome Study III.

Sampling and sample size
A sampling frame including all households within recognised boundaries of the eight study villages was generated from Participatory Wealth Ranking data. All households in these villages were eligible for inclusion in the IMAGE Study Baseline survey. Households in settlement areas outside village boundaries were not included in the sampling frame. 200 households were randomly selected in each of the eight study villages (total sample size 1600). A household in this study was defined as a group of people who are permanently resident on the same property (or dwelling) and who eat from the same pot of food when staying at home. Within selected households, all individuals aged 14-35 years at the date of interview were eligible for inclusion in the study. Individuals listed as permanent household members were eligible for inclusion, including those household members currently staying away from the home. The total expected sample size, including adjustment for people who refuse and those who we cannot trace, is 3000.
**Study procedures: Baseline**
A survey covering all villages was conducted during the three months prior to IMAGE being made available in the intervention villages. “Household questionnaires” and “Young person questionnaires” were completed in all selected households. Study recruits were asked to provide a sample of Oral Mucosal Transudate (OMT), using a specially designed collection device (OraSure), which is tested for the presence of antibodies to HIV.

**Study procedures: Follow up**
Households and individuals interviewed in the baseline survey will be re-interviewed during a final survey conducted three years after the introduction of IMAGE to Intervention villages. Repeat OMT samples will also be collected at this time.

**Analysis**
The primary focus of this evaluation is to examine the impact of the operation of the IMAGE programme within communities on the population group who are most vulnerable to new HIV infection. As for Cohort Study II, outcomes of interest will include longitudinally measured changes in predictors of sexual behaviour, sexual behaviour and HIV infection. The primary study analysis will compare differential changes over time in relevant indicators between young people in the Intervention and Comparison villages. Statistical analysis will take account of matching and the community-randomised design of the study and multivariate statistical techniques will be used to adjust for baseline differentials in indicator distribution and potential confounders where appropriate.

The IMAGE Study Baseline Survey team presented their work to colleagues at Wits Rural Facility at the end of the survey.
6.5 Routine data collection systems

6.5.1 SEF Monitoring Information

As part of their routine procedures SEF capture information on a number of pre-designed data collection forms. While the primary use of this data is programmatic, the information collected has relevance for the evaluation component of the IMAGE study. In particular SEF collect information on details of loan application, centre meeting attendance and loan repayment details. In addition regular business evaluations and impact monitoring are also conducted. SEF data will provide details on:

- Type of Business
- Size of loan
- Value of business
- Business location
- Current loan cycle
- Duration of SEF involvement
- Loan plans
- Repayment schedule
- Time between loans (cycle length)

6.5.2 Clinic and health service utilisation records

Introduction of Voluntary Counselling and Testing for HIV to the primary health care clinics in the region where the IMAGE study is taking place is an important intervention in its own right and in line with the aims of the South African Department of Health. The records associated with this service, as well as the routine clinic data collection systems, provide a further important source of information that may be analysed with reference to the IMAGE programme.
• IMAGE attempts to influence the risk of HIV infection and gender-based violence through targeting the environment in which they occur.
• The pathways through which IMAGE may positively impact health-related outcomes are likely to be complex and non-linear
• IMAGE has the potential to reach a wide population through high levels of community involvement
• Strengths of the IMAGE study include its integrated approach and its efforts to include best practice methodology from studies of micro-finance programs and HIV prevention initiatives.
• Limitations of the IMAGE study include the likelihood of loss to follow up of cohort study recruits, and the low number of communities involved.
• The IMAGE study is an important attempt to examine complex social processes through the application of multiple data collection and analysis methodologies, in the context of an action-based programme of research and implementation.

The conceptualisation of HIV/AIDS as a medical problem to be dealt with through health sector solutions has resulted in a strong biomedical focus in HIV prevention. HIV/AIDS has strongly challenged this focus, but broadening our approach raises many new challenges, both in designing and evaluating interventions. The IMAGE study is a research programme designed to investigate the potential role of an environmental level intervention in reducing vulnerability to HIV and gender-based violence in South Africa.

7.1 ENVIRONMENTAL INTERVENTIONS

Environmental interventions aim to have a positive impact on health related outcomes by targeting forces that define the environment in which those outcomes occur. Environmental factors of importance in the context of HIV transmission in South Africa include poverty, labour migration and gender inequalities. IMAGE aims to critically engage these issues as a way of enabling individuals to make decisions and take actions that protect them from HIV and GBV.

However, programmes that seek to improve well-being or to change entrenched gender inequalities are complex. Groups that specialise in interventions aimed at
altering these factors (usually NGOs, CBOs, and non-health governmental departments) may not be based in the health sector. They may lack expertise in research design and have only limited information on the epidemiology and spread of HIV/AIDS within communities. Optimum intervention design and testing will be best achieved through partnership between such groups, health specialists and research institutions. Yet such partnerships are easier to describe than to implement. Additionally, the causal pathway between environmental factors and sexual behaviour or HIV incidence is complex and not immediately obvious, making it difficult to convince funders of the need for or relevance of such work.

The benefits of environmental interventions may also be slow to accrue. In the context of a rapidly spreading HIV epidemic it is perhaps not surprising that there is a desire amongst policy makers to be seen to act, to act now, and to see immediate changes as a result of their actions. Such a pressure does not support critical examination of environmental interventions, whose benefits may be diffuse and slow to develop. The evaluation of such programmes is also problematic. Slowly accrued benefits are difficult to capture in research programmes. These limitations may make controlled studies an unfair test since outcome evaluations suggesting limited or no impact on biological outcomes collected after only 2-3 years may persuade policy makers against such programmes. Finally, there are practical difficulties associated with the design and conduct of studies on environmental interventions. Studies may require allocation (or randomisation) of intervention at the level of the cluster (village, town, country, even region). Such studies are logistically challenging and are costly in terms of time, expertise and money.

These factors may reflect why the IMAGE study is one of a limited number of explicit attempts to influence sexual behaviours and reduce vulnerability to HIV infection and gender-based violence through targeting the environment in which they occur. But HIV has posed serious challenges to the way we need to think about the relationship between health and disease in populations. Despite seeing many important advances in our understanding of the basic science, the epidemiology of infection, and novel approaches for the care and treatment of people living with AIDS, there has been a relentless progression of the disease in country after country. Indeed, it is unclear what effect prevention efforts have had in controlling the scale of the pandemic\(^6\). There is a desperate need for research programmes that face the complexities associated with environmental interventions and their study, and contribute towards a greater understanding of the role they can play in the fight against HIV.
7.2 Can IMAGE prevent HIV infections?

For IMAGE to positively impact on sexual behaviour and/or HIV incidence, complex causal webs will need to operate. Unlike many prevention interventions, IMAGE aims to influence the behaviours of those at risk of HIV infection by targeting the environment in which they live. This approach is not without problems. Sustainable welfare benefits of micro-finance programmes may take many years to accrue, while the Sisters for Life training curriculum is a newly developed approach.

However, the framework in Chapter 3 describes potential pathways through which IMAGE may have positive impacts. IMAGE has a number of strengths in terms of its potential to change behaviour and strengthen resistance to HIV. It seeks to engage a large number of households within rural villages, and through this shape reproductive and sexual health decision making within the household unit. Through enrolling many households to the programme and actively encouraging dissemination by programme participants, it is hypothesized that positive impacts may diffuse, spread and influence social norms in the community at large. IMAGE seeks not only to impart knowledge, or to improve welfare, but aims to do these in tandem, potentially strengthening and reinforcing one set of impacts with another. In addition, there are many pathways through which change might occur from the individual, to the household, to the community at large. IMAGE has the potential to affect many such pathways simultaneously, setting it apart from more targeted prevention interventions, such as the syndromic management of STDs, which have a more direct pathway of effect.

Few studies have evaluated the potential for environmental level interventions to be developed as tools for HIV prevention. Yet such interventions have many characteristics that may lend them great strength in this regard. The IMAGE study provides an opportunity to explore the relationships between factors at these many levels.

7.3 Strengths and limitations of the IMAGE study

For any benefits to be identified in a research programme, that programme must be appropriately designed. The design of the IMAGE study has been carefully constructed with reference to limitations and strengths of previous research. Attention has been paid to issues of recall bias, selection bias and interviewer bias. Furthermore, the study aims to capture the complete impact of the programme by following up all women who enroll and capturing
"diffusion" effects in the community at large. To our knowledge this comprehensive design is unmatched elsewhere in assessments of micro-finance programmes. Most importantly, the study will add a new and important contribution to both the poverty alleviation and HIV prevention literatures through its examination of both issues together.

Nevertheless, there are limitations to the design of the programme reported. Firstly, impact will be measured after a maximum of only three years, so only benefits that accrue within this period will be captured. Secondly, longitudinal cohort studies traditionally suffer from problems related to cohort attrition, which are of particular relevance among a highly mobile population. It is likely that a significant number of study recruits will be lost to follow up over the 3 year programme operation, both decreasing statistical power and introducing bias since those who are lost to follow up often differ importantly from those who are not.

When a public health intervention is applied at community level and a randomised trial design is employed then impact analysis of the data must also be at the level of community. For analysis, individual data are summarised to reflect community characteristics. Where communities are paired, as in the IMAGE study, a minimum of six community pairs are required for the application of a suitable non-parametric test. Increasing the number of individuals from whom data is gathered within each community only marginally improves statistical power beyond a threshold. However, the parametric t-test is relatively robust to violations of assumptions of normality and might also be used. Recent high profile HIV prevention studies such as the STD treatment trials in Mwanza, Rakai and Masaka employed this method of analysis after standardising community data for age and sex differences. Due to practical constraints the IMAGE study employs four matched pairs of villages.

Figure 7 suggests that:

- the total sample size required increases with $k$ (the intra-cluster correlation coefficient) sharply after a threshold for each power level,
- the total sample size required is much lower for an indicator that is more common in the population (e.g. found in 30% of those interviewed),
- the three different cohort pairs will have different power to detect changes in indicators since they all employ different expected sample sizes.
When four cluster pairs are employed, the sample size required within each cluster to detect a statistically significant difference on a binary outcome depends on the power required and also on the level of clustering of that outcome (measured by \( k \), the intra-cluster correlation coefficient). We have calculated sample sizes required to detect differences in (A) HIV incidence over 3 years, and (B) a different hypothetical indicator of change that is found in 30% of the population at baseline, with 4 community pairs for different levels of intra-village pair clustering of responses (\( k \)).

Notes: Power given is to detect significance at 5% level. No adjustment has been made for intra-household clustering. (A) For HIV incidence, the calculations assume seroconversion rate in control villages 9% over 3 years, to detect a drop to 4.5% in intervention villages. 20% HIV prevalence at baseline, 20% dropout over 3 years. (B) For theoretical indicator, no other assumption have been made.
The previous calculations suggest that statistical power to detect changes in indicators after three years with a statistical test is likely to be low in all three cohort studies. However, if indeed there is a consistent effect of IMAGE, the picture that we can paint from our data will give a convincing and potentially influential message to the public health world. The result from an appropriately conducted significance test, albeit with relatively low statistical power, will be a small, but helpful contribution to this picture. In line with the IMAGE study approach, we propose to use a number of techniques to maximise the utility of the results collected.

These will include:
- an in-depth evaluation of process and causal pathways,
- triangulation and correlation of indicators of change,
- indicator selection based on the distribution of baseline data and taking into account intra-community clustering,
- analysing baseline data to provide different perspectives on questions of interest within the work.

The IMAGE study emphasises the integration of qualitative and quantitative techniques throughout the work. This conceptualisation, of a rigorously designed programme of evaluation in which multiple analyses, both qualitative and quantitative, will be used to "paint a picture" rather than focussing on hypothesis tests of individual indicators, is in line with the broader goals of the programme. If indeed there is a consistent impact of IMAGE, the study data will provide a potentially influential message to the public health world.

**7.4 Who does the IMAGE study affect?**

The results of the IMAGE study will be of interest to a variety of different stakeholders. The research will contribute towards a critical understanding of the links between poverty, gender-based inequalities and vulnerability to HIV infection. IMAGE brings together perspectives from the health and development sectors, employing pedagogical models rooted in gender studies and health promotion, and evaluation methods framed by epidemiology, economics and social anthropology. On the one hand, the programme is an attempt to generate ‘best-practice models’ for micro-finance organizations and other community-based NGO’s and CBOs operating in high HIV prevalence regions. On the other, the work is an attempt to expand the scope of research questions and interventions strategies engaging public health issues, highlighting the need for a broader development focus.
Finally, the work seeks to explore the need for governments to develop and successfully implement policies and programmes that work effectively between sectors. Policies and procedures that strive for single solutions to complex social problems may not be sufficient. Rather, the IMAGE study seeks to contribute towards an understanding of which combination of strategies, engaging at multiple levels, will foster an effective response to the pervasive health and development challenges faced by communities.

7.5 Conclusion

The IMAGE study is a programme of work that has been designed “from the ground” in rural South Africa. Academic institutions, the Department of Health and Welfare and a poverty-alleviation NGO, each with their very different emphases and restrictions, have worked hand-in-hand to design a programme of work that represents a unique opportunity to examine from many angles the potential for developmental programmes to have a role in preventing HIV infections and gender-based violence. In addition to making an important contribution to scientific knowledge, the work will also see the development of a training manual for micro-finance NGOs wishing to address HIV with their clients, the continual feedback of results to community members, the development of the skills of young African researchers, and a model for partnership between NGO and academic workers.
Appendix 2: Data Collection

An in-depth discussion of issues relating to the data collection in the study are beyond the remit of this monograph. Copies of the 3 primary questionnaires (Household, Young Person, Senior Female) are available on request from RADAR or on the RADAR website (www.ac.wits.za/radar), as are copies of the manuals used to guide fieldwork. However, a number of issues pertinent to the data collection processes are detailed below.

Questionnaire design and piloting
All questionnaires were designed specifically for use in the IMAGE study. However during the design of questionnaires, substantial use was made of the available literature on questionnaire design relating to issues as diverse as household poverty and livelihood strategies, micro-finance impact assessment, sexual behaviour, social capital, gender based violence and a wealth of other fields. A large number of questionnaires were reviewed, and the most relevant, and innovative components of these questionnaires were taken forward for pilot.

The questions that finally made it into the IMAGE study questionnaires, and many more besides were piloted extensively. A number of different settings were used for piloting, including market stalls, hospital waiting rooms and supermarket car parks. However, the bulk of piloting work was done in the village of Welverdiend in the Limpopo Province. The piloting process involved approximately 100 interviews with each of the different questionnaires. The majority of pilot interviews were observed, and extensive structured notes on the reception to and ways of asking questions were taken. Weekly review meetings were used to take the questionnaire development process forward through extensive discussions on, amongst other issues, the relevance, cultural appropriateness, relative value and time for administration of individual questions. From inception to finalisation the process of questionnaire development took about one year. A brief report of the results of piloting work in Welverdiend work is available on request from RADAR (in English and XiTsonga).

Recruitment and training of fieldworkers
All fieldwork involving the 3 primary data collection tools, was performed by locally recruited, female fieldworkers. Fieldworkers were recruited in an open process through advertisements placed in all of the study villages, and were educated to at least matriculant level. All interviews were conducted in the
preferred language of the respondent, which was primarily, but not exclusively, Sepedi.

Primary training on questionnaire administration took the form of a 4 week course, which encapsulated 1 week of HIV/counselling/gender awareness training, 2 weeks of classroom based training on questionnaire administration and 1 week of field based training in a local village that is not part of the main IMAGE study. All fieldworkers were required to pass an assessment before proceeding to interviewing as part of the IMAGE study team.

Fieldworkers in the IMAGE study, and the data they collect, are monitored at all stages of the data collection process. Fieldworkers have a supervisor meeting each week in which they discuss problems and questionnaires are checked, and there are also regular full team meetings to discuss issues coming up in fieldwork.

Ongoing quality assurance
A number of steps have been implemented to ensure a high quality of data reaching data capture and analysis stages. This includes eyeball checking of all questionnaires from the field before acceptance for data entry. All questionnaires are reviewed by the interviewer, by another field team interviewer, and by a “central” checker who is directly involved in the data management process (3 checks). Additionally spot checks and revisit interviews by supervisors ensure that data quality is high, and that results are reproducible.
Every questionnaire from the IMAGE study is checked at least 3 times.
APPENDIX 3 : LABORATORY PROCEDURES

Vironostika HIV Uni-Form II Oral Fluid is an enzyme-linked immunosorbent assay (ELISA) for the qualitative determination of antibodies to human immunodeficiency virus type 1 and/or 2 (anti-HIV-1, anti-HIV-2 and anti-HIV-1 group O) only with oral fluid specimens obtained by using the OraSure collection device. A mixture of HIV-antigens coupled to horseradish peroxidase (HRP) serves as the conjugate with tetramethylbenzidine (TMB) and peroxide as the substrate. Upon completion of the test, the development of colour suggests the presence of antibody to HIV-1, HIV-2 and/or HIV-1 group O, while no or low colour development suggests the absence of antibody to HIV-1, HIV-2 and HIV-1 group O. Specifically, microelisa wells are coated with a mixture of HIV-antigens: HIV-1 p24, HIV-1 gp160, HIV-1 ANT70 peptide, and HIV-2 envpeptide (amino acids 592-603). The assay is indicated as an aid in the diagnosis of HIV-1, HIV-2 and HIV-1 group O infection.

It has been reported that infectious HIV-1 can be isolated from the oral fluid of some infected patients. Oral fluid for HIV-1, HIV-2 and HIV-1 group O testing, or mucosal transudate, is the fluid derived from the passive transport of serum components through the oral mucosa into the mouth. When detectable in oral fluid specimens, infectious virus is present at low levels compared with blood and may be inactivated by salivary inhibitors. The OraSure Specimen Collection Device enhances the flow of mucosal transudate across the mucosal surfaces onto an absorptive cotton pad. Antibodies are among the components in mucosal transudate and OraSure and Episcreen specimens. Oral fluid contains a number of enzymes that degrade antibodies. The OraSure device includes preservatives that are effective in protecting antibodies from degradation.

The assay was carried out strictly adhering to the manufacturer’s guidelines. Briefly, to process the oral fluid specimen, the OraSure specimen vial is centrifuged and specimen is eluted from the collection pad. The eluate is diluted and added to the microelisa wells. Each microelisa well contains an HRP-labelled conjugate sphere of the same HIV-antigen mixture. The specimen diluent, which is added to the wells first, will dissolve the conjugate sphere. Then the test sample or appropriate control containing anti-HIV-1, anti-HIV-2 or anti-HIV-1-group O is incubated in the microelisa wells. With the presence of antibodies to HIV-1, HIV-2 or HIV-1-group O a solid phase antigen/anti-HIV/enzyme labelled antigen complex is formed. Following a wash procedure and incubation with TMB substrate, colour develops which turns yellow when the reaction is
stopped with sulfuric acid. If anti-HIV-1, anti-HIV-2 and/or anti-HIV-1 group 0 is present in the sample, an intense colour develops. However, when the sample is free of anti-HIV-1, no or low colour forms with the addition of substrate.
APPENDIX 4 : DATA STORAGE AND MANAGEMENT

Many of the IMAGE study data collection processes result in the capture of information to computer databases. The IMAGE study survey data is held, and much processing work is done, in Microsoft Access Databases. Survey data is captured by field staff into purpose built databases with an interface designed to as much as possible replicate the data holding form (e.g. questionnaire, or PWR form).

Data capture, as with data collection, is subject to a number of processes designed to minimise errors. While an in depth discussion of these processes is also beyond the remit of this monograph, the primary processes are summarised below:

- Validation rules applied to data capture processes (e.g. if the coded answer to a question can only take the values 1, 2 or 3, the computer database does not allow any other data to be entered)
- Eyeball checking is performed on 20% of data entry. Inconsistencies are referred back to the original questionnaire and data entry person.
- Weekly review of data set contents to establish problems with data entry processes.
- Post-entry logical validation queries are applied to the data sets during and after the data capture process to identify logical problems with captured data. These can range from simplistic queries (for example, identifying records where a male is recorded as taking the oral contraceptive pill), to more complex queries relating data from a number of different questions and data sets. All questionable data is referred back to the raw data.

Data is backed up weekly to CD and all data is password protected.

The aim of the IMAGE study data collection and management process is to develop a fully integrated data set relating to all aspects of the IMAGE study. In part this is achieved by the development of a fully relational database, in which information from one part of the study process can be directly linked to information from another part of the study. Data is encoded so as to ensure it is not possible to link data to an individuals name or household location.

Qualitative data is stored and analysed using Nud*ist.
Appendix 5: Ethical Issues

The study has been approved by ethical committees at both the University of the Witwatersrand, South Africa (Protocol Number M991108, approved 31/01/00), and the London School of Hygiene and Tropical Medicine (Reference number 598, approved 06/09/00). A number of ethical issues were identified during the study design process, and some are detailed below. A more thorough examination of these issues is available on request from RADAR (“Rigor, Reality, Right and Wrong: Ethical Implications in the Design of a large scale HIV prevention study”, James Hargreaves, Oral Presentation at Wits Rural Facility, March 2001).

<table>
<thead>
<tr>
<th>ISSUE</th>
<th>ETHICAL CONCERN</th>
<th>JUSTIFICATION</th>
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<tbody>
<tr>
<td>Is the question of importance?</td>
<td>The study must address an issue of importance to a wider population than that under study.</td>
<td>This study addresses issues that are of widespread importance both in South Africa and beyond. HIV/AIDS is perhaps the most important issue facing South Africa today. There have been widespread calls for the evaluation of HIV prevention programmes that address “environmental” issues that can contribute to HIV transmission.</td>
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<tr>
<td>Control Villages</td>
<td>Is it “fair” to conduct a study in which an intervention thought to be beneficial is held back from some communities so that they might be use for comparison purposes?</td>
<td>The benefits of Micro-finance programmes are not fully understood, in particular with reference to the behavioural outcomes under study in this work. The use of a “control” group strengthens the assessment such that the conclusions that are drawn from the work are much stronger and more likely to be valid. Comparison villages benefit from their involvement in the programme through a guaranteed expansion of services to include these villages at year 3, and in the fast-tracked roll-out of VCT services to these villages.</td>
</tr>
<tr>
<td>&quot;Randomisation&quot;</td>
<td>Is randomizing the provision of such an important intervention “playing god with people’s lives”?</td>
<td>Randomisation was performed to further strengthen the evaluation and reduce bias. This was felt, in fact, the fairest way to assign intervention given that the decision to use control villages had been made and justified as above. Selecting intervention villages randomly removes the potential</td>
</tr>
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72
People should give their consent to be involved in such a programme. All village leaders were approached by SEF and HSDU acting together to explain the programme and its components. Only after presentation in these forums was further work continued. All individuals recruited to the programme give their “informed consent” for their involvement in all parts of the programme.

In the study, individuals will be asked to give a sample that will be tested for HIV but they will not receive the result.

HIV testing was felt to be a hugely important component to the programme, both in its own right as a contextual variable and as an indicator of impact. The results will be stored in such a way as to de-link HIV status information and demographic information. All results will thus be confidential from not only the sample donor, but also all RADAR programme staff. All sample donors are referred to voluntary counselling and testing services in their local clinic, where they can receive their results in an environment where they also receive counselling and the potential for ongoing support.

The study will involve collecting data that may be sensitive, personal and culturally inappropriate for discussion.

Sexual behaviour data is of core importance to answering the research questions set. All interviews are conducted with the full consent of the interviewee, and are completely confidential. All interviews also finish with a c.5 minute “information” session in which issues that have come up during the interview are discussed. Free condoms are distributed at this time. Any misconceptions, e.g. about HIV transmission, that come up in the interview are corrected by the interviewer in this session. Referral sheets, detailing information on other freely available services that may be of importance for particular situations,
### APPENDICES

<table>
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<tr>
<th>Taking a lot of people’s time</th>
<th>Doing the interviews takes time, and time is a valuable commodity, particularly for poor people.</th>
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<tbody>
<tr>
<td>Questioning Young people</td>
<td>Interviews are conducted at the discretion of and most appropriate time for the interviewees. All interviews have been designed to take less than half an hour. While, no renumeration is provided for taking part in the interview process, the “information and free condoms” section of the interview is hoped to make the interview a worthwhile process for those involved.</td>
</tr>
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</table>

Young people are the key target group for information and HIV prevention strategies. 14 years is the youngest age at which an HIV test can be performed without guardian consent in South Africa, and this guideline was incorporated into the fieldwork. Young people may be those that gain most from the end-of-interview information sessions. Interviewers are trained in administering questions to these young people and issues that affect them directly.

e.g. the experience of gender based violence, are also passed on to respondents.
REFERENCES


18. Hargreaves, J.R. et al. Socioeconomic Status and risk of HIV infection in an Urban


63. Welling, K. & Cleland, J. Surveys on sexual health: recent developments and


