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HIV TESTING, TREATMENT AND PREVENTION

GENERIC TOOLS FOR OPERATIONAL RESEARCH



World Health
Organization



Population Council

CONTENTS

ACKNOWLEDGEMENTS	iii
ABBREVIATIONS AND ACRONYMS	iv
INTRODUCTION	1
THE UTILIZATION OF HIV TESTING AND COUNSELLING	6
1. Background	6
1.1 Rationale: why operational research is needed on the utilization of HIV testing and counselling	6
1.2 Definitions and terms for different types of testing and counselling	7
2. Factors and programme strategies	8
2.1 Factors that influence the demand for HIV testing and counselling	8
2.2 Factors that influence the uptake and quality of testing and counselling services	9
2.3 Factors that influence the ethical dimensions of testing and counselling	10
3. Research objectives and questions	11
4. Methods	11
4.1 Study populations and study design	11
5. Variables and survey questions	12
5.1 Variables and survey questions to ask among clients	12
5.2 Variables and survey questions in the Provider Instrument	14
HIV STIGMA AND DISCRIMINATION	19
1. Background	19
1.1 Rationale: why operational research is needed on HIV stigma and discrimination	19
1.2 Manifestations and patterns of HIV stigma and discrimination	19
2. Factors and programme strategies	20
2.1 The influence of stigma on HIV testing, treatment, disclosure and prevention	20
2.2 Factors that influence levels and patterns of HIV stigma and discrimination	21
2.3 Programme strategies to reduce stigma and discrimination	21
3. Research questions	22
4. Methods	22
4.1 Study populations and study design	22
4.2 Measuring HIV stigma and discrimination	24
5. Variables and survey questions	25
ADHERENCE TO ANTIRETROVIRAL THERAPY	31
1. Background	31
1.1 Rationale: why research is needed on adherence to antiretroviral therapy	31
1.2 Definitions: how researchers define adherence to antiretroviral therapy	31
1.3 Patterns and levels of adherence	32
2. Factors and programme strategies	32
2.1 Factors that influence adherence to antiretroviral therapy	32
2.2 Interventions and programming to support adherence	33
3. Research objectives and questions	34

4. Methods	36
4.1 Study populations and study design	36
4.2 Methods and measures: an overview of the literature	36
4.3 Recommended methods and measures	37
5. Variables and survey questions	38
5.1 Variables and survey questions about adherence in the Adherence Module of the Client Instrument	38
5.2 Variables and survey questions about factors that influence adherence	41
5.3 Variables and survey questions for key informants working in the health facility	43
5.4 Variables and survey questions for providers	43

HIV PREVENTION IN THE CONTEXT OF SCALED-UP ACCESS TO HIV TREATMENT 47

1. Background	47
1.1 Rationale: why research is needed on HIV prevention among those receiving ART	47
2. Factors and programme strategies	47
2.1 Factors that influence HIV prevention in the context of scaling up treatment	47
2.2 Programme strategies related to HIV prevention in the context of treatment	49
3. Research objectives and questions	50
4. Methods	51
4.1 Study populations and study design	51
4.2 Measuring sexual risk behaviour	51
5. Variables and survey questions	52
5.1 Variables and survey questions related to prevention among individuals living with HIV	53
5.2 Additional variables and questions for research on prevention	54
5.3 Variables and survey questions related to prevention for health care providers	55

Client Instrument Document

Provider Instrument Document

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ABBREVIATIONS AND ACRONYMS

AIDS	Acquired immunodeficiency syndrome
ACTG	AIDS Clinical Trials Group
ART	Antiretroviral therapy
ARVS	Antiretroviral (medicines)
BCC	Behaviour change communication
BSS	Behavioural Sentinel Surveillance
CDC	United States Centers for Disease Control and Prevention
DAART	Directly administered antiretroviral therapy
DHS	Demographic and Health Survey
DOT	Directly observed treatment
DOTS	Directly observed TB treatment, short course
FHI	Family Health International
HAART	Highly active antiretroviral therapy
HIV	Human immunodeficiency virus
IDU	Injecting drug use/user
IEC	Information, education and communication
M&E	Monitoring and evaluation
MEMS	Medication event monitoring system
MERG	Monitoring and Evaluation Reference Group of UNAIDS
MSM	Men who have sex with men
NNRTI	Non-nucleoside reverse transcriptase inhibitor
OR	Odds ratio
PMTCT	Prevention of mother-to-child transmission (of HIV)
PLHA	People living with HIV or AIDS
RCT	Randomized controlled trial
STD	Sexually transmitted disease
STI	Sexually transmitted infection
TASO	The AIDS Support Organization (Uganda)
TB	Tuberculosis
UNAIDS	Joint United Nations Programme on HIV/AIDS
UNICEF	United Nations Children's Fund
USAID	United States Agency for International Development
VAS	Visual analogue scale
VCT	Voluntary counselling and testing
WHO	World Health Organization

INTRODUCTION

GENERIC TOOLS FOR OPERATIONAL RESEARCH ON HIV

1. RATIONALE

The combined efforts of countries and international partners have resulted in substantial advances in HIV treatment and prevention. Nonetheless, access to key HIV services remains low in many settings around the world, and there are still major research gaps about the best way to expand HIV testing, prevention and treatment, especially in resource-limited settings. The World Health Organization (WHO) has endorsed the “learning by doing” approach, which advocates that public health strategies to scale up HIV treatment and prevention services be continuously reviewed, evaluated and revised, so that the results of research can inform programmes as quickly as possible (WHO 2006). Along with monitoring and evaluation, operational research is a central component of the process of gathering and analysing data to inform HIV programmes and policies.

There are many different definitions of operational research (WHO and the Global Fund 2008), and here, we use a pragmatic definition of operational research as “the science of better” or, more specifically, as research designed to improve the performance of programmes and policies. This volume focuses on health services and is, therefore, addressed to programme managers and researchers with an interest in conducting operational research to inform HIV policies, programmes and services.

While numerous instruments have been developed for operational research on HIV, there have been few efforts to review what is known about existing data collection tools or to help researchers select among the many tools that are available. The multiplicity of tools and approaches hinders efforts to track progress in providing services for testing, treatment and prevention. The lack of standardized approaches to data collection also hampers comparisons across settings, limiting the potential to draw lessons about how different models of service provision function in the field. To address this gap, in 2006, the World Health Organization’s HIV Department initiated a project to develop generic tools for operational research on HIV. These tools are designed for data collection on HIV testing, treatment and prevention programmes in multiple settings. They are called generic because, while they are standardized, they lend themselves to adaptation to particular country situations.

2. DESCRIPTION OF THE GENERIC TOOLS PROJECT

The Generic Tools project is part of WHO’s broader efforts to facilitate operational research on HIV testing, treatment and prevention. To identify the information needed to improve HIV programmes, the HIV Department of WHO held international meetings, multi-stakeholder consultations and local workshops, and reviewed the evidence and the availability of data collection tools. These activities highlighted a number of research questions that were amenable to operational research, had relevance in diverse settings, and had the potential to improve programmes and strengthen the evidence base for policies. These research questions are grouped under the following four broad topics, which correspond to the four substantive chapters in this volume:

- 1. *The utilization of HIV testing and counselling.*** In particular, what are the barriers and facilitators to the uptake of HIV testing and counselling? How do different service provision models influence the uptake and quality of services? And, what are the ethical implications of practices related to consent, confidentiality and counselling?
- 2. *HIV stigma and discrimination.*** What are the consequences of disclosure, including patterns and levels of HIV stigma and discrimination? To what extent are HIV stigma and discrimination associated with the utilization of health services?
- 3. *Adherence to antiretroviral therapy.*** Specifically, how can researchers measure adherence and the factors that influence adherence? What are levels and patterns of adherence in different settings? And, how can programmes support adherence?
- 4. *HIV prevention in the context of scaled-up access to HIV treatment.*** What are the levels and patterns of high-risk behaviours among patients receiving HIV treatment? Does access to antiretroviral therapy influence risk behaviour and perceptions of the risks of HIV?

These research questions represent a first phase of work in this area, to be complemented by others as resources become available.

3. DEFINITIONS AND TERMINOLOGY

Because the words “topics”, “questions” and “tools” have multiple meanings that can lead to confusion, we propose to use these terms as follows. Topics refer to the four topics identified by the chapter titles, noted above. Questions may refer to either research questions or to items in a questionnaire that respondents are asked during an interview (survey questions). Throughout this volume, we have tried to use specific wording to distinguish between the two. The survey questions are clustered together to form modules, and the modules combine into two main research instruments: a Client Instrument and a Provider Instrument. The word “tools” refers to the complete set of literature reviews, research questions, methodological recommendations, variables and instruments provided in this volume for each of the four selected topics.

4. APPROACH AND METHODOLOGY

The research questions formulated in this volume can be investigated through various study designs, but the volume focuses primarily on health facility-based, cross-sectional survey research. When information at more than one point in time is desirable, researchers can conduct repeated cross-sectional surveys or use the instruments with longitudinal study designs. In most cases, the study populations for data collection envisioned by these chapters include clients and providers at health facilities; however, the chapters suggest ways to include study populations outside the clinic, such as non-users of services, when such comparisons are needed. Researchers who would like more detailed suggestions for designing operational research projects on HIV may find it helpful to consult the publication entitled, *Designing HIV/AIDS intervention studies: an operations research handbook*, published by the Population Council (Fisher et al 2002).

While simple survey designs facilitate the conduct of research, it is often desirable to triangulate multiple sources of information and to combine different approaches to data collection. For example, qualitative methods provide an important complement to quantitative surveys, and it is recommended that they be included in the design of operational research whenever possible. Qualitative methods can elicit respondents’ perspectives on key topics and provide broad insights into the situations that are investigated. In this volume, the qualitative component is limited to some open-ended questions in the Client and Provider Instruments. Further use of qualitative methods is encouraged, however, including semi-structured key informant interviews, observations at health facilities, in-depth interviews, focus groups and textual analyses of important documents, such as guidelines or media reports. For more guidance, we recommend: *Qualitative research methods: a data collector’s field guide*, published by Family Health International (Mack et al. 2005).

5. HOW THIS VOLUME WAS PUT TOGETHER

The Generic Tools volume is the result of the collective efforts of many individuals. During the first phase of the work, a team of researchers reviewed the published and unpublished literature on each selected topic, summarized the evidence, compiled available instruments, took stock of existing data collection approaches and identified the essential information needed for operational research on HIV. In parallel with this process, the WHO held several international consultations with researchers, managers and country representatives to discuss research priorities in the field of HIV. Subsequently, a group of experts drafted chapters summarizing the evidence on the four selected topics. These chapters formulated priority operational research questions, recommended preferred approaches to data collection and included draft research instruments for data collection. The Population Council collaborated closely with WHO on this phase of the work. After the four chapters were drafted, they were extensively revised to produce the consolidated set of tools and instruments included in this volume.

While the organization of the four chapters varies, they all share a common core structure, as follows:

1. A background section that spells out the rationale for conducting operational research on the selected topic, based on a review of the literature;
2. A summary of the literature concerning what is known about the factors that influence the key outcome;
3. A section that formulates the operational research questions to be addressed;
4. A methodology section about study populations and study design;
5. A discussion of variables and survey questions/questionnaire items.

This volume also includes two data collection instruments that address the research questions developed in the four chapters. The first instrument is designed to be used with clients at health facilities, while the second instrument is designed for use among health care providers. Each instrument includes at least one module that corresponds to each of the four chapters. As a result, the full instruments are very long, and it is clearly neither feasible nor desirable to administer them in full. To help researchers select the sections that are most relevant to a given research project, the instruments are organized into modules that correspond to different chapters. Much effort was invested to maximize consistency, minimize redundancies, and simplify skip patterns in order to enable researchers to keep only those sections that are most pertinent to their project. Even within individual modules, however, researchers may need to identify which sections to include and which to omit. A detailed description or “map” of the Client Instrument is provided at the end of this introduction to help researchers select the appropriate sections. Electronic versions of the instrument are also provided on the WHO website.

Although the full instruments in this volume have not been subjected to a formal validation process, they are based on a number of recognized instruments that have been validated or at least field-tested. For example, previous versions of the Testing and Counselling Client and Provider Modules were used in the Multi-country African Testing and Counselling (MATCH) study, coordinated by WHO in four African countries. The Disclosure, Support and Stigma Modules in the Client and Provider Instruments are based on validated instruments in the literature, the field testing experience of the Horizons Program/Population Council, and recommendations of the USAID-convened Interagency Stigma and Discrimination Indicators Working Group. The Adherence Module includes survey items that were part of several research projects recently conducted by the French National Agency for Research on AIDS (ANRS, Agence Nationale de Recherche sur le Sida), including the VESPA survey on HIV-positive individuals in France, the EVAL survey on access to antiretroviral therapy in Cameroon and the MANIF2000 cohort of drug users in France. The Prevention Module is based on well recognized instruments that have been widely used for population-based HIV surveys, including those conducted by the Centers for Disease Control and Prevention and by the Demographic and Health Surveys. While the instruments in this volume are expected to perform well in the field, it is important for researchers to pilot and pre-test them, in order to assess whether they are appropriate to the context in which they will be used. Improved versions are planned on the basis of further use in the field.

6. HOW TO USE THE CHAPTERS AND INSTRUMENTS

Researchers should engage in a careful preparatory phase of work before using the operational research tools presented in this volume. They will need to assess the situation being investigated, identify the specific problem to be addressed, refine the research questions, select the most appropriate study design, define the study population(s), design a sampling plan, develop field procedures and anticipate how they will analyse their data. The chapters in this volume can serve as a basis for such discussions, but they are not fully formed research protocols or simple recipes to be applied. Other steps, both technical and strategic are necessary. Regarding technical content, researchers may find it useful to consult the publication entitled, *Framework for operations and implementation research in health and disease control programs*, a document designed for Global Fund-supported operational research programmes (The Global

Fund 2008). In addition, WHO encourages researchers to use a multi-stakeholder process that involves researchers, national programme managers, those who support research and those who may use the results. Researchers can find advice about this phase of work in the brochure entitled, *Conducting operational research: strategic and managerial guide for applicants* (WHO 2007). Other preparatory tasks may include the following:

- ▶ Conduct a situation analysis or rapid assessment to summarize what is known about the selected topic in the country. This will be the basis for formulating the research questions to be addressed through operational research, discussing the feasibility and trade-offs of different study designs and deciding how to design sampling plans and field procedures.
- ▶ Develop a multi-stakeholder process to commission the situation analysis, discuss the results, and foster a common approach to the project.
- ▶ Conduct formative research in order to gain information about the context and gather locally appropriate terminology.
- ▶ Adapt, translate, field-test and revise the instruments. Include country-specific information in the instruments as needed, by revising the survey questions and the response categories.
- ▶ Combine these tasks with training members of the research team.
- ▶ Secure ethical clearance for the research and adapt the informed consent sections of the instruments (see the WHO Research Ethics website for guidance and useful documents on ethical clearance at www.who.int/rpc/research_ethics/en/.)

The instruments presented in this volume have been extensively revised, but they would benefit from further improvements based on additional field experiences in different settings. WHO is planning to disseminate these tools and encourage their use in countries around the world, with the goal of regularly updating, improving and possibly expanding them to address other topics on which further evidence is needed.

The operational research section of the WHO HIV Department website includes electronic versions of the chapters and instruments, information about operational research activities, as well as links to instruments and email addresses. Researchers who use these tools in the field are urged to share their experiences and suggestions by going to the following link: <http://www.who.int/hiv/topics/operational/generic>.

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DETAILED CONTENTS (OR "MAP") OF THE CLIENT INSTRUMENT

MODULE AND SUB-SECTION	SUB-SAMPLE	QUESTION NUMBERS	NEVER TESTED OR DECLINED TO SAY	TESTED, WITH NEGATIVE OR UNKNOWN STATUS	TESTED POSITIVE AND WILLING TO DISCLOSE
<i>Sociodemographic Module</i>					
Sociodemographics	All respondents	2.1–2.15	✓	✓	✓
<i>Testing and Counselling Module</i>					
HIV testing: filter questions	All respondents	3.1–3.3	✓	✓	✓
First HIV test	Tested more than once	3.4–3.10		✓	✓
Most recent test	Have tested, ever	3.11–3.23		✓	✓
Pre-test services and experience	Have tested, ever	3.24–3.28		✓	✓
Consent	Have tested, ever	3.29–3.37		✓	✓
Results of HIV test	Have tested, ever	3.38–3.41		✓	✓
Post-test services	Received results	3.42–3.47		✓	✓
Confidentiality	Received results	3.48–3.49		✓	✓
HIV status	Received results	3.50–3.51		✓	✓
HIV-negative or indeterminate results	Results negative or indeterminate	3.52–3.54		✓	
HIV-positive results	HIV+	3.55–3.56			✓
Follow-up care and support	HIV+	3.57–3.63			✓
Non-user, attitudes and knowledge	Never tested	3.64–3.83	✓		
General knowledge and attitudes about testing	All respondents	3.84–3.94	✓	✓	✓
<i>Disclosure, Support and Stigma Module</i>					
Disclosure	All respondents	4.1–4.6	✓	✓	✓
Stigma — negative judgements, fear of contact and enacted stigma	HIV- and status unknown	4.7–4.14	✓	✓	
Disclosure to others, HIV-positive	HIV+	4.15–4.23			✓
Reactions to the disclosure of HIV-positive status	HIV+ who disclosed to others	4.24–4.31			✓
Experience with stigma and discrimination	HIV+	4.32–4.42			✓
Support	HIV+	4.43–4.51			✓
<i>Adherence Module</i>					
Antiretroviral therapy	Receiving ART	5.1–5.6			✓
Social support	Receiving ART	5.7–5.18			✓
Access	Receiving ART	5.19–5.22			✓
Food security	Receiving ART	5.23–5.24			✓
Health status	Receiving ART	5.25–5.26			✓
Perceived side-effects	Receiving ART	5.27–5.34			✓
Antiretroviral therapy regimen (prescribed doses)	Receiving ART	5.35			✓
Adherence over the past three days	Receiving ART	5.36–5.37			✓
Adhering on weekends	Receiving ART	5.38–5.39			✓
Adherence over the past one month	Receiving ART	5.40–5.46			✓
Treatment interruption	Receiving ART	5.47–5.49			✓
Changes in adherence over time	Receiving ART	5.50–5.54			✓
<i>Prevention Module</i>					
Time since diagnosis and ART initiation	All HIV+ respondents	6.1–6.3			✓
Sexual activity and partners	All HIV+ respondents	6.4–6.8			✓
Regular partner relationships	Sexually active HIV+	6.9–6.17			✓
Non-regular partner relationships	Sexually active HIV+	6.18–6.24			✓
Commercial sex	Sexually active HIV+ males	6.25–6.29			✓
MSM	Sexually active HIV+ males	6.30–6.38			✓
Concurrency	Sexually active HIV+	6.39			✓
Fertility intentions and family planning methods	HIV+ with regular partner	6.40–6.44			✓
Knowledge and attitudes related to HIV and ART	All HIV+ respondents	6.45–6.49			✓
Knowledge of people infected with HIV	All HIV+ respondents	6.50–6.52			✓
Treatment optimism	All HIV+ respondents	6.53			✓
<i>Alcohol and Drug Module</i>					
Alcohol use	All HIV+ respondents	7.1–7.2			✓
Drug use	All HIV+ respondents	7.3–7.12			✓

CHAPTER 1

THE UTILIZATION OF HIV TESTING AND COUNSELLING

1. BACKGROUND

1.1 Rationale: Why operational research is needed on the utilization of HIV testing and counselling

While there is consensus that knowledge of HIV status should be universal and that rapid scale-up of testing is needed at the global level, there are debates about the best way to expand testing and counselling for HIV. Before treatment became available, the possibility that routine testing might lead to adverse consequences for individuals seemed to outweigh the public health benefits of people knowing their status; consequently, there was little support to expand testing other than through client-initiated testing (commonly known as Voluntary Counselling and Testing). With the availability of treatment, however, the debate has shifted. The exceptionalism that characterized public health responses to HIV — whereby measures such as routine testing and notification, widely practiced for other diseases, were not acceptable for HIV — came to be less defensible (Bayer 1991).

Scaled-up testing has been increasingly advocated both as a gateway to treatment and prevention and as a way to “normalize” and destigmatize HIV (De Cock and Johnson 1998; De Cock et al. 2006; Koo et al. 2006). Research showing that screening for HIV is cost-effective (Bozzette 2005) bolstered the position of those in favour of expanding testing programmes, and there have been calls to incorporate HIV testing and counselling into health services such as prenatal care, care for sexually transmitted infections (STIs), hospitalization and even general primary care. Mathematical models suggest that universal testing followed by immediate antiretroviral therapy for all individuals who test positive could, in theory, reduce new HIV cases by 95% within 10 years (Granich et al. 2008). This analysis has re-energized the debate about the desirability and feasibility of rapidly scaling up testing. It has also highlighted the important research gaps that remain about the best way to expand testing and counselling. The need for operational research is especially acute in resource-limited settings where health systems are weak, in low-prevalence epidemics where key populations at higher risk are hard to reach and in settings where there are particular concerns about protecting individual rights as testing becomes routinized.

Barriers and facilitators to uptake of testing and counselling

One important research gap is the need to understand more about the barriers to the uptake of testing. Around the world,

the proportion of the population who know their HIV status is generally low. In 23 countries that conducted Demographic and Health Surveys between 2005 and 2007, the proportion of adult women who reported having ever been tested and received their results ranged from a low of 2% in Niger to a high of 45% in Ukraine; the median was about 11% for women and 10% for men, and the figures were slightly lower for countries of sub-Saharan Africa (9% of women and 8% of men) (WHO 2008). Even in more developed countries, such as the United States of America, an estimated 20% to 30% of HIV-positive individuals are unaware of their serostatus (Glynn and Rhodes 2005). Such low utilization of testing and counselling indicates that obstacles are considerable, and programmes need a better understanding of how to overcome them.

In recent years, numerous projects have tried to expand access to both client- and provider-initiated testing, through routine testing in prenatal care programmes, home-based testing, free-standing testing and counselling centres, and national campaigns to encourage key populations at higher risk to be tested. The diversity of testing models underscores the need for comparative analyses of how different policies and programmes operate, how they affect the uptake of testing, whether uptake is accelerated when treatment becomes available, to what extent stigma acts as a barrier to testing and, conversely, whether expanded testing increases awareness and reduces stigma.

Changes in the provision of testing and counselling in resource-limited settings

Operational research is also needed to examine how different models of testing and counselling affect quality of care, health outcomes and patient rights. There are wide variations in the quality and acceptability of different models of testing and counselling around the world. Differences in the availability and organization of human and financial resources affect the quality of counselling. In resource-limited settings, staffing constraints, overloaded facilities and ambivalence among providers often result in insufficient counselling. And in many settings, questions have been asked about the usefulness of pre-test counselling at health facilities, with some observers recommending that it be omitted altogether (Koo et al. 2006). It is unclear whether the omission of pre-test counselling facilitates testing by eliminating a possibly cumbersome practice or whether it diminishes the quality of testing services because clients do not receive needed advice

or information. Understanding the issues surrounding counselling represents a major challenge for the utilization of testing, and more evidence is needed to inform guidelines regarding pre- and post-test counselling, and to tailor requirements to the particular type of testing, whether client- or provider-initiated.

Another research gap is the effect of different models of HIV testing and counselling services on sexual risk behaviour, because results of studies have not been consistent. On the one hand, studies from Kenya, Trinidad and Tobago and the United Republic of Tanzania suggested that testing and counselling could have a beneficial effect on prevention behaviour among couples who were counselled together (The Voluntary HIV-1 Counseling and Testing Efficacy Study Group 2000). A meta-analysis of seven studies from developing countries published between 2000 and 2005 found that testing and counselling was associated with a significant but moderate decline in unprotected sex (Denison et al. 2008). Recent research from Uganda suggests that appropriate provision of testing and counselling can lead to adopting safer behaviour among HIV-positive individuals (Bunnell et al. 2006). On the other hand, the meta-analysis mentioned above did not find a decline in the number of sex partners among HIV-positive individuals or serodiscordant couples, and studies from the United States and Zimbabwe have reported that high-risk sex increased following rapid HIV testing among men who tested negative (Metcalf et al. 2005; Corbett et al. 2007). Thus, the evidence supports both caution and optimism about the effect of HIV testing on sexual risk behaviour, and more research is needed to determine what type of service delivery or package of services maximizes the preventive effects of testing and counselling while minimizing any potential negative consequences.

Ethical dimensions of testing and counselling

Last but not least, operational research is needed to address the ethical dimensions of HIV testing and counselling practices. Recommendations to expand testing raise numerous questions about how to protect public health while safeguarding individual rights and minimizing the potential stigma, discrimination and violence that may follow disclosure of HIV-positive status (Maher et al. 2000; UNAIDS Reference Group on HIV/AIDS and Human Rights 2005; Rennie and Behets 2006). These questions are especially important in settings where HIV is found predominantly among marginalized groups, such as sex workers, men who have sex with men or injecting drug users. Different models of testing may require different strategies to ensure informed consent and confidentiality. Research is needed to examine the circumstances under which consent is obtained, the extent to which health services protect confidentiality in different settings, and whether referral, treatment and prevention services are provided after clients receive their test results.

Special attention needs to be directed to fear of stigma and discrimination, reportedly one of the main obstacles to the use of HIV services. Comparisons across settings can help contribute to a better understanding of how stigma varies from setting to setting. One important hypothesis to examine relates to the influence of the epidemiological context. Stigma and

discrimination are generally thought to be higher in settings where HIV is concentrated among marginalized populations such as injecting drug users, sex workers or men who have sex with men. Systematic evidence is, however, scant. One comparative study in low (Viet Nam) and high prevalence settings (Ethiopia, the United Republic of Tanzania and Zambia) found more commonalities than differences in the forms and levels of HIV stigma and discrimination (Ogden and Nyblade 2005). This underscores the need for better documentation of the links between measures of stigma and contextual factors.

1.2 Definitions and terms for different types of testing and counselling

The terminology regarding testing has evolved in response to changes in policies and in the debates surrounding HIV testing, treatment and prevention. In 2007, the World Health Organization (WHO) and the Joint United Nations Programme on HIV/AIDS (UNAIDS) issued a publication entitled, *Guidance for Provider-Initiated Testing and Counselling in Health Facilities*, which built on earlier consultations and policy statements (WHO and UNAIDS 2007). Just under a year earlier, the Centers for Disease Control and Prevention (CDC) had called for routinely testing people aged 13 to 64 years and for simplifying the process of obtaining consent (CDC 2006). In a number of countries around the world, policies have also shifted towards increasing access to HIV testing. The 2007 WHO-UNAIDS guidance recommends that health care providers advise patients to take an HIV test as a standard part of medical care in the following situations: for any patients exhibiting signs that may be related to HIV infection; for all patients attending health facilities in settings with generalized HIV epidemics; and, in settings with low HIV prevalence, for patients who are seen at certain types of health facilities, such as those providing services for tuberculosis or STIs.

The WHO-UNAIDS guidance document seeks to avoid the potential confusion of earlier terminology about “opt-in” and “opt-out” testing in medical settings. It also aims to prevent possible misunderstandings about the word “routine”, which can mean offering testing to all patients, but has sometimes been used to refer to “routinely” testing without informing patients or seeking their consent. The new formulation distinguishes between two types of HIV testing, both voluntary:

- ▶ **Client-initiated HIV testing and counselling** (commonly known as Voluntary Counselling and Testing or VCT) involves individuals actively seeking HIV testing and counselling. Client-initiated HIV testing and counselling is conducted in a wide variety of settings including health facilities, stand-alone facilities outside health institutions, mobile services, community-based settings and even people's homes.
- ▶ **Provider-initiated HIV testing and counselling** refers to HIV testing and counselling recommended by health care providers to patients attending health care facilities. Providers are to recommend testing as a standard component of medical care when patients exhibit clinical manifestations that might result from underlying HIV infection, at health facilities that

serve populations where the risks of exposure to HIV infection are thought to be considerable and to all patients in high prevalence settings. While this type of testing can be routine under certain conditions, it should never be mandatory or compulsory.

2. FACTORS AND PROGRAMME STRATEGIES

The socio-behavioural factors that influence HIV testing and counselling can be assessed by gathering information about users, providers, their interactions and the context of those interactions. These factors can be grouped as follows:

- ▶ **those related to the demand for testing and counselling**, including access to services and expectations regarding care, risk perceptions, attitudes and behaviours regarding disclosure, stigma and gender;
- ▶ **those related to the provision and quality of testing and counselling services**, including providers' abilities and attitudes, institutional support for providers, the resources available in health facilities and interactions around testing and counselling;
- ▶ **the ethical dimensions of testing and counselling**, including practices around consent and confidentiality that affect patients' rights, and clients' attitudes towards consent, confidentiality and counselling.

The way in which these factors influence the uptake and quality of testing services depends on the type of epidemic. For example, in low prevalence settings, obstacles such as access and stigma may disproportionately affect key populations at higher risk, such as sex workers, men who have sex with men and injecting drug users. (While earlier formulations referred to "risk groups", more recent literature refers to "most-at-risk-populations" (MARPs) or key populations at higher risk.) Concerns about scaling up HIV testing are heightened in settings where such groups are marginalized from a legal, economic or social point of view. The next chapter in this volume identifies some key operational research questions related to HIV stigma and discrimination and proposes a tool to collect the data needed to address those questions. These materials can be adapted to address the issues that are most relevant to the particular populations at higher risk in a given setting.

2.1 Factors that influence the demand for HIV testing and counselling

Barriers to access

Studies of health care utilization repeatedly document the importance of barriers to access, including distance to a facility, cost of services, transportation and time constraints. That these factors may influence the decision to seek HIV testing as well as the decision to return for results is suggested by global statistics showing low use of testing services, especially in resource-limited settings. Before rapid tests became widely available, a number of

studies also showed that a substantial proportion of individuals who were tested did not receive their results. In some settings where the percentage of the population tested reached 80% to 90%, the percentage who returned for results hovered around 60% (Cartoux et al. 1998; Coovadia 2000). Such discrepancies have been documented in populations as diverse as clients at STI clinics in the United States, male factory workers in Zimbabwe and women receiving antenatal care services in Côte d'Ivoire, Kenya, South Africa and Zambia (Obermeyer and Osborn 2007). Rapid tests, testing at convenient locations and times, as well as home-based testing have the potential to reduce these obstacles (Wolff et al. 2005), and operational research can document how different models for providing testing and counselling may or may not increase access and uptake.

Reluctance to acknowledge risk

An important barrier to testing is the reluctance of individuals to acknowledge that they are at risk, as documented in a recent literature review (Obermeyer and Osborn 2007). In settings as diverse as Brazil, Canada, Ethiopia, Thailand, the United Kingdom, the United Republic of Tanzania and the United States, individuals' behaviours and risk perceptions are frequently at odds with objective measures of risk and with professional recommendations (Moatti and Souteyrand 2000; Obermeyer 2005). The reasons for this discrepancy are complex. Risk perceptions are shaped by social and psychological factors; the meaning of HIV tests is not simply a matter of information about serostatus; and the decision to be tested is tied to relationships, emotions and the resources that individuals have for dealing with the diagnosis (Antelman et al. 2001; Klitzman and Bayer 2003). Research can contribute to uncovering how these complicated social factors play out in particular contexts.

Fear of stigma, discrimination and violence

Often the explanation for why people do not take HIV tests or return for results is fear. People may fear the life-threatening nature of HIV infection, as well as the negative social consequences that may accompany a diagnosis, such as rejection by loved ones, loss of a job or housing, discrimination and even physical violence. Fear of stigma and discrimination is reported to be a major barrier to testing in countries as diverse as Botswana, Ethiopia, Ghana, India, Indonesia, South Africa, Thailand, Uganda, the United Republic of Tanzania, the United States and Zimbabwe (ICRW 2002; Day et al. 2003; Herek et al. 2003; Hutchinson et al. 2004; Kalichman and Simbayi 2003; Weiser et al. 2006). In view of such fears, some studies suggest that clients' perceptions of how confidentiality is handled in a health facility may also influence their willingness to be tested (Fylkesnes and Siziya 2004).

Fear of stigma, discrimination and violence also affects the decision to disclose HIV status (Yoshioka and Schustack 2001; Medley et al. 2004). Rates of partner disclosure by those living with HIV vary widely from study to study, but they are generally low, typically ranging from one fifth to slightly more than one-half (Heyward et al. 1993; Kalichman and Nachimson 1999; Nebie et al. 2001; Maman et al. 2003). Solid evidence about the adverse consequences of HIV disclosure is still limited; however some studies have documented negative reactions from family, friends,

employers and the community in 3% to 15% of cases (Gielen et al. 2000; Medley et al. 2004; Passin et al. 2006). Evidence suggests that discrimination is also a problem in health care settings, and some observers have noted that health workers may discourage testing if they discriminate against HIV-positive patients by treating them differently, using excessive precautions or withholding appropriate care (Bishop et al. 2000; Foreman et al. 2003; Paxton et al. 2005).

Few studies have explored the effect of stigma on HIV testing using quantifiable measures, and most of these consist of cognitive measures (e.g. what percentage of a given population hold particular negative beliefs about people living with HIV) rather than measures of actual attitudes or behaviours (Parker and Aggleton 2003; Deacon et al. 2005; Nyblade 2006). In order to have a better understanding of the role of stigma and fear of discrimination as a deterrent against testing and as an adverse consequence for those who disclose their HIV status, there is a need for well designed measures of stigmatizing attitudes and behaviours and for better evidence about the extent of stigma and discrimination in health facilities and in the broader society. To that end, the next chapter in this volume summarizes the evidence on HIV stigma and discrimination, formulates possible operational research questions and suggests approaches to measurement in different settings.

Gender

Gender is another factor that powerfully shapes motivations to test and the consequences of testing. Evidence suggests that women and men experience different barriers to access, perceive risks differently and fear different sorts of discrimination. In some settings, men tend to underestimate their risk for HIV infection more frequently than do women, despite reporting more high-risk behaviours (Riess et al. 2001). Women often have more fears about testing than men (Sahlu et al. 1999; Stein and Nyamathi 2000). The negative consequences of disclosure are more frequently documented for women, and several studies show that it is among pregnant women that fears of abuse as a possible consequence of testing positive for HIV are most manifest (Temmerman et al. 1995; Coulibaly et al. 1998; Gielen et al. 2000; Gielen et al. 2001; Maman et al. 2001a; Maman et al. 2001b; Manzi et al. 2005).

Women's decisions about testing may be complicated by their plans to have children, their husbands' opinions and considerations such as breastfeeding (Aka-Dago-Akribi et al. 1999; Sahlu et al. 1999; de Paoli et al. 2004). A recent comparative study in four Asian countries (India, Indonesia, the Philippines and Thailand) found that men were more likely than women to be tested because they had HIV-related symptoms, whereas women were more likely to test because their partner tested positive (Paxton et al. 2005). In these and other settings, women may become aware of risks only once their partner is ill, and they may not suspect that they were exposed until then (Obermeyer et al. Forthcoming). For all these reasons it is important for operational research studies to conduct gender analyses of behaviours and attitudes related to HIV testing.

2.2 Factors that influence the uptake and quality of testing and counselling services

How testing and counselling are provided: different models

New approaches to the delivery of testing services are showing some success. Rapid tests at convenient times (such as night-time) and locations (such as homes, workplaces, health facilities and mobile clinics) have increased the numbers of people who have been tested as well as the proportion of clients who receive their results (Day et al. 2004; Mahto and Higgins 2004; Mermin et al. 2005; Corbett et al. 2006; Rotheram-Borus et al. 2006). Home-based testing and counselling in four Ugandan villages increased acceptance of testing from 10% to 46%, eliminated differences in acceptance between women and men and appeared to be an effective way to reach family members (Wolff et al. 2005). Interviews and focus group discussions suggested that home testing avoided some of the inconvenience, fears and costs of facility-based tests. National level data from Uganda confirmed the high acceptability of giving blood and receiving results in the course of a household survey; and a qualitative study conducted in parallel with that Demographic and Health Survey did not uncover major problems of understanding or coercion (Yoder et al. 2006). The vast majority of respondents consented to give blood samples for HIV tests and to receive the results at home. A Cochrane review confirms that home-based testing does increase uptake (Bateganya et al 2007).

Integrating provider-initiated testing in clinical settings appears to overcome many of the barriers that hindered earlier efforts and has been found to have unexpectedly high acceptability. In settings around the world, utilization increases rapidly when testing is routinely offered during antenatal care (Simpson et al. 1998; Etiebet et al. 2004). Pregnant women are often inclined to be tested if they think it can benefit their baby (Simpson et al. 1998; Jha et al. 2003; Etiebet et al. 2004; Perez et al. 2006). Routine provider-initiated ("opt-out") testing seems to be more acceptable and to cause less anxiety for women than "opt-in testing", perhaps because this approach is ostensibly done for the benefit of the baby, does not make assumptions about women's behaviours and hence does not threaten women's sense of moral worth (Sobo 1994; Boyd et al. 1999; Etiebet et al. 2004).

Similar positive attitudes towards provider-initiated HIV testing have been observed outside of prenatal care as well. When hospitalized patients in the United States were asked how they would feel about provider-initiated HIV testing, most responded positively (Greenwald 2006). More than two thirds of clients at a tuberculosis clinic in Kinshasa, the Democratic Republic of the Congo, preferred provider-initiated ("opt-out") testing (whereby the test would be performed unless they declined), notwithstanding common perceptions that it would be difficult to decline the test (Corneli et al. 2008). The acceptance of testing increased considerably after providers began to recommend the test routinely in postpartum wards in Botswana (Thior et al. 2007), paediatric wards in Uganda (Nawavvu et al. 2006) and Zambia (Kankasa et al. 2006), maternity wards in Uganda (Homsy et al. 2006) and STI clinics in Uganda (Semafumu and Ngabirano 2006).

Such results are encouraging, and they highlight the different factors that can facilitate the uptake of HIV testing. Operational research is needed to examine whether they will be replicated as expansion continues (Glick 2005) and to establish whether the successes observed in well-resourced projects can also be achieved in resource-limited settings.

Communication strategies and provider-client interactions

Research on programmes provides useful insights into the types of communication strategies that may increase the uptake of HIV testing at the individual and community levels. Operational research can also help to evaluate the messages that accompany the offer of an HIV test and the communication of results. When providers personalize information about the risks of HIV and frame messages in terms of personal gains and losses, clients are more likely to decide to be tested, consistent with research showing that individuals need to translate abstract notions of risk into personal terms (Kalichman and Coley 1995; Apanovitch et al. 2003; Tambashe et al. 2003). Because of the implications of a positive diagnosis, health workers need to take great care when communicating about the test, in order to avoid misunderstandings and to convey the seriousness of the diagnosis without leading the patient to despair.

Other aspects of the provider-client interactions influence clients' decision to have an HIV test and to comply with recommendations. These include providers' background characteristics (such as gender or ethnic group), attitudes, perseverance and the extent to which providers are able to gain clients' trust and build good rapport (Marelich et al. 2002; Worthington and Myers 2003; Anderson et al. 2005; Passin et al. 2006; Zimba et al. 2006). Operational research can evaluate the extent to which strategies effectively communicate key messages about HIV test results, treatment and prevention. At the community level, media campaigns have been effective in increasing the uptake of testing in some settings. For example, Burkina Faso documented a relatively high rate of testing (at a time when treatment availability was limited), thanks in large part to yearly national campaigns designed to reach the general population as well as key populations at higher risk (Some 2003; PAMAC 2004). Comparisons of different approaches can help identify the elements that contribute to improved communication strategies.

Health care facility resources and the role of counselling

Although numerous guidelines have been formulated to improve testing and counselling, there are great variations in the quality of these services around the world. When health systems are weak and resources are stretched too thin, providers may have insufficient training, time or space to provide high quality testing or counselling. Studies from both developed and developing country settings have found widespread problems such as insufficient time for counselling (Ruiz et al. 2002), inadequate information and poor quality counselling for clients from less-privileged segments of society (Brown 1993). Even when a facility has a policy of routinely recommending HIV testing and counselling, providers may not consistently follow the policy (Coovadia 2000). In some settings, providers decide to whom to recommend

a test based on subjective criteria such as their assumptions about which clients can handle bad news (Gibney et al. 1999). Operational research can help identify those dysfunctions that may be amenable to improvements.

Until recently, pre- and post-test counselling have always been considered integral and essential parts of HIV testing. Pre-test counselling is typically designed to give information and obtain consent, while post-test counselling may address additional information, encourage preventive behaviours and include referrals to care depending on the test results. What exactly is conducted under the heading of "counselling" varies a great deal, however, and evidence is needed about the effect of different approaches on the uptake of testing and access to follow-up care. Resource constraints and a lack of evidence about usefulness have eroded support for pre-test counselling in some settings, in favour of concentrating those resources on post-test counselling (Koo et al. 2006). The implications of this type of change are unclear, and operational research is needed to explore the consequences of different approaches to counselling.

Providers and the institutional support they receive

In recent years, attention has increasingly been drawn to the implications of the serious human resource crisis in many settings for HIV service provision (WHO 2006). It is important to distinguish different types of providers in terms of their background and training, including whether they are specialists or laypersons who received training, for example as counsellors. When it comes to HIV testing, much is expected of providers "on the front lines", but little is known about how they cope. In addition to practical difficulties, resource constraints and the emotional dimension of their work on HIV, providers may have justifiable concerns about occupational exposure to HIV, particularly where protective measures are inadequate or are difficult to implement. There are also considerable variations in the availability and quality of the services that health providers can access for their own needs. For example, some research suggests that providers need access to self-testing for HIV or other special services to encourage them to learn their own HIV status in a confidential and non-stigmatizing way (Bongololo et al. 2007). In terms of the quality of HIV services, while some health care providers are effective, others may feel ambivalent about testing or may have doubts about their ability to provide care (Brouwer et al. 2000; Sherr et al. 2001; Sliet et al. 2001; de Paoli et al. 2002; Chi et al. 2004). Operational research is needed to gain insights into testing and counselling from the perspective of providers and to understand the training, time, resources and institutional support that providers need. The question of how to support providers so that they gain clients' trust is an important one, and answers are likely to refer to both the capacity of the providers themselves and the functioning of the health system in which they operate.

2.3 Factors that influence the ethical dimensions of testing and counselling

Attitudes, practices and policies regarding consent

The expansion of testing has heightened awareness of the ethical dimensions of testing and counselling and the need to

protect the rights of those who are tested (Rennie and Behets 2006); however, evidence about the magnitude of the problem of testing without consent is limited. There are indications that nearly everywhere, clients are sometimes tested without their knowledge; this was documented a decade ago in Europe, where an estimated 10% to 20% of respondents had been tested without their knowledge (McCann and Wadsworth 1991; McCann 1992; Schrooten et al. 2001). Similarly, India's private hospitals are said to conduct mandatory testing on prospective surgical patients, and some studies have documented that many Indian patients are tested without consent (Elamon 2005; Sheikh et al. 2005). More information is needed about the extent to which guidelines about consent are in fact implemented. Even when given a choice, clients or survey respondents do not always feel free to decline the offer of an HIV test. They may accept an HIV test because they are used to agreeing to health professionals' requests, because they think that agreeing to a test will improve the care they receive, because they do not think they can decline, or because they have a diffuse sense that refusing would have adverse consequences (Williams et al. 1997; Abdool Karim et al. 1998; Leach et al. 1999; Mitchell et al. 2002; Yoder and Konate 2002; Weiser et al. 2006). It is important to document problems related to obtaining consent in different settings, to assess the extent to which client perceptions and expectations influence their willingness to be tested, and to explore which forms of consent are appropriate in different settings.

Attitudes, practices and policies regarding confidentiality

Confidentiality is another important ethical dimension of testing and counselling that has implications both for patients' rights and for the public health objective of increasing utilization of testing, since perceptions of how confidentiality is handled may influence clients' willingness to be tested (Fylkesnes and Siziya 2004). Laws, governmental policies, institutional policies, available resources and prevailing attitudes are all factors that influence the extent to which health workers protect the confidentiality of medical information in health care settings. Policies differ considerably across settings and are rapidly changing. In Singapore, for example, the Health Ministry made it mandatory to inform the spouses of HIV patients several years ago (Anon. 2005); and the possibility of allowing health workers to disclose patients' status to their partners has been discussed in some African countries, where it has been referred to as "beneficial disclosure" (National AIDS and STD Control Programme of Kenya 2004; Jack 2005).

Evidence suggests that lack of confidentiality can be a serious problem in many settings. In a comparative study in India, Indonesia, the Philippines and Thailand, 34% of HIV-positive respondents reported that health care workers had revealed their HIV status to someone else without their consent (Paxton et al. 2005). In some settings, health workers do not have a positive view of patient confidentiality and may even see confidentiality as a way to protect irresponsible individuals (Seidel 1996). Patient confidentiality is often compromised by established practices in health services and by differential regard for clients' rights (Brown 1993; Sherr et al. 2001).

More information is needed about how changes in the provision of testing and counselling and in the process of securing consent and ensuring confidentiality will affect utilization, quality of care, and the protection of clients. Empirical evidence on practices and attitudes in multiple settings can be drawn from reports by clients of their experiences, providers' views and reports of what happens at health facilities, as well as observations of the process of testing and counselling at health facilities. This evidence can help identify innovative ways to expand testing while protecting patient rights.

3. RESEARCH OBJECTIVES AND QUESTIONS

It may be useful to organize the many operational research questions that can be formulated regarding HIV testing and counselling into three groups: those dealing with users of services, those dealing with providers and those related to practices around testing (see box on next page).

Other operational research questions may also be relevant in different settings. For example, researchers may want to explore whether the use of testing and counselling influences preventive behaviour, such as levels of unprotected sex, and questions may be formulated to examine the links between HIV testing and high- or low-risk behaviours. Researchers may also need to refine their research questions depending on the nature of the epidemic in a given setting. For example, in concentrated epidemics, researchers may need to focus on lines of enquiry most relevant for understanding the implications of scaling up testing and counselling for key populations at higher risk, such as sex workers or men who have sex with men.

4. METHODS

4.1 Study populations and study design

In this volume, we have opted for simple study designs that make it possible to investigate these research questions mostly by gathering cross-sectional data at health facilities. The instruments presented in this volume combine quantifiable, closed-ended questions with open-ended questions to elicit information about attitudes, perceptions and experiences. Information is to be collected in the following ways:

- ▶ conducting surveys to interview users and non-users of testing services to compare the factors that influence the uptake of testing (e.g. gender and stigma) and to find out about the conditions of testing and the consequences of disclosure; and
- ▶ interviewing providers and key informants to obtain information about policies, programmes and services related to testing, counselling, confidentiality and consent.

The two core instruments presented in this volume are: a Client Instrument that can be administered at health facilities and a Provider Instrument, to be used with health personnel

OPERATIONAL RESEARCH QUESTIONS ABOUT TESTING AND COUNSELLING (T&C)

1. Understand motivations, behaviours and experiences related to testing and disclosure:
 - How do users and non-users of T&C services compare in terms of sociodemographic variables such as residence, gender, socioeconomic status and profession?
 - To what extent are knowledge of HIV, attitudes about risks, access to services and other social factors associated with testing behaviour?
 - What experiences have clients had with regard to different models of testing?
 - What factors are associated with clients' perceptions, motivations and behaviours related to T&C and obtaining results?
 - What are patterns and levels of disclosure? What factors influence disclosure?
 - How do users and non-users of T&C services compare in terms of attitudes about and fear of stigma and discrimination?
 - To what extent is the availability of testing, counselling and treatment associated with stigma and discrimination?
 - Using a gender analysis, how and to what degree does gender influence the T&C experience, disclosure behaviours and consequences? How and to what degree does gender influence attitudes about, fear of, and actual experiences of stigma and discrimination?
2. Analyse the provision of appropriate services around testing and counselling:
 - How are T&C services delivered in different facilities and settings, and how do these different models vary in terms of uptake, clients' responses to the offer of testing and disclosure behaviours?
 - What are providers' experiences with T&C in relation to their own life trajectories, training, work conditions, perceptions, motivations and satisfaction?
 - To what extent do health workers fear exposure to HIV in the course of their work, what protective measures do they have access to, and what is their experience with accidental exposure?
 - What interactions and communication patterns occur between providers and clients in the context of T&C? To what degree are providers able to gain the trust of clients?
 - How do different service delivery models link clients to needed care, treatment and support services after testing?
3. Investigate the ethical dimensions of testing and counselling:
 - What are practices related to informed consent and confidentiality in different facilities and settings?
 - Which practices related to informed consent and confidentiality result in better outcomes regarding clients' satisfaction with their decision and the protection of their privacy?
 - What constraints and challenges do providers face in relation to informed consent and confidentiality?
 - What are the experiences, attitudes, priorities and concerns of clients with regard to consent and confidentiality, and how do these attitudes and beliefs influence their choices with respect to testing, counselling and disclosure?
 - To what degree do ethical practices (or perceptions about the ethical practices in a given facility) influence clients' responses to T&C services?

and counsellors at health facilities. We recommend collecting additional qualitative data through in-depth interviews with people living with HIV, focus group discussions with individuals who have not been tested and key informants who are knowledgeable about programmes and health facilities, and by developing an observation checklist to be used at health facilities.

5. VARIABLES AND SURVEY QUESTIONS

The Testing and Counselling Modules of the Client and Provider Instruments in this volume were originally developed as part of the MATCH (Multi-site African Testing and Counselling for HIV) study that addressed some of the research questions formulated in this chapter. Earlier versions of the instruments were used in Burkina Faso, Kenya, Malawi and Uganda, and they were revised prior to being included here.

5.1 Variables and survey questions to ask among clients

Several modules of the Client Instrument in this volume gather

data to address the research questions identified in this chapter, including the following:

- ▶ **the Sociodemographic Module**, which collects data on variables such as gender, socioeconomic status, ethnicity, residence (etc.) that are clearly important for understanding uptake and other dimensions of testing;
- ▶ **the Testing and Counselling Module**, which gathers data on variables related to service provision and factors that influence the uptake, quality and ethics of testing and counselling; and
- ▶ **the Disclosure, Support and Stigma Module**, which collects data on levels of stigma, patterns of disclosure and reactions of friends, family and community members.

Even though the Disclosure, Support and Stigma Module of the Client Instrument is formatted as a separate module, it was designed to be used together with the Testing and Counselling Module to ensure that operational research on

testing and counselling consider the consequences of disclosure. Researchers who wish to study the effects of testing and counselling (or a combination of testing and other services) on sexual behaviour may want to use the Testing and Counselling Module in combination with the Prevention Module to compare those who have been tested with those who have not. This would require some adaptation of the questionnaire, however, since the Prevention Module was designed for respondents who have already tested positive for HIV.

The particular survey questions that respondents are asked in the Client Instrument will depend on whether or not respondents have had an HIV test, and if so, whether they have tested positive for HIV and are willing to disclose their status to the interviewer. The instrument is designed with skip patterns to accommodate these different possibilities, and the table below lists key variables or topics included in the Client Instrument.

The Testing and Counselling Modules of the Client and Provider Instruments in this volume were designed to consider the possibility that some HIV testing may occur outside a health facility, in settings such as people’s homes and workplaces. Researchers who are specifically interested in testing in such settings may want to adapt the questionnaire by adding some

questionnaire items and deleting others. Types of questions that may be explored in relation to home testing include:

- ▶ whether respondents were informed about providers coming to their home in advance; how they were informed and what they were told about testing;
- ▶ who and how many health workers came to the home to offer and conduct testing and counselling;
- ▶ whether other household members were offered testing and whether they accepted;
- ▶ whether respondents discussed the test with other household members before and after the test;
- ▶ whether respondents were influenced by other household members;
- ▶ the extent to which respondents perceived that providers who came to the home were able to protect their privacy and confidentiality; and
- ▶ what respondents think about being offering HIV testing and counselling in the home.

An instrument to be used during an HIV testing campaign would likely have to be considerably shortened to make it possible to recruit participants. In that case, it may be necessary to omit all the open-ended questions and to add a few questions to ask

VARIABLES AND TOPICS RELATED TO TESTING AND COUNSELLING, DISCLOSURE, SUPPORT AND STIGMA IN THE CLIENT INSTRUMENT

TESTING AND COUNSELLING MODULE	DISCLOSURE, SUPPORT AND STIGMA MODULE
<p><i>For respondents who have never been tested:</i></p> <ul style="list-style-type: none"> ■ Knowledge and attitudes about HIV ■ Knowledge of anyone who has been tested, of someone living with HIV ■ Knowledge of testing facilities ■ Access to testing facility ■ Attitudes towards HIV testing, confidentiality of results and disclosure ■ Ever experienced an offer of a test ■ Reasons for not having/refusing a test <p><i>For all respondents who have been tested, regardless of HIV status:</i></p> <ul style="list-style-type: none"> ■ HIV test (first and most recent), circumstances and reasons for testing ■ Experience of testing, counselling and consent ■ Attitudes about consent, confidentiality and disclosure ■ Obtaining results and post-test care: experience and attitudes <p><i>For respondents who inform interviewer that they are HIV negative:</i></p> <ul style="list-style-type: none"> ■ Reaction to test results <p><i>For all respondents who inform interviewer about their HIV-positive status:</i></p> <ul style="list-style-type: none"> ■ Follow-up received, including medication and care ■ Reaction to test results 	<p><i>For respondents who are HIV-negative, do not know their status or decline to reveal their status to an interviewer:</i></p> <ul style="list-style-type: none"> ■ Stigmatizing attitudes ■ Personal knowledge of people who have experienced HIV stigma, discrimination or violence ■ Knowledge of support groups for people with HIV <p><i>For respondents who disclose their HIV-positive status to an interviewer:</i></p> <ul style="list-style-type: none"> ■ Disclosure behaviours and motivations ■ Reactions to disclosure by family and friends ■ Experiences of stigma and discrimination by others ■ Negative self-perception and behaviours (internalized stigma) ■ Discrimination in health care settings ■ Participation in support groups, social services or other assistance programmes ■ Perceptions about negative and positive consequences of learning HIV status

clients and providers how testing during a campaign compares to testing at other times, in terms of the factors that encourage or hinder people from testing.

5.2 Variables and survey questions in the Provider Instrument

Similar to the Client Instrument, there are several modules in the Provider Instrument that are important for operational research on Testing and Counselling, including the Sociodemographic and Work Module, the Testing and Counselling Module, the Fear of Infection and Work Safety Module, and the Disclosure, Support and Stigma Module. The box to the right presents an overview of key variables addressed in these modules of the Provider Instrument.

VARIABLES RELEVANT TO TESTING AND COUNSELLING IN THE PROVIDER INSTRUMENT

- Demographics
- Work background (work history, job function, education, training and work routine)
- Practices, perspectives and attitudes related to:
 - Testing
 - Pre-test counselling
 - Consent
 - Privacy and confidentiality
 - Post-test counselling
 - Follow-up care and support
 - Disclosure
- Fear of infection
- Practices related to implementation of universal precautions
- Accidental exposure and action taken
- Observation of discrimination at health facilities
- Stigma

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CHAPTER 2

HIV STIGMA AND DISCRIMINATION

1. BACKGROUND

1.1 Rationale: why operational research is needed on HIV stigma and discrimination

Since the early days of the AIDS epidemic, stigma and discrimination have been recognized as obstacles to HIV prevention, treatment and support (UNAIDS 2007). The classic definition of stigma refers to “an attribute that is deeply discrediting”, which results in the reduction of a person or group “from a whole and usual person to a tainted, discounted one” (Goffman 1963). It has been argued that stigma may also reflect and reinforce existing power structures, social control, mistreatment and marginalization of disenfranchised groups (Parker et al. 2002; Parker and Aggleton 2003; Link and Phelan 2006). HIV discrimination may include behaviour that is harmful, intolerant, underrating or prejudicial against people living with HIV and their families and is often called “enacted stigma” to underscore the idea that discrimination can be considered a manifestation of stigma, or at least, an end result (Jacoby 1994; Nyblade and MacQuarrie 2006).

Operational research is needed to address a number of key research gaps regarding HIV stigma and discrimination. First, there is a need for better definitions and quantitative measures. Such measures could be used to gather comparable data about patterns and levels across different geographic, sociodemographic and cultural settings. Standardized, reliable measures could also facilitate baseline data collection for programmes designed to reduce stigma and discrimination. There is also a need for qualitative research to explore the experiences and perspectives of those living with HIV and to assess the extent to which they encounter stigma and discrimination on the one hand, and support, tolerance and compassion on the other.

Quantitative and qualitative research can be used to help programme managers and policy-makers formulate more effective interventions to improve the health, wellbeing and quality of life of individuals living with HIV in various cultural and demographic contexts. Measuring stigma can also help alert programme implementers to negative unintended consequences of interventions. For example, highlighting certain risk behaviours as ‘bad’ may exacerbate stigma against those who engage in those behaviours; and tailoring HIV prevention messages for populations that are already marginalized — such as sex workers or men who have sex with men — may increase discrimination against those groups (Nyblade and MacQuarrie 2006).

While many studies have suggested that stigma and discrimination are obstacles to HIV prevention, testing and treatment, their precise role is poorly understood. As noted in the previous chapter, there are particular research gaps about the role of stigma that have important implications for testing and counselling policies. For example, proponents of provider-initiated testing and counselling argue that these policies may decrease levels of HIV stigma by normalizing testing and increasing access to treatment (Weiser et al. 2006; Wynia 2006). On the other hand, many opponents fear that provider-initiated testing may jeopardize the confidentiality and voluntariness of testing, with negative consequences for vulnerable populations (Kippax 2006; Wynia 2006). Future research has the potential to clarify some of these questions as well as to indicate whether stigma may become less pervasive in a society once health-preserving treatments are accessible to most people living with HIV (Castro and Farmer 2005).

In the remainder of this chapter, we summarize information on the manifestations and correlates of HIV stigma and discrimination, the implications for HIV prevention, testing and treatment, and the measures and methods used to study stigma and discrimination. The chapter also formulates a number of operational research questions and proposes a set of easily administered measures of stigma.

1.2 Manifestations and patterns of HIV stigma and discrimination

The precise nature of HIV stigma and discrimination varies depending on the setting; the local context influences which attitudes and behaviours are most salient and the extent to which certain groups are stigmatized, such as female sex workers, men who have sex with men, injecting drug users or migrant populations. However, evidence suggests that stigma has some broadly similar manifestations around the world, across a wide range of cultural, environmental and sociodemographic settings (Aggleton et al. 2005; Nyblade and MacQuarrie 2006). The following are commonly documented expressions of stigma:

- ▶ **Fear of casual transmission and refusal of contact.** In some settings, HIV stigma manifests as an exaggerated or unreasonable fear of contracting HIV through casual or non-invasive contact (Nyblade et al. 2005). This can lead to a desire to avoid casual or social contact with those living with HIV in schools, marketplaces, workplaces and health care settings.

- ▶ **Negative judgements about people living with HIV.** Value judgements about the moral conduct or the worth of people living with HIV may express blame, accusation and moral condemnation (Policy Project 2003; Ogden and Nyblade 2005; Pulerwitz et al. 2008).
- ▶ **Internalized stigma, also called self-stigma.** Internalized stigma is a frequently described experience of individuals living with HIV and may include feelings of shame, hopelessness and guilt, social withdrawal and a tendency not to use existing treatment or support services (Thomas et al. 2005; Brouard and Wills 2006; Simbayi et al. 2007a). Evidence suggests that internalized stigma may aggravate psychiatric morbidity among people living with HIV (Van Brakel 2006).
- ▶ **Discrimination ('enacted stigma') in family or community settings.** Enacted stigma may include a broad range of harmful actions against individuals who are known or suspected of having HIV or AIDS (and/or their families), including rejection, exclusion from social or ritual events, gossip, ridicule, verbal harassment, abandonment, divorce, expulsion from their homes, removal of economic support, denial of property and, in some cases, physical violence (Aggleton et al. 2005; Varas-Diaz et al. 2005; Maman et al. 2006).
- ▶ **Discrimination ('enacted stigma') in institutional settings.** Enacted stigma may occur within institutions such as workplaces, health-care services, prisons and schools. Increased attention to the possibility of stigma in medical settings has resulted in studies documenting discrimination against people living with or suspected of having HIV in health care settings in a variety of contexts (Bharat et al. 2001; Mahendra et al. 2007; Oanh et al. 2008), including withholding medical care, providing inadequate care and implementing discriminatory policies regarding patient consent and confidentiality (Aggleton et al. 2005).
- ▶ **Discriminatory laws and policies.** In many countries, legal systems have limited the rights of HIV-positive individuals, either explicitly or by failing to enforce the laws or protect human rights. For example, in some settings, laws or policies have restricted the right of people living with HIV to travel or migrate internationally, to receive comprehensive care, to consent freely to testing or even to engage in certain professions (Aggleton et al. 2005). In other settings, laws are not enforced, and legal systems do not protect the rights of people living with HIV.
- ▶ **Compounded or "layered" stigma.** Compounded stigma refers to HIV-related stigma that mutually reinforces and legitimates pre-existing stigma and discrimination against marginalized groups such as sex workers, injecting drug users or men who have sex with men (Parker et al. 2002). Increased levels of stigma and discrimination may also be directed against HIV-positive individuals who contribute relatively few economic or social resources to their communities (Reidpath et al. 2005). When HIV comes to be associated with certain marginalized groups, individuals living with HIV may be afraid to disclose

their HIV status because they think others may suspect them of being homosexual (in the case of men) or accuse them of being promiscuous or sex workers (in the case of women) (Parker et al. 2002). In concentrated epidemics, marginalized groups at higher risk of HIV may come to be seen as responsible for the spread of HIV, and members of the 'general' public may be less likely to perceive themselves to be at risk, even when they engage in high-risk behaviours.

2. FACTORS AND PROGRAMME STRATEGIES

Stigma can be considered both a determinant of health-related outcomes and an outcome in itself. For programmes that aim to achieve other health behaviours or outcomes, operational research may explore stigma as a factor that may influence the programme's intended key outcomes. For example, a study may investigate the influence of stigma on uptake of testing and counselling or adherence to treatment. In other cases, operational research may focus on stigma reduction as a central programme objective. For example, a programme might aim to increase HIV-related knowledge as a means of reducing unreasonable fear of contagion and the resulting avoidance of people living with HIV. This section summarizes what is known about the extent to which stigma and discrimination influence HIV testing, treatment and disclosure, the key factors that are correlated with stigma and the main programme strategies that have been developed to address stigma.

2.1 The influence of stigma on HIV testing, treatment, disclosure and prevention

Utilization of HIV testing and counselling

As noted in the previous chapter, numerous qualitative and quantitative studies from around the world have found that stigma and fear of discrimination are associated with a reluctance to seek HIV testing and counselling or with client anxiety at testing sites (Fortenberry et al. 2002; Herek et al. 2003; Kalichman et al. 2005; Hutchinson and Mahlalela 2006; Iyaniwura 2006; Weiser et al. 2006; Obermeyer and Osborn 2007). For example, studies from South Africa and Botswana found that individuals who had not been tested for HIV reported significantly higher levels of stigmatizing attitudes than those who had been tested (Kalichman and Simbayi 2003; Hutchinson and Mahlalela 2006; Weiser et al. 2006). A study of truck drivers in Brazil found that the odds of having had an HIV test decreased by 4% for every unit increase on a 15-item scale measuring stigmatizing attitudes (Pulerwitz et al. 2008). And, fear of the negative consequences of a positive test result, such as social rejection, abandonment and violence, has been reported as an impediment to testing in settings around the world — particularly by women (Maher et al. 2000; Maman et al. 2001; UNAIDS 2007; Sambisa 2008).

Care and treatment-seeking

Research has documented that fear of stigma and discrimination represents an important barrier to treatment and care (Heijnders and van der Meij 2006). Fear of stigma and discrimination has been identified as a barrier to adherence to antiretroviral

therapy in research from settings such as China, South Africa and the United States (Nachega et al. 2006; Peretti-Watel et al. 2006; Rintamaki et al. 2006; Weiser et al. 2003). For example, respondents receiving HIV treatment in urban areas of the United States reported skipping doses because they were afraid that their status would become known to family or friends (Rao et al. 2007). In South Africa, adherence was considerably lower among respondents who reported fear of being stigmatized by their sexual partner (Nachega et al. 2004; Rintamaki et al. 2006). This evidence suggests that studies on adherence to antiretroviral therapy should include variables related to fear of stigma and should ask respondents whether they feel a need to take their medications in secret. Questions on these factors are, therefore, included in the Adherence Module of the Client Instrument in this volume.

HIV status disclosure and prevention

Evidence suggests that stigma and fear of discrimination may represent an important barrier to certain types of harm-reduction behaviours (Chen et al. 2005; Liu et al. 2006) and may decrease willingness to disclose HIV status (Clark et al. 2003; Ford et al. 2004; Dias et al. 2006; Liu et al. 2006; Simbayi et al. 2007b; Pulerwitz et al. 2008). Stigma and fear of discrimination have frequently been studied as factors that influence levels of HIV disclosure. In fact, disclosure has often been considered a proxy measure for stigma, as people living with HIV are more likely to disclose their status to those around them in low-stigma contexts, where they expect fewer negative consequences (Nyblade and MacQuarrie 2006). As noted in the previous chapter, rates of partner disclosure by people who know that they are HIV-positive vary widely, but these rates are often low (Heyward et al. 1993; Kalichman and Nachimson 1999; Nebie et al. 2001; Maman et al. 2003). For example, a review of 15 studies from sub-Saharan Africa and Asia found that rates of partner disclosure by women who tested positive for HIV ranged from 17% to 80%, with the lowest rates reported by women tested in prenatal care settings (Medley et al. 2004). Lowering fears of stigma, discrimination and violence might reduce barriers to HIV disclosure and contribute to better HIV prevention.

2.2 Factors that influence levels and patterns of HIV stigma and discrimination

Studies from diverse settings have found a number of factors to be correlated with levels and patterns of HIV stigma and discrimination at the individual, community and societal level. At the individual level, research has often explored the link between HIV knowledge and stigma, including understanding the modes of transmission or personally knowing someone with HIV. Evidence suggests that personal contact with individuals living with HIV is associated with fewer stigmatizing beliefs (Birmingham and Kippax 1998; Schiff et al. 2003). Some studies have found evidence that lower knowledge about HIV transmission is correlated with greater stigmatizing attitudes against people living with HIV (Dias et al. 2006; Kalichman et al. 2006); however, other evidence suggests that a better understanding of HIV transmission alone does not necessarily reduce the fear of casual contact (Herek et al. 2002). One study found that higher levels of medical knowledge about HIV among

health workers was correlated with higher levels of stigmatizing attitudes and discriminatory behaviours; researchers suggested that job seniority may have allowed highly educated senior doctors to avoid caring for HIV-positive patients by delegating these tasks to junior level staff (Deacon and Boule 2007). Thus, operational research should be mindful of the complex links between knowledge and stigma.

Sociodemographic characteristics such as gender, ethnicity, class, profession and identification with a marginalized group (e.g. sex workers, injecting drug users, men who have sex with men or mobile populations) also influence stigma (Parker et al. 2002). In many settings, women's lower socioeconomic status appears to increase their vulnerability to discrimination following a positive HIV test. In locations as diverse as Ethiopia, India, Mozambique, the United Republic of Tanzania, Viet Nam and Zambia, studies have found that women experience more HIV-related stigma than men (ICRW 2006). A study from the United Republic of Tanzania found that nearly two thirds of women with HIV reported stigma in the past year, compared with less than half of men. Women may also be more vulnerable than men to extreme consequences such as physical violence by intimate partners (UNAIDS 2007). Qualitative research in settings such as Côte d'Ivoire found that women's reluctance to be tested or to disclose their HIV status was closely related to their perceived socioeconomic vulnerability (Coulibaly et al. 1998).

At the community or societal level, HIV stigma and discrimination may be influenced by factors such as the prevalence and patterns of HIV in the area, the degree of competition and conflict over scarce resources, the availability of testing and treatment services, the extent of programmatic activity that has taken place and the levels of pre-existing stigma against marginalized groups (Parker et al. 2002; Parker and Aggleton 2003; Castro and Farmer 2005; Deacon et al. 2005; Reidpath et al. 2005). For example, as mentioned earlier, it is possible that compounded stigma may be especially prevalent in settings where the epidemic is concentrated among marginalized groups.

Laws and policies are other institutional or societal level factors that can influence levels of discrimination against those living with HIV, including policies that restrict their right to travel, to opt out of testing, to give consent before partner notification and to obtain certain kinds of medical treatment (Parker et al. 2002). An analysis of HIV stigma and discrimination in Latin American health care settings concluded that institutional policies have discriminated against people living with HIV indirectly by failing to ensure that staff are adequately trained to diagnose and treat HIV and AIDS and directly through policies that explicitly refuse care for AIDS patients (Foreman et al. 2003). A study from Beijing, China, found that hospital and government policies were the major source of discriminatory interactions between health workers and people living with HIV (Yang et al. 2005).

2.3 Programme strategies to reduce stigma and discrimination

Many programmes have aimed to reduce HIV stigma and discrimination and to increase support for people living with

HIV (Aggleton et al. 2005). The following section summarizes some common strategies drawn from reviews of published and unpublished programme evaluations (Brown et al. 2001; Brown et al. 2003; Heijnders and van der Meij 2006), including a 2005 UNAID review of “successful” programmes (Aggleton et al. 2005). Except where noted, many of these strategies have not been rigorously evaluated, so while some show promise, more research is needed before we can say which approaches are effective in different settings.

Counselling and peer support groups

Counselling has been used to resolve issues with family and community members and to teach coping skills. Interventions studies suggest that counselling may reduce anxiety and distress, reduce negative consequences of disclosure and improve attitudes towards people living with HIV (Brown et al. 2003). Counselling and “mediated disclosure” can be used to help clients who test positive for HIV consider how to disclose their status to partners and others in a way that reduces risks to their physical safety and emotional wellbeing (Maman et al. 2006). Peer support groups have also been shown to benefit people living with HIV in terms of self-esteem, coping skills and social integration (Heijnders and van der Meij 2006).

Mobilizing care and support among family and community members

Numerous initiatives have included efforts to recruit, mobilize, support and/or train family members, local volunteers, traditional healers, religious leaders and other community members to support and care for HIV-positive individuals and their families (Aggleton et al. 2005). In addition to improving health outcomes, these initiatives generally aim to increase emotional and material support for HIV-positive individuals, to improve their quality of life, to reduce stigma and discrimination and, in some cases, to improve adherence to HIV treatment. A qualitative evaluation from Haiti suggests that recruiting community members as peer supporters (*accompagneurs*) to provide psychosocial support has lowered the levels of social isolation and stigma experienced by individuals living with HIV (Behforouz et al. 2004; Mukherjee et al. 2006).

Education, awareness raising and advocacy

Many initiatives have aimed to raise awareness, dispel misconceptions and reduce negative attitudes about people living with HIV at the national level, the community level or among key populations at higher risk for HIV. Strategies include mass media, participatory education, mobilizing community leaders and empowering individuals living with HIV to lead advocacy or awareness activities. Some initiatives focus narrowly on HIV or AIDS, while others address broader issues such as pre-existing stigma against marginalized populations at higher risk, issues related to sexuality or tolerance and compassion towards those affected by HIV (Aggleton et al. 2005). Information-based strategies seem to be most effective at reducing stigma when combined with other approaches (Brown et al. 2001); for example, simply increasing knowledge about transmission has not always reduced concern about contracting HIV through casual contact (Herek et al. 2002).

Antidiscrimination measures within institutions

Institutional initiatives have included efforts to reduce HIV stigma and discrimination within health facilities, workplaces, schools, prisons, etc. (Aggleton et al. 2005). For example, health sector initiatives have included efforts to increase access to integrated, comprehensive HIV care, antidiscrimination health care policies, and sensitizing and training health workers to change attitudes and reduce discriminatory behaviour within health care facilities (Aggleton et al. 2005).

Human rights, legal and policy Interventions

There have been many efforts to address HIV discrimination by promoting and protecting the human (and legal) rights of people living with HIV, including the rights to freedom of movement, property, employment, education, consent, confidentiality and access to services. Specific strategies have included mobilizing communities to demand respect for the rights of those living with HIV, advocating for legal and policy reforms (e.g. at the government level) and efforts to enforce laws or seek redress in the courts when rights are violated (Parker and Aggleton 2003; Aggleton et al. 2005; Heijnders and van der Meij 2006).

3. RESEARCH QUESTIONS

The box on the following page presents selected operational research questions that are likely to be relevant in multiple settings. The first, third and fifth questions are descriptive, designed to assess the extent and manifestations of stigma among different study populations. Two questions concern the association between stigma and health behaviours, including HIV testing and disclosure. Questions six and seven explore the factors that influence health workers’ fears about HIV exposure. The final research question addresses the effectiveness of strategies to reduce stigma, though it may require instruments and study designs such as comparison groups that go beyond the materials provided in this volume.

4. METHODS

4.1 Study populations and study design

This chapter highlights three key populations (listed below) for the operational research on stigma and discrimination proposed in this volume. Triangulating data by including more than one of these populations as participants in a study is a way to get a more complete picture of stigma from multiple perspectives.

- ▶ **People living with HIV.** Research among people living with HIV can provide insights into the patterns and levels of HIV stigma and discrimination, the patterns and consequences of disclosure and the ways in which experiences and fears of stigma and discrimination influence testing, treatment, adherence, disclosure and prevention.
- ▶ **Health care workers.** Research among health care workers can give an indication of the forms of stigma and discrimination and barriers to appropriate care that people living HIV may

OPERATIONAL RESEARCH QUESTIONS ABOUT HIV STIGMA AND DISCRIMINATION

1. To what extent do people living with HIV experience different forms of stigma, discrimination and (conversely) support in different contexts (family, community and health facilities)?
2. To what degree are levels of stigma or fear of discrimination associated with HIV disclosure?
3. What are the forms and levels of HIV stigma and discrimination as reported or observed by the general population (specific populations to be determined by the research project)?
4. To what extent does stigma or fear of discrimination influence service utilization, including HIV testing and treatment; and to what extent do the availability and utilization of HIV testing and treatment influence levels of stigma in a community?
If data on stigma and on testing can be collected at more than one point in time, then the question may also be formulated as follows:
To what extent does the normalization or routinization of HIV testing and treatment decrease the extent of stigma towards people living with HIV?
5. What are the levels and patterns of stigma and discrimination in health care settings as reported or observed by health care workers?
6. To what extent do health care workers fear occupational exposure to HIV through invasive procedures (e.g. needle sticks) on the one hand, and through casual or non-invasive contact on the other?
7. To what extent are health workers fears of transmission associated with the levels of protective measures in the facility?
8. *For interventions research studies:* What combination of interventions leads to reduced levels of stigma and discrimination on the one hand, and increased support for people living with HIV on the other?

face within the health care system, as well as the challenges that health care workers face as they carry out their work and try to help patients protect their health and wellbeing.

► **'General' populations and key populations at higher risk of HIV.**

The Client Instrument in this volume is designed to collect information on HIV stigma and discrimination among general users of health facilities (specifically, those who have not been tested for HIV, those who do not wish to reveal their HIV status and those who have tested negative). With adaptation, this portion of the instrument can be used to gather data on levels of stigma among a general population of adults living in a particular community.

Depending on the local epidemiology of HIV, portions of the instrument can also be adapted for use among key populations at higher risk of HIV (e.g. sex workers, men who have sex with men or injecting drug users).

When designing HIV studies and programmes, several issues related to sampling methodology and ethics should be considered. First, HIV-positive individuals who are particularly at risk of stigma and discrimination may be marginalized and hard-to-reach. The sampling strategy for studies among people living with HIV may need to go beyond members of organizations such as support groups, in order to avoid sampling only those people who are well integrated into known social networks (UNAIDS 2005). To reach individuals who are not easily accessible, special data collection strategies can be used, such as Respondent Driven Sampling, a variant of "snow-ball" sampling (Abdul-Quader et al. 2006; Johnston et al. 2008). However, it should be noted that programmes that are designed for key populations at higher risk

must take special care not to stigmatize these populations further by drawing attention to their particular HIV-related vulnerability.

Studies that explore discrimination and violence against individuals living with HIV should also consider the ethical guidelines developed by WHO for researching violence against women (Watts et al. 2001). While these guidelines were not developed for research on HIV stigma, they are relevant for research that asks women direct questions about physical or emotional violence, as the Client Instrument does in this volume. In particular, researchers should ensure that:

- Field procedures should ensure privacy during interviews and the confidentiality of respondents' answers.
- All interviewers who ask respondents about violence should receive training in HIV stigma and violence against women. Interviewers gathering this type of data among marginalized, most-at-risk populations, such as sex workers or men who have sex with men, may also need training about the nature and patterns of pre-existing stigma and discrimination against those groups.
- Researchers should choose a study design that minimizes distress for respondents as a result of participating in the research. One important strategy is to offer respondents information about local sources of violence-related services and support at the end of each interview, if any such resources are available.
- In settings where these resources do not exist, researchers should consider developing some short-term support mechanisms by collaborating with local health care or social services organizations.

4. 2 Measuring HIV stigma and discrimination

Nyblade and MacQuarrie (2006) and other have synthesized what is known about how to operationalize various “domains” or dimensions of stigma and discrimination for different study populations. The box below lists examples of ways to measure stigma among people living with HIV, health workers and the general population.

If the study design requires a summary measure of stigma, multiple survey items can be combined into an index whereby responses for each item are summed together to form a stigma score. Using a greater number of items is generally preferable, since each item may capture important nuances in attitudes and behaviours. Alternatively, the items can be analysed individually to explore specific elements of stigma (Berger et al. 2001). It should be noted, however, that while most survey items presented in this chapter are framed negatively (e.g. “HIV is a punishment for bad behaviour”), items can be framed positively (e.g. “clients who are sex workers deserve to receive the same level and quality of care as other clients”). During the creation of an index, researchers need to code items in the same direction, so that both negatively and positively framed items have higher scores for more highly stigmatizing responses.

As noted earlier, the manifestations of stigma and discrimination are often very context specific, and it is essential to pre-test instruments in order to ensure that selected items are appropriate and relevant for the local context. Comparative research across different contexts can also help identify core quantitative measures that can be used across diverse settings.

Most items presented in this chapter are designed to be used with Likert-style response categories. Studies using these items generally used 3- or 5-point response categories. Five-point response categories may include: strongly agree, agree, undecided/unsure, disagree and strongly disagree. Using five options enhances the variability of responses and permits greater understanding of the nuances of stigma. However, five options can be difficult to respond to, particularly for respondents with limited literacy skills. A 3-point scale — including: agree, undecided/unsure and disagree — permits more variability and nuance than a simple yes/no response; it is more intuitive for respondents and easier to administer than the 5-point option.

Finally, this chapter focuses on quantitative measures of stigma and discrimination that may have the potential to provide comparable data on across different cultural and epidemiological contexts. However, purely quantitative studies can miss rich and nuanced information that can be tapped using qualitative methods. Triangulating quantitative and qualitative data can provide a more complete picture of stigma in a particular setting, as well as explain behaviours or detect unintended consequences of programmes. Both the Client and the Provider Instruments in this volume contain open-ended questions. In particular, the Client Instrument contains a detailed set of open-ended questions about disclosure behaviours and outcomes. Researchers may want to administer these questions to a subset of respondents, depending on the study objectives and resources available.

The types of research questions that can be answered through qualitative research are different from those that are typically answered using quantitative methods. Rather than measuring

WAYS TO OPERATIONALIZE THE EXTENT OF STIGMA FOR DIFFERENT STUDY POPULATIONS

Extent of stigma and discrimination feared or experienced by HIV-positive individuals

What proportion of people living with HIV:

- report internalized stigma such as feelings of shame because of their HIV-positive status;
- report experiencing stigma, discrimination or violence;
- express fear of stigma and discrimination if their HIV status were suspected or known, including fear of being seen using HIV services; fear of disclosing their status or fear of having their status disclosed by others;
- (or conversely) report support, compassion or tolerance from family members, members of social network, health care workers, community at large, etc.; or
- express fear of stigma or discrimination because they belong to a marginalized group (compounded stigma).

Extent of fears, discriminatory behaviours or negative attitudes expressed or observed by health workers

What proportion of health workers:

- express fear of contracting HIV in the course of their work through casual contact;
- express negative judgements against those living with HIV;
- report discrimination against HIV-positive patients at health facilities; or
- express negative judgements about key marginalized populations at higher risk of HIV (compounded stigma).

Extent of stigma and discrimination among general populations

What proportion of the general population:

- have adequate knowledge about HIV transmission and treatment;
- fear contagion through casual contact with people living with HIV;
- report knowing an HIV-positive individual who has experienced stigma or discrimination;
- (or conversely) report instances of support or tolerance towards people living with HIV; or
- express negative judgements about key marginalized populations at higher risk of HIV (compounded stigma).

the extent of stigma or testing hypotheses about the amount of change associated with a programme strategy, qualitative methods are well suited to gather contextual information, to explore the expressions of stigma that occur in a community and to investigate the reasons why certain quantitative results were found. To answer these questions, a study might use an array of methods such as observation, life stories, in-depth interviews and document reviews, in addition to more common qualitative methods such as focus groups or key informant interviews.

5. VARIABLES AND SURVEY QUESTIONS

This section describes variables and survey questions that can be included in research instruments on stigma and discrimination. It is based on a review of the literature, the comments of experts on drafts of this document, and the recommendations and field-testing experience of the Interagency Stigma and Discrimination Indicators Working Group convened by the United States Agency for International Development (USAID) (Nyblade et al. 2005; Nyblade and MacQuarrie 2006; Nyblade 2006). The items recommended here have been chosen in part because they are believed to be least context-specific. Additional ways to formulate survey items to measure different dimensions of stigma can be found in the references cited in this chapter.

Some but not all survey items discussed in this chapter are included in the Client or Provider Instruments in this volume — where multiple items were available, we have selected the most frequently recommended and/or the least context-specific. Most stigma-related items in the Client Instrument can be found in the Disclosure, Support and Stigma Module, but some appear in the Testing and Counselling Module (such as those related to forced testing). Similarly in the Provider Instrument, stigma-related items may appear in the Disclosure, Support and Stigma Module, but some appear in the Fear of Infection and Work Safety Module. As a result, researchers who want to investigate HIV stigma without using the full Testing and Counselling Module of the Client Instrument may need to extract some of the stigma-related questions from the Testing and Counselling Module for that purpose.

KEY VARIABLES RELATED TO STIGMA AND DISCRIMINATION

- a. Attitudes and behaviours related to disclosure
- b. Fear of contagion through casual contact
- c. Fear of contagion through occupational exposure (for health workers)
- d. Negative judgements about people living with HIV/Internalized stigma
- e. Discrimination and violence ('enacted stigma')
- f. Compounded/layered stigma
- g. Community norms
- h. Attitudes about human rights (e.g. forced testing)

a. Attitudes about and patterns of HIV disclosure

Many studies (along with the instruments in this volume) have included survey questions to explore attitudes, behaviours

and experiences related to HIV disclosure, including whether individuals living with HIV have revealed their status and the role of health workers in that process (Medley et al. 2004; Maman et al. 2006).

b. Fear of contagion through casual contact

Fear of HIV transmission through casual contact has been measured in many quantitative and qualitative studies. Survey items gauging this dimension of stigma typically measure the percentage of respondents who express fear of contracting HIV from casual contact with HIV-positive individuals or a desire to avoid casual contact. One way to formulate this type of question is: "Would you rather not touch someone with HIV (or AIDS) because you are scared of infection?" Frequently recommended questionnaire items for surveys among the general population have included:

Would you fear getting HIV from any of the following:

- ▶ hugging a person with HIV or AIDS?
- ▶ working next to a person with HIV or AIDS?
- ▶ sitting next to a person with HIV or AIDS?
- ▶ caring for a person with HIV or AIDS?
- ▶ buying fresh vegetables or meat from a shopkeeper with HIV or AIDS?

Among individuals living with HIV, survey questions can be used to explore their personal perceptions of inappropriate fears of contagion among the people with whom they interact, as in the following:

Please indicate whether you agree or disagree with each of the following statements:

- ▶ Some people are afraid to touch me once they know I have HIV.
- ▶ Some people have physically backed away from me once they learned I have HIV.

c. Fear of contagion through occupational exposure (for health workers)

In some situations, a research goal may be to understand the prevalence of reasonable fears of HIV transmission by health workers as compared with inappropriate fears of contagion through non-invasive contact. For example, items exploring this issue may include:

How concerned would you feel about getting HIV if you had to do any of the following. Would you feel very concerned, somewhat concerned or not at all concerned if you had to:

- ▶ take the blood pressure of a person with HIV or AIDS?
- ▶ change the bed linens of a person with HIV or AIDS?
- ▶ change the clothes of a person with HIV or AIDS?
- ▶ give an injection to a person with HIV or AIDS?
- ▶ dress the wound of a person with HIV or AIDS?

Researchers can assess health workers' access to and use of protective measures and the proportion of health workers who express fear of contracting HIV because of inadequate safeguards in the facility. The Provider Instrument in this volume contains

detailed questions about these topics. The extent of institutional safeguards available to health workers may be measured by determining what proportion of health workers report access to universal precautions, cases of accidental exposure to HIV in their workplace and access to HIV post exposure prophylaxis in cases of accidental exposure.

d. Negative judgements about people with HIV/internalized stigma

Many quantitative studies have measured the percentage of a population who express negative judgements or blame towards people living with HIV. This dimension has been less frequently measured than the fear of casual contact (Nyblade and MacQuarrie 2006), but a variety of survey items have been developed for use among the general population, health care workers and individuals living with HIV. These measures focus on whether respondents view HIV infection as a punishment, whether respondents believe that individuals living with HIV deserve blame for getting infected, and whether respondents believe that HIV infection brings shame upon those living with HIV or those associated with them.

NEGATIVE JUDGEMENTS ABOUT PEOPLE LIVING WITH HIV: EXAMPLES OF SURVEY ITEMS
<p><i>For measuring attitudes among the general population</i> Indicate your agreement or disagreement with each statement:</p> <ul style="list-style-type: none"> ▶ AIDS is a punishment for bad behaviour. ▶ People with AIDS deserve blame for getting the disease. ▶ People with AIDS should be ashamed of themselves.
<p><i>For measuring experiences of negative judgements by individuals living with HIV</i> Indicate your agreement or disagreement with each statement:</p> <ul style="list-style-type: none"> ▶ Some people act as though it is my fault I have HIV. ▶ People say I deserve it for things that I have done. ▶ People seem uncomfortable being around me once they learn I have HIV.
<p><i>For measuring self-directed negative judgement by individuals living with HIV (internalized stigma)</i> Indicate your agreement or disagreement with each statement:</p> <ul style="list-style-type: none"> ▶ I sometimes feel worthless because I am HIV positive. ▶ I feel guilty because I have HIV. <p>In the past 12 months, have you ever found yourself avoiding or isolating yourself from friends or family because of your HIV status?</p>

e. Discrimination and violence (enacted stigma)

Among the general population, discrimination can be measured by gathering data on the proportion of respondents who personally know someone who has experienced HIV-related discrimination. To minimize under-reporting, discrimination is usually measured by asking respondents to report 'observed' stigma rather their own discriminatory behaviours. To reduce the possibility that respondents might refer to the same incidents reported by the media or well-known throughout a community, it is recommended that survey items ask about whether the respondent personally knows anyone who has experienced HIV-related discrimination. The reference period should be relatively long (most commonly 12 months), since observable acts of discrimination may not occur with great frequency. Surveys of the general population

can use the following recommended items for measuring discrimination:

Do you personally know someone who has had the following happen to him/her in the past 12 months because they had HIV or AIDS? Someone you know was:

- ▶ **excluded from social events?**
- ▶ **abandoned by a spouse or partner?**
- ▶ **abandoned by other family members?**
- ▶ **verbally abused or ridiculed?**
- ▶ **physically assaulted?**
- ▶ **fired from work or lost their job?**
- ▶ **expelled from their home?**
- ▶ **had property taken away?**
- ▶ **denied health services?**

For research among people living with HIV, personal experiences of discrimination can be measured using the same sub-items, prefaced with the question: "In the last 12 months, has any of the following happened to you when you thought it was because of your HIV status?"

For research among health workers, survey questions can ask whether respondents have observed colleagues treating patients with HIV differently than other patients. Because of concerns about social desirability bias and reporting personal discrimination, it is preferable to ask providers about observed discrimination among colleagues rather than their own discriminatory behaviour. Examples of items measuring discrimination in health care settings include:

In the past 12 months, have you seen or observed the following happen in this health facility because a client was known to have or was suspected of having HIV or AIDS?

- ▶ **Staff seemed uncomfortable with a client because of his or her HIV status?**
- ▶ **Health worker gossiped about a client's status?**
- ▶ **Client was ignored or received less care than other clients?**
- ▶ **Client was denied care that he or she should have received?**
- ▶ **Staff used excessive precautions with clients suspected of having HIV or AIDS (e.g. used latex gloves for non-invasive procedures)?**
- ▶ **Client was treated with disrespect or abused?**

When measuring discrimination in health care settings, it can be difficult to determine whether discrimination results from institutional policies or from personal attitudes and choices on the part of individuals, but this is an important factor to consider. Qualitative methods are useful for investigating the institutional policy environment in which discrimination takes place.

f. Compounded or layered Stigma

Compounded stigma is complex and difficult to measure accurately through survey questions. Examples of traditional survey items that have been used to gain a preliminary sense of layered stigma include:

Indicate your agreement or disagreement with each statement (*specific most-at-risk-populations can be substituted depending on local contexts*):

- ▶ **Female sex workers are to blame for spreading HIV.**
- ▶ **Clients who are sex workers deserve to receive the same level and quality of care as other clients when they need health care.**
- ▶ **Homosexuality is the cause of HIV.**
- ▶ **Injecting drug users are to blame for spreading HIV in this community.**
- ▶ **Men who have sex with other men are to blame for spreading HIV in this community.**

One challenge, however, is that in concentrated epidemics, the belief that HIV prevalence is highest among a particular marginalized group may be a component of compounded stigma as well as an accurate reflection of the epidemiology of HIV in that setting. There are no well-established quantitative measures of compounded stigma, but some researchers have suggested that a factorial design can be used to disentangle different layers of stigma. For example, researchers can ask the same question about men and women living with HIV, or about different groups such as sex workers on the one hand and injecting drug users on the other (Reidpath and Chan 2005; Chan et al. 2007). Properly disentangling compounded or layered stigma may require detailed instruments and analyses across different variables that are beyond the scope of the instruments in this volume. Whether it is worth investing in such research depends on the particular context. Qualitative research can also be used to explore these connections and may yield useful insights.

g. Measures of social norms and anticipated reactions

A number of studies of stigma include questions about what attitudes and behaviours respondents would expect from others (usually other people in their community), but these have not been included in the Client Instrument in this volume. Some researchers think that such questions provide a measure of social norms and of inclinations to stigmatize, while others are sceptical of hypothetical questions about undefined “communities”. The

extent to which hypothetical questions are useful may depend on the context and study objectives. Anticipated reactions to people living with HIV can be measured by whether respondents agree or disagree that:

In my community (*to be defined*):

- ▶ **A man who has HIV would be abandoned by his partner.**
- ▶ **A woman who has HIV would be abandoned by her partner.**
- ▶ **A person living with HIV would be neglected.**
- ▶ **A person living with HIV would be avoided.**
- ▶ **A person living with HIV would be verbally abused or teased.**
- ▶ **A person living with HIV would not be allowed to go to work/school.**

Another variable that has been used to measure stigma is the percentage of people reporting willingness to care for or to help people living with HIV or AIDS. The survey questions can be phrased as: “Imagine that you find out that one of your friends is HIV-positive. Would you still be friends with him or her?” Another possible survey question is: “If a member of your family became sick with AIDS, would you be willing to care for her or him?”

h. Attitudes about the rights of individuals living with HIV

Some studies have sought to explore opinions among the general population or among health workers about human rights issues that affect people living with HIV. For example, this dimension can be gauged by asking respondents about their support for specific rights of people living with HIV such as:

Indicate your agreement or disagreement with each statement:

- ▶ **I think patients with AIDS do not have the right to the same quality of care as other patients.**
- ▶ **Women with HIV should be prevented from having children.**
- ▶ **People suspected of having HIV should be required to be tested.**

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CHAPTER 3

ADHERENCE TO ANTIRETROVIRAL THERAPY

1. BACKGROUND

1.1 Rationale: Why research is needed on adherence to antiretroviral therapy

Adherence, “the extent to which a person’s behaviour – taking medication, following a diet and/or executing lifestyle changes, corresponds with agreed recommendations from a health care provider” (WHO 2003), is a crucial element for scaling up HIV treatment. Concerns about poor adherence have sometimes been used to deny or delay access to care to those populations that were expected to be less adherent to antiretroviral therapy, even though it has been shown that “pre-treatment” information is less predictive of adherence than a patient’s experience with treatment (Spire et al. 2002). Recent evidence shows that good adherence can be achieved in low-resource settings (Fong et al. 2003; WHO 2003; Mills et al. 2006), but it is clear that maintaining high adherence over time requires adequate support and remains one of the greatest challenges in both high- and low-resource settings (Gill et al. 2005).

Suboptimal adherence to antiretroviral therapy has implications at both an individual and a population level. For individual patients, studies have demonstrated that adherence to antiretroviral therapy, however it is measured (unannounced pill count, electronic monitoring systems or self-reports), is a strong predictor of HIV outcomes, as measured by virological response (Bangsberg et al. 2000; Paterson et al. 2000; Nieuwkerk et al. 2001a), CD4 lymphocyte count (Paterson et al. 2000; Carrieri et al. 2003; Wood et al. 2004), progression to AIDS (Bangsberg et al. 2001; Bouhnik et al. 2005), hospitalization (Paterson et al. 2000) and death (Hogg et al. 2000; Garcia de Olalla et al. 2002; Wood et al. 2003). The clinical implications of adherence are most evident in the initial months of treatment (Carrieri et al. 2003), supporting an argument that research and interventions should pay particular attention to the factors that influence adherence in the earliest phase of treatment.

One of the greatest public health concerns about poor adherence to antiretroviral therapy is that suboptimal adherence — including taking fewer pills than prescribed, taking doses at the wrong time and interrupting treatment — may lead to the development of drug-resistant viral strains. Drug resistance can render first-line drugs ineffective for patients and require second-line drugs that are more complex, more costly and carry greater side-effects

and risks of drug interactions (Clotet 2004; Negredo et al. 2006). Among small cohorts of patients in African populations, drug-resistant strains of HIV have emerged in both treatment-naïve and treatment-experienced patients (Adje-Toure et al. 2003; Koizumi et al. 2006). The risk of drug resistant strains as a consequence of suboptimal adherence has also been documented in settings such as China (Han et al. 2005) and India (Hira et al. 2004; Balakrishnan et al. 2005).

Many research gaps remain about the best way to monitor patterns of adherence over time (Bangsberg 2008), the levels and patterns of adherence in different settings, and the factors and circumstances that lead to suboptimal adherence, including treatment interruption. Addressing these research gaps may contribute to improved clinical care and better informed HIV treatment policies and programmes. Researchers may also want to explore the links between poor adherence and treatment abandonment, though a full exploration of treatment discontinuation and retention issues is beyond the scope of the instruments in this volume.

1.2 Definitions: how researchers define adherence to antiretroviral therapy

Nonadherence to treatment can occur when a patient takes medication at the wrong time, skips doses, interrupts treatment for a period of time or abandons treatment altogether (WHO 2003). It should be noted that this chapter concentrates on medication taking — the first element of the WHO definition of adherence. Diet and lifestyle changes, the other two elements, are addressed to some degree in this volume (e.g. a few questions about food security in the Client Instrument and a detailed discussion of sexual behaviour in the Prevention chapter); however, researchers who want to explore these elements in more depth may need additional data collection tools, depending on the purpose of the research.

Adherence to antiretroviral therapy has been measured in different ways, most commonly as a percentage of prescribed pills taken or picked up on time over a given period of time (Bangsberg 2008). Adherence can be analysed as a continuous variable (Gross et al. 2006) or as a categorical variable that distinguishes ‘optimal’ from ‘suboptimal’ adherence (high from moderate from low, good from poor). While some researchers have reported adherence as a percentage of prescribed pills taken over a given period

of time, suboptimal adherence can also be defined to include patterns such as mistimed doses (Liu et al. 2006), treatment interruptions (Raffa et al. 2006) and treatment discontinuation (Bangsberg 2008).

Studies have traditionally used a threshold of 95% or more to distinguish between optimal and suboptimal adherence (Ammassari et al. 2001; Cederfjall et al. 2002; da Silveira et al. 2003; Weber et al. 2004; Chesney 2006; Simoni et al. 2006a). This threshold was based on evidence that near perfect adherence (95% or more) to existing regimens was needed to achieve optimal patient outcomes, such as a lower risk of virological failure, increased CD4 lymphocyte count and lower hospitalization rates, especially during the early phase of treatment (Paterson et al. 2000; Arnsten et al. 2001; Carrieri et al. 2003). Similarly, several studies found a skewed bell-shaped relationship between drug-resistance and adherence to single protease inhibitor therapy, whereby moderate to high (80% - 90%) adherence was associated with the greatest risk of drug-resistant mutations (Bangsberg et al. 2004; Harrigan et al. 2005; King et al. 2005). However, this body of research was largely based on non-boosted protease inhibitors which are being rendered obsolete by newer treatment regimens (Bangsberg et al. 2007).

Recent studies suggest that ritonavir-boosted protease inhibitors (and to a lesser degree non-nucleoside reverse transcriptase inhibitors — NNRTIs) appear to be more ‘forgiving’ than older regimens, as they achieve viral suppression even in the face of moderate adherence of 70% or more (Weiser et al. 2004; Maggiolo et al. 2005; Bangsberg et al. 2007; Wainberg et al. 2007). Evidence also suggests that the adherence level needed to prevent drug resistance depends on the length of time on treatment, the variant of the virus and the host genome (Bangsberg et al. 2007). For example, near perfect adherence (95–100%) appears to be especially important during the first four to six months of treatment, before viral suppression has been achieved, regardless of regimen (Wainberg et al. 2007). Therefore, researchers agree that maximum adherence remains a worthy goal for all regimens, though it may be difficult to attain for many patients (Gardner et al. 2006; Wainberg et al. 2007).

It is also important to note that average adherence levels are only one dimension of optimal adherence. Research indicates that patterns of adherence over time, including selective drug taking, treatment interruptions and treatment discontinuation may be just as important as average adherence levels (Gardner et al. 2005; Bangsberg 2008). Treatment interruption — missing pills for at least 48 consecutive hours — appears to have a considerable influence on virological response (Raffa et al. 2006) and is a major risk factor for resistance to nevirapine and probably to other NNRTIs (Oyugi et al. 2007). Studies indicate that treatment modification and discontinuation of at least part of their drug regimen occurs among a substantial proportion of patients, with serious consequences for health outcomes and drug resistance (Ahdieh Grant et al. 2001; Bangsberg et al. 2007; Kiguba et al. 2007).

In sum, while clinical practice is changing rapidly, the evidence underscores the importance of high levels of adherence, including

the lack of treatment interruptions, for the successful scale-up and sustainability of antiretroviral therapy programmes. Researchers continue to recognize a threshold of 95% or higher as ‘optimal’ adherence, especially during the early phase of treatment. After six months, researchers may want to measure adherence as a continuous variable, especially for more forgiving regimens, rather than using rigid distinctions between adherent and nonadherent patients. Ideally, researchers will also use operational definitions of adherence that include patterns of medication taking (e.g. interruptions) in addition to overall averages, as well as measures that monitor adherence levels over time.

1.3 Patterns and levels of adherence

Adherence to treatment of chronic diseases in general tends to be around 60% (WHO 2003). Studies that have examined adherence to antiretroviral therapy around the world have found a wide range of levels. A meta-analysis of published studies found that 55% of North American patients (range: 26%-86%) and 77% of African patients (range: 30%-100%) achieved ‘optimal’ adherence to antiretroviral therapy (Mills et al. 2006). These observed proportions of patients who achieve high adherence are similar to the findings of longitudinal studies of French patients initiating antiretroviral therapy (Carrieri et al. 2001). Observed adherence levels have been slightly higher in the Italian and the Swiss cohorts (70%) (Ammassari et al. 2004; Glass et al. 2006) and lower in the Dutch cohort (47%) (Nieuwkerk et al. 2001b).

Evidence indicates that high adherence to antiretroviral therapy may be difficult to sustain over time. For example, a study from France followed patients over three years and found that only 26% of patients were able to maintain consistently “high” adherence throughout the follow-up period (Carrieri et al. 2003). Similar findings have been reported from other settings (Bangsberg 2008). As patients’ trajectories of adherence may diminish over time, it is crucial for clinicians to monitor adherence levels and intervene before the virus has an opportunity to rebound (Bangsberg 2008). It is also important for researchers to learn more about why — and to what degree — individual and contextual factors influence adherence to antiretroviral therapy over time. This may require two levels of information, namely: measures to assess patients’ adherence levels at different points in time and information about contextual and individual factors that influence adherence. One area that remains to be fully explored is whether there are relationships between patterns and factors associated with missing doses and those involved in stopping treatment altogether. For example, do most patients who abandon treatment do so after missing more and more doses, and are those who adhere poorly to antiretroviral therapy at risk of abandoning treatment altogether?

2. FACTORS AND PROGRAMME STRATEGIES

2.1 Factors that influence adherence to antiretroviral therapy

Understanding the factors that influence adherence to antiretroviral therapy is essential for designing strategies to optimize adherence, and the evidence has been growing rapidly,

both in high-resource settings (Chesney 2000; Ammassari et al. 2001; Ickovics et al. 2002; Spire et al. 2002; Reynolds et al. 2004) as well as in resource-limited settings (Pinheiro et al. 2002; Fong et al. 2003; Orrell et al. 2003; Weiser et al. 2003; Nachega et al. 2004; Nemes et al. 2004; Stout et al. 2004; Byakika-Tusiime et al. 2005; Safren et al. 2005). Qualitative studies carried out in resource-limited settings provide useful insights regarding contextual barriers to adherence and how to design programme strategies to address them (Hardon et al. 2006).

There are different ways to group the factors that influence adherence to antiretroviral therapy, ranging from conceptual frameworks that simply distinguish between individual and contextual factors, to those frameworks that include more detailed categories. Here, we adapt the framework used in the WHO review of adherence (2003) and distinguish the following interacting dimensions:

- ▶ **Health care and system-related factors (service delivery of ART).** These include reimbursement systems and the cost of medications and consultations, drug distribution systems and the availability of medicines, access to health services, levels of confidentiality in the health care setting and the conditions of the medical encounter.
- ▶ **Patients' clinical condition and therapy-related factors.** These include stage of the disease, severity of symptoms, complexity of drug regimens, side-effects, toxicities and their management, degree of diet restrictions and lifestyle changes required by the regimen and the occurrence of co-morbidities, e.g. depression or drug or alcohol abuse.
- ▶ **Social and demographic patient-related factors.** These include socioeconomic status, food security, residence, employment and other sociodemographic variables.
- ▶ **Other patient factors, such as how treatment fits into patients' lives.** These factors may include forgetfulness, schedule, attitudes and knowledge about HIV treatment, and whether patients feel they need to take their medications in secret (for more detail, see the chapter on stigma and discrimination in this volume).
- ▶ **Social context and social interactions.** These include factors such as the degree of social support (and conversely discrimination) that patients experience from partners, families and friends (etc.), as well as interactions with providers and trust of health services.

It is sometimes useful as a first step to conduct a situation analysis in order to identify the general structural and social factors that influence access to medicines and the ability to take them. These factors may include, for example, the costs of medications in a given country, the extent to which antiretroviral therapy medications are regularly supplied to health facilities, the availability of food and water in the area, the accessibility of the health facilities where HIV treatment and care are provided, the extent of law enforcement actions against groups such as drug

users or those exchanging sex for survival and the degree to which stigma discourages HIV-positive individuals from revealing their status. This information can be collected at the aggregate level through key informant interviews and also by asking individuals about their experiences. Other factors, particularly those related to patients, require individual data collection.

It is also important for researchers to examine the length of time that patients have been taking antiretroviral therapy. Factors associated with poor or nonadherence in the first few months may be quite different than those factors that have the greatest role in poor adherence over the long run. For example, those who have just begun taking antiretroviral therapy may have to deal with major physical and social changes, including side-effects, new daily routines, fear of disclosing their status to others (in some cases), uncertainty about the benefits of antiretroviral therapy and possible modifications to their regimen. On the other hand, after two or three years, patients may experience improvements in their overall health, but fatigue from having to take medication multiple times a day.

2.2 Interventions and programming to support adherence

Although substantial descriptive data are now available on the consequences and factors that influence nonadherence in a variety of populations, until recently, much of the available evidence on adherence interventions consisted of descriptions of demonstration projects (Williams et al. 2006), and few studies were able to determine whether adherence interventions are associated with improved virological or immunological outcomes (Pradier et al. 2003). More recently, the evidence has grown, and a number of controlled studies have examined programme strategies to improve antiretroviral therapy adherence. Programme strategies to improve adherence can be categorized as follows:

- ▶ **treatment-related**, including simplification or correction of regimens, management of side-effects, treatment of depression, improved drug management and supply systems;
- ▶ **adherence patient education and counselling**, including counselling to improve medication management skills and to help patients overcome barriers to adherence;
- ▶ **community/peer support**, including the peer support, (*accompagneurs*) programme in Haiti (see Stigma chapter), or support groups for people living with HIV; and
- ▶ **programmes that address socioeconomic constraints**, such as free or subsidized medicines, transportation or food supplements, or income-generating opportunities.

Individual level interventions

A systematic review, based on 19 relevant randomized controlled trials from high-income countries, found that programmes that were most successful in improving adherence were provided to individuals over long periods of time and emphasized practical medication management skills (Rueda et al. 2006). A meta-analysis of randomized controlled trials of clinic-based patient education, counselling and various devices to prompt patients

to take their medications found that participants who received education and counselling were significantly more likely (OR=1.5) to reach the optimal level of 95% adherence and to have an undetectable viral load (OR=1.25) than those who were not offered such counselling (Simoni et al. 2006b).

The importance of counselling, over and above external reminders (as highlighted in the meta-analysis) was confirmed by a recent multi-centre trial in the United States. This trial compared the effects of an electronic medication alarm system with those of “medication managers” — clinic staff who were given two days of training on how to conduct adherence counselling and how to help patients identify and overcome barriers to adherence. Medication managers were found to significantly increase levels of optimal adherence, which was not the case for the electronic medication alarms (Mannheimer et al. 2006).

While randomized controlled trials are important ways to measure the effect of individual interventions, they are limited when trying to assess the effectiveness of community-based approaches or programmes that aim to overcome socioeconomic constraints. Also, trials that standardize interventions cannot assess the effect of tailored approaches that match adherence interventions to patient needs at different stages of treatment (Gordon 2006). Therefore, it is necessary to complement randomized controlled trials with other sorts of intervention studies, especially in low-resource settings.

Community level interventions

Evidence about the potential benefits of a variety of community level strategies is growing. Community-based interventions in Haiti and Rwanda, including the use of peer supporters (*accompagnateurs*), have been shown to improve adherence and outcomes (Mukherjee et al. 2006). Home-based counselling and home-delivery of drugs appear to be effective in increasing adherence and decreasing viral loads (Weidle et al. 2006). Directly administered antiretroviral therapy (DAART) has been adapted and modified from the directly observed therapy (DOT) strategy used in the management of tuberculosis, and this approach seems to be acceptable (Pearson et al. 2006) and to increase optimal adherence (Luchters et al. 2008). Some evidence suggests that strategies that alleviate the cost of transportation and address food insecurity — which represent major obstacles in resource-limited settings (Hardon et al. 2007) — may improve Body Mass Index (BMI), weight and CD4 counts (Gisha Mugisha et al. 2006; Samuels et al. 2008a; Samuels et al. 2008b). However, confirmation of these findings will require further studies with careful measurement of adherence levels and the use of control groups.

3. RESEARCH OBJECTIVES AND QUESTIONS

In order to monitor adherence and inform interventions to support adherence, it is essential to have standardized information across

sites and over time. But since adherence is a dynamic process that changes over time and is shaped by multiple factors, an overly rigid “determinants” framework would miss important dimensions of the process of adherence — in particular, the patient perspective and the broader societal forces that influence behaviours. Even within the context of operational research, it is possible to consider some of these factors, including patients’ experiences, the strategies they use to adhere to treatment and the wider social context of medication taking, including social networks.

Recent research has begun to pay attention to such factors and has recognized the contribution of qualitative methods in improving explanations for adherence, particularly those that have to do with patients’ views, what influences those views and how those views affect behaviour (Golin et al. 2002; Nachega et al. 2006; Sankar et al. 2006). There are calls for combining medical and social perspectives and for using multi-disciplinary teams (Frick et al. 2006; Friedland 2006). This chapter focuses on ways to standardize the measurement of adherence and its key determinants using closed-ended questions that can be asked in all settings, but it also includes open-ended questions that can capture the individual and context-specific dimensions of adherence.

The Adherence Module of the Client Instrument in this volume is designed to facilitate operational research in order to inform programmes and improve antiretroviral therapy delivery. The instrument addresses the operational research questions listed in the box on the next page.

The first of these three research questions (adherence levels over time) can be answered by analysing the quantitative survey data from the Adherence Module of the Client Instrument in this volume. The second set of questions (about factors that influence adherence) can be answered through regression analyses of survey data collected using various modules in this volume. The third set of research questions can best be answered using both statistical analyses of quantifiable data and qualitative methods based on responses to the open-ended questions in the Client Instrument. Further data collection and analysis can be carried out to explore patients’ own perspectives on the factors that influence adherence, using qualitative methods such as narrative techniques.

Additional research questions that may be considered in different settings

In addition to the core research questions addressed by the instruments in this volume, researchers may want to investigate a host of other factors that influence adherence, as illustrated in the box on page 35. In some cases, the Adherence Module already includes the survey questions needed to investigate these questions; in other cases, researchers would need to add additional survey items.

KEY OPERATIONAL RESEARCH QUESTIONS ABOUT ADHERENCE

1. What proportion of antiretroviral therapy patients have suboptimal adherence?
 - What proportion of patients have suboptimal (or high, moderate and low) adherence after 4 months, 6 months, 1 year, 2 years (etc.)?
2. What factors are associated with optimal or suboptimal adherence?
 - Health care system: Is poor adherence associated with inconsistent supply of ART, higher cost of treatment, distance from the clinic or other facility-related barriers to access?
 - Patients' clinical condition and therapy: Is poor adherence associated with more complex treatment regimens or occurrence of side-effects or co-morbidities?
 - Social and demographic patient-related factors: Is poor adherence associated with patients' socioeconomic status? Is it associated with food security?
 - Other patient factors: Is adherence associated with factors such as attitudes and knowledge about ART and HIV and whether patients take their medications in secret?
 - Social context: Is poor adherence associated with low levels of social support, high perceived stigma or experiences of discrimination?
3. How does the situation of patients' lives influence sustained adherence to antiretroviral therapy?
 - How do patients fit antiretroviral therapy into their daily routines?
 - What are the primary reasons that nonadherent patients skip doses or interrupt their therapy? Do these patterns differ at different times of year or over the course of treatment?
 - How do factors such as patients' socioeconomic status, food security, knowledge and attitudes and income-generating activities influence adherence?
 - How do family members and other social networks support or impede patients' adherence?

ADDITIONAL RESEARCH QUESTIONS ABOUT THE INFLUENCE OF VARIOUS FACTORS ON ADHERENCE

Health Care Delivery

ART initiation and retention criteria	Do guidelines with more stringent criteria for patients initiating and remaining in antiretroviral therapy programmes result in better adherence?
Waiting and consultation time	Does the time patients must spend in the clinic influence their adherence?
Availability of essential medications	Does the availability and cost of drugs for AIDS-related illnesses influence adherence?
Comprehensive care	Do services that provide comprehensive care and treatment for co-morbidities (malaria, TB, substitution treatment, hepatitis, etc.) achieve higher levels of adherence than those that do not?
Laboratory services and clinical monitoring	Does the availability of laboratory services and regular feedback to patients on their clinical indicators influence adherence?
Refill interval	Do patients at facilities that require patients to come for refills every month have better adherence than patients at facilities with longer refill intervals?
Number of patients enrolled in the ART programme	Is the size of antiretroviral therapy programmes associated with patients' adherence?
Providers' knowledge of ART and adherence	How well do different types of providers understand antiretroviral therapy management and the importance of adherence?

Patients' Health

Concurrent therapies	How do patients integrate antiretroviral therapy with other treatment modalities, including traditional and "neo-traditional" remedies, and how does this influence adherence?
Depression	How do depression, anxiety and hopelessness influence adherence?
Alcohol and drug use	Do patients who abuse alcohol or drugs have worse adherence than those who do not? How does substitution treatment influence adherence to ART?

Other Patient-related Factors

Economic activity	How do patients' income-generating activities and food security influence their adherence, and how does this change over time?
Perceptions and knowledge about ART	How do patients understand antiretroviral therapy and how does this influence adherence?
Perceptions of adherence	What meaning and importance do patients attribute to adherence, and how does this change over the course of their treatment?
Perceptions of own health status	Do the perceptions that patients have of their own health status influence adherence?

Social Interactions

Quality of interactions with patients	What counselling skills do providers use when interacting with patients (e.g. listening, respect, time for questions, confidentiality, non-judgemental interaction, etc.)?
Attitudes towards providing adherence support	What are providers' attitudes when providing adherence support to patients (disciplinary vs. patient-centred, and value vs. resent time spent on adherence counselling), and how does this influence adherence?
Stigma	What role does stigma or discrimination play in adherence?
Perception of relationships with health workers	How do patients perceive their relationships with health care providers, particularly with regard to trust and honesty, and how does this influence their adherence?

4. METHODS

4.1 Study populations and study design

The primary study population for operational research on adherence is that of patients taking antiretroviral therapy, because their perspectives and experiences are essential to inform interventions and service delivery to improve adherence practices. Some additional information may be elicited from key informants, health care providers, representatives of AIDS care organizations and family and friends (including peer supporters or *accompagnateurs*) of patients taking antiretroviral therapy.

Patients can be recruited in the clinic setting, using all patients on antiretroviral therapy as a sampling frame. Patients should be sampled to include variability on key variables, such as sex, time on antiretroviral therapy, etc. If possible, data should be collected at several points in time, since adherence may change over time. But cross-sectional data at a single point in time can also be useful, as they can give a snapshot of patients' experience. When designing a sampling plan, researchers should consider the possibility that a certain proportion of patients will abandon treatment or modify their regimens after treatment has begun. Gathering data among this group may provide another important perspective on the factors that influence adherence to antiretroviral therapy.

Ideally, research methods should integrate both qualitative and quantitative data collection from multiple sources, creating a comprehensive picture of the multi-faceted influences on adherence. Qualitative methods are valuable because they can elicit salient issues for a particular group and can shed light on the social context of adherence. They can be used to explore and explain the findings of a quantitative survey, or as part of formative research to understand adherence, to elicit the topics and to inform the measurements to be used for a quantitative study. Qualitative data can be collected through individual interviews, focus group discussions and observations. They are generally analysed through a process of coding and content analysis for themes and patterns (Ulin et al. 2005).

In addition to the topics and open-ended questions that are suggested in the Adherence Module of the Client Instrument, qualitative data collection on adherence may include narrative techniques of asking people about their lives, events that have occurred since being diagnosed with HIV, their daily routines and how taking antiretroviral therapy fits into those routines. Narrative accounts give respondents a chance to identify what factors or circumstances they consider most relevant to their situation and to describe social interactions that influence adherence.

4.2 Methods and measures: an overview of the literature

Adherence is frequently assessed based on some form of observation or patient self-report. Observational methods include medication event monitoring systems (MEMS — an electronic pill cap that records when it is opened), pill counts (either at pharmacy refills or unannounced visits), pharmacy refill records and directly observed therapy. Self-reported methods use questionnaires that are either self-administered or administered

by an interviewer. Most self-report measures ask patients to recall the proportion of times that they correctly took their medications over a defined time period.

Variability in the observed levels of adherence to antiretroviral therapy may depend on the way adherence is measured (e.g. pill counts, MEMS, self-reports, etc.) and — in the case of face-to-face interviews — who collects the information (e.g. a physician, social worker or peer). It is, therefore, important to define standardized measures, to clarify appropriate study designs and methods, and to foster comparability across studies.

All measures of adherence have limitations, including those that are based on “objective” measures rather than self-reports. For example, there are errors and biases in measures such as electronic drug monitoring and pill counts (Berg and Arnsten 2006). Even laboratory measurements can be misleading: while drug plasma concentration levels may offer a direct measure of recent drug consumption in the preceding 24 hours, they may also be biased by the possibility that patients who are not usually adherent may take their medications appropriately the day prior to the medical examination and hence be classified as adherent. Thus, the decision of which method to use will depend on the trade-offs the investigator is ready to make (see Table on next page).

Despite their potential disadvantages, self-report measures of adherence are highly correlated with clinical measures of viral load (Nieuwkerk and Oort 2005) and other measures of adherence, such as pill counts and MEMS (Arnsten et al. 2001; Liu et al. 2001; Wagner 2002; Oyugi et al. 2004). In addition, self-report measures are often chosen because they are easier, less costly and more feasible to administer than other measures of adherence. Appropriate selection of questions, a non-judgemental approach that includes normalizing language and good interviewer training can greatly improve the validity and reliability of self-reports.

Self-report measures of adherence take many forms, and standardization is necessary to enable comparisons across studies. Some self-report measures involve asking patients to recall the proportion of pills or the proportion of times that they correctly took their medications over the previous three days, four days, one week or one month. In shorter periods (three or four days) patients are asked to recall which doses they took or did not take, each day. There has not been any evidence to suggest a difference between the validity of a 3- or 4-day measure, suggesting that a 3-day measure may be chosen for its easier administration (Simoni et al. 2006a). Instead of using a 1-week measure that also includes the weekend, a question about adherence during the weekend can be added in those settings where weekday and weekend routines are expected to differ. A 1-month measure seeks to elicit an estimate by respondents of their overall adherence. It may be measured using quantitative or qualitative categories or using a visual analogue scale (VAS) that asks respondents to indicate how high their adherence was over the previous month. The VAS provides an ordinal measure of adherence and allows respondents to express suboptimal

adherence without having to admit to missing specific doses and may be desirable in some settings. In other settings, carefully worded questions about different levels of adherence may facilitate accurate responses.

Given the potential of self-report measures to overestimate adherence as a result of desirability bias (whereby respondents tend to give ideal rather than accurate answers), some studies combine multiple questions into a composite measure. Scores based on self-reports have been shown to correlate with virological and immunological response (Carrieri et al. 2003) and with clinical progression and mortality (Bouhnik et al. 2005), and this approach is increasingly used to differentiate between more and less adherent respondents (Kleeberger et al. 2001).

Since there is no gold standard to measure adherence, it is not possible to recommend a single tool, and it is preferable to include more than one measure of adherence (Berg and Arnsten 2006). In addition, optimal measures in research settings are not necessarily the same as those in clinical settings (Chesney 2006), and some “tailoring” is necessary for the specific objectives of the project. A single instrument may include multiple self-report measures, as well as additional questions about missing pills over the weekend or during periods of illness, and about treatment interruptions and discontinuations. Questions on self-reported adherence should

always be preceded by language that normalizes suboptimal adherence and gives respondents permission to provide an honest response, even if it is incongruent with what they perceive as the ideal behaviour (Simoni et al. 2006a).

4.3 Recommended methods and measures

For the purpose of the instruments in this volume, we propose multiple measures that can be combined to provide a comprehensive view of adherence. These measures are based on the literature. The selection of measures and methods reflects our efforts to take account of the situation in resource-limited countries, where laboratory facilities to measure viral loads are lacking and where patient outcomes are largely based on clinical assessments. Specifically, we recommend the following:

- ▶ **Monitor adherence at several points in time.** We recommend monitoring adherence at several points in time, both because adherence varies over the duration of treatment and because longitudinal measures make it possible to predict the risk of virological failure.
- ▶ **Use self-reported methods when resources are limited.** Self-reports of adherence are likely to be the best option to measure adherence in resource-limited settings, because they are inexpensive and relatively easy to collect.

THE TRADE-OFFS OF DIFFERENT METHODS TO MEASURE ADHERENCE

METHOD	ADVANTAGES	DISADVANTAGES
MEMS (electronic pill cap)	<ul style="list-style-type: none"> ■ Sensitive in detecting nonadherence ■ Useful for pharmacokinetic studies 	<ul style="list-style-type: none"> ■ Costly ■ Relies on the assumption that pills are taken when, and only when, the pill cap is removed ■ Feasible only in specific contexts
Unannounced Pill count	<ul style="list-style-type: none"> ■ Relatively easy ■ Sensitive in detecting nonadherence 	<ul style="list-style-type: none"> ■ Requires accurate knowledge of the number of pills that a patient should have at a given period ■ Feasible only in specific contexts ■ Assumes that patients keep their pills in one location ■ May violate patients' privacy and result in involuntary disclosure if conducted outside the clinic
Pill count at pharmacy refills	<ul style="list-style-type: none"> ■ Relatively easy 	<ul style="list-style-type: none"> ■ Requires accurate knowledge of the number of pills that a patient should have at a given period ■ Assumes that the patient presents all remaining pills ■ Not adaptable to all settings ■ May overestimate adherence
Pharmacy refill records (monitoring on-time pick-up)	<ul style="list-style-type: none"> ■ Relatively easy 	<ul style="list-style-type: none"> ■ Relies on accurate record-keeping ■ May overestimate adherence
Directly observed therapy	<ul style="list-style-type: none"> ■ Useful when feasible ■ Sensitive in detecting nonadherence (missed visit=missed daily dose) 	<ul style="list-style-type: none"> ■ Costly and time-consuming ■ Time burden on patient ■ May violate patients' privacy and result in involuntary disclosure
Self-report (self-administered questionnaires or face-to-face interview)	<ul style="list-style-type: none"> ■ Easy ■ Sensitivity depends on instrument, interviewer and general approach, but can be quite high 	<ul style="list-style-type: none"> ■ Relies on patients both to recall the pills they have taken and to report this truthfully ■ May overestimate adherence if respondent gives the desirable response ■ The choice of questions, way of questioning and terms chosen are crucial

► **Ask about adherence in multiple ways.** In order to reduce the desirability bias, we recommend asking about adherence in several different ways. A composite measure can be created in order to differentiate between adherent and nonadherent respondents.

► **Use a minimum set of core questions to assess adherence and add more detailed questions if needed.** In this chapter, we propose a core set of questions that appear in the Adherence Module of the Client Instrument. This chapter also suggests some additional questions for researchers who need more detailed information on adherence, for example, during the initial phase of treatment when adherence is crucial for the durability of treatment response.

5. VARIABLES AND SURVEY QUESTIONS

The Adherence Modules of the Client and Provider Instruments in this volume are designed to gather data on the levels and patterns of adherence to antiretroviral therapy and on factors that may influence adherence. The rest of this section summarizes those variables and provides recommendations for constructing questionnaires.

5.1 Variables and survey questions about adherence in the Adherence Module of the Client Instrument

The Adherence Module of the Client Instrument contains questions that gather data on the following types of variables:

VARIABLES IN THE ADHERENCE MODULE OF THE CLIENT INSTRUMENT

- a. Length of time on antiretroviral therapy
- b. Antiretroviral therapy regimen (prescribed doses)
- c. Three day recall of adherence
- d. Circumstances of/reasons for nonadherence in the past 3 days
- e. Adherence on weekends
- f. One-month estimate of adherence
- g. Circumstances of/reasons for nonadherence in the past month
- h. Modifying time that medications are taken
- i. Treatment interruption
- j. Changes in adherence over time

a. Length of time on antiretroviral therapy

Knowing how long the respondent has been taking antiretroviral therapy helps differentiate between the induction phase (the first 4–6 months) and the maintenance phase of treatment.

How long ago did you first start taking antiretroviral therapy to manage your HIV?

Number of months ago: _____

Number of years ago: _____

b. Antiretroviral therapy regimen (prescribed doses)

In order to determine patients’ adherence to their prescribed antiretroviral therapy, it is important to establish the prescribed regimen, including the names of the medications and the number of pills to be taken at different times of day. Unless the interviewers have access to patients’ medical records, interviewers will need to ask respondents to identify their prescribed medication. If the clinic only prescribes a small number of regimens, it may be possible to obtain the information from a key informant prior to the interview.

The following table should be completed according to the prescribed antiretroviral therapy dosing, not the respondents’ actual behaviour. This information may be

NAME OF MEDICATION	MORNING DOSE	MIDDAY DOSE	EVENING DOSE	DAILY TOTAL
	# of pills	# of pills	# of pills	# of pills
1.				
2.				
3.				
Source of information above (patient, clinic, medical record, etc.):				

obtained from the patient, the provider or the health care facility. Cross out all non-applicable boxes.

c. Three-day recall of adherence

A detailed 3-day recall will elicit specific information on which pills were not taken, as well as whether respondents ever took pills later than the prescribed time. This exercise requires thorough training of interviewers. To complete this set of questions, the interviewers should reference the table that was completed for the prescribed antiretroviral therapy regimen in order to complete the names of all medications. They should then walk the respondents through each of the last three days. To facilitate recall, interviewers should use memory prompts. For example, they may first ask respondents to think about yesterday and what they were doing and if there was anything unique about the day, before asking whether they took their antiretroviral therapy.

This set of questions should be prefaced by normalizing language in order to reduce social desirability bias (Vinten 1998). The normalizing language suggested here has been adapted from language used in other studies (Simoni et al. 2006a), but should be piloted and adapted to the study setting. When fixed dose regimens are used, the table can be simplified by deleting the first column and including only a single row.

Many patients find it difficult to take all their medications as prescribed. We would not be surprised if you have missed taking some of your medications over the last few days. We are trying to find out how difficult it is for patients to take their medications, and what things make it difficult. Please answer these questions as honestly as you can about your own experiences.

The following table should be completed according to the antiretroviral medications that were actually taken over the last three days. Use memory prompts to facilitate accurate recall. (“What did you do yesterday morning? Did you take any HIV medications that morning?” If yes: “Which pills? How many of each?”) If the respondent reports missing a pill/dose, circle the cell and assign it a number.

NAME OF MEDICATION	# of pills prescribed	YESTERDAY	DAY BEFORE YESTERDAY	3 DAYS AGO
		# of pills taken	# of pills taken	# of pills taken
1.				
2.				
3.				

d. Circumstances of/reasons for nonadherence in the past 3 days

The reasons for missed doses can be investigated by using open-ended questions that ask respondents about the circumstances of and reasons for not taking their medications as prescribed. Asking about circumstances may elicit better information about poor adherence than simply asking for the reason(s). As noted earlier, each time a respondent reports having taken fewer pills than prescribed, the box should be circled and numbered (e.g. missed dose #1, missed dose #2). For each circled box, the interviewer should ask the following questions:

What circumstances led you to miss taking your medication as recommended on (name the day and the medication missed as identified in the previous question)? Probe for what happened and why.

Missed Dose #1 _____

Missed Dose #2 _____

Missed Dose #3 _____ (etc.)

e. Challenges adhering on weekends

Information on adherence on weekends can help differentiate between adherent and nonadherent patients, since changes in routine make it more difficult to keep to the prescribed regimen. Again, the question is prefaced with normalizing language in order to facilitate disclosure of poor adherence. Additional information can be elicited using an open-ended question about what happened.

Some people find it difficult to take their antiretroviral therapy medications on the weekends. Thinking about the past month, how many times did you miss taking a dose of your medication on a weekend?

- never
- once
- twice
- three or more times

f. One-month estimate of adherence

In order to get a 1-month estimate of adherence, we propose three options, namely: a single question about how often patients followed their prescribed antiretroviral therapy regimen over the previous month, a linear visual analogue scale (VAS) and a modified VAS. The first option — the single question — may be preferable for ease of administration, but the VAS may be chosen because it elicits information on a continuous scale and offers visual, rather than verbal, response choices. In some contexts, the linear VAS has been found to be highly correlated with viral load (Oyugi et al. 2004). The third option, a modified VAS, uses a bead count that was developed for use in low-resource countries, but its association with virological outcomes has not been established. Researchers may want to choose which measure to use for a 1-month estimate based on the results of piloting the instrument in the particular setting.

In the linear VAS, interviewers show respondents a line with two endpoints, where the left end represents “no pills taken” and the right end represents “all pills taken”. They then ask respondents to indicate where on the line their own performance fell regarding pill-taking in the previous one month. The coders will later measure the marked point in order to estimate the one-month self-report of adherence. In the modified VAS (Hardon et al. 2006), interviewers show respondents a jar of beads with the number of pills they *should* have taken the previous month. For example, if a respondent should have taken one pill twice a day, the jar will include 60 beads. The respondents are asked to transfer the beads to another jar to indicate the number of pills they actually *did* take in the previous month. The proportion of beads transferred from one jar to the other represents the estimated 1-month self-report of adherence. Visual analogue scales are useful for obtaining an overall measure of adherence.

THREE WAYS TO ASK ABOUT 1-MONTH ESTIMATES OF ADHERENCE

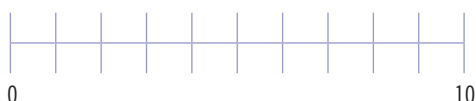
QUESTION ABOUT 1-MONTH ADHERENCE

We know that it is difficult to take all your antiretroviral therapy just as the doctor prescribed. Would you say that in the past month you:

- totally followed prescriptions
- generally followed prescriptions but with some deviations
- often modified timing and quantities
- almost never followed prescriptions
- interrupted treatment

LINEAR VISUAL ANALOGUE SCALE

Now I would like to ask you to estimate how much of your prescribed ART you took in the previous month. It is not likely that most people would take all of their doses. A mark at the left end where there is a number zero means you have taken no ART medications. A mark in the middle means you have taken about half of your ART medications. A mark on the right end where you can see the number ten means you have taken every single dose of your ART medications. Please put a mark on this line somewhere between zero and ten to describe your best guess about how much of your prescribed ART you took in the previous month.



MODIFIED VISUAL ANALOGUE SCALE USING BEADS

This jar of beads represents the number of pills you were supposed to take last month. I want you to move the beads to this jar to represent the number of pills you swallowed last month. In other words, if you swallowed only half your pills you would move half the beads into this jar. Or, if you swallowed all the pills you would move all the beads into this jar. We would not be surprised if you missed some of your pills in the previous month.

g. Circumstances and reasons for nonadherence in the past month

The Adherence Module of the Client Instrument asks respondents about the circumstances that led to missed and mistimed doses of their antiretroviral therapy. In addition, it contains the following three open-ended questions to gather qualitative information on barriers to adherence and the factors that make it easier for patients to achieve adherence:

OPEN-ENDED QUESTIONS ABOUT CIRCUMSTANCES THAT INFLUENCE ADHERENCE

- In general, what helps you take your medications on time?
- In the past month, what circumstances led you to miss taking your pills on time?
- What other things make it difficult to take all your medications on time?

h. Modifying the time that antiretroviral therapy medications are taken

The Adherence Module also contains detailed questions about whether respondents have ever taken multiple doses of their medication at one intake, for example:

During the past month, how often did you take a double dose of ART medication after missing a dose?

- never
- once
- sometimes
- frequently

Researchers may also want to ask respondents whether they have medications that are supposed to be taken more than once a day. If they say yes, then the interviewer can ask: "At any point during the past month, did you ever take all your daily doses of this (these) medication(s) in one intake?" The survey instrument can then ask about how often this occurred.

i. Treatment interruption

The Adherence Module in the Client Instrument measures treatment interruption by asking whether a respondent ever interrupted treatment during the previous six months, and if so, for how long. As noted earlier, evidence suggests that interrupting treatment for at least 48 consecutive hours increases the risk of resistance to nevirapine and probably to other NNRTIs (Oyugi et al. 2007). These questions are followed by an open-ended question about the circumstance that led to the respondent interrupting treatment.

During the past six months, did you ever stop taking your antiretroviral therapy for 48 hours or longer?

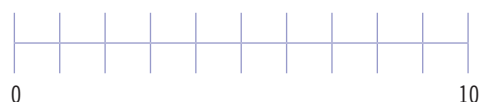
If yes: How long did you stop taking your antiretroviral therapy?

- for more than 48 hours and less than a week
- from one to two weeks
- for more than two weeks and less than one month
- for more than one month

j. Changes in adherence over time

Survey items can also be used to gauge changes in adherence over time. For example, the linear VAS can be used to ask respondents who have been on treatment for at least 2 months to recall the first month when they started treatment and to estimate their adherence level as follows:

Thinking of the first month when you started antiretroviral therapy, please put a mark on this line to describe your best guess about how much you followed prescriptions.



5.2 Variables and survey questions about factors that influence adherence

To identify the factors that influence adherence, we suggest the following variables to be considered in operational research. The variables that researchers choose in a particular setting will depend on the type of epidemic and common modes of transmission in the study sites. For example, researchers may want to include a module on drug use where appropriate (see the Prevention chapter for more information). In addition, formative research, anecdotal evidence and programme experiences may suggest other variables for inclusion. Unless indicated, the questions below are intended to be answered by patients currently taking antiretroviral therapy.

VARIABLES RELATED TO FACTORS THAT MAY INFLUENCE ADHERENCE IN THE CLIENT INSTRUMENT

- a. Demographic variables [in the Sociodemographic Module]
- b. Social support
- c. Access to the clinic
- d. Food security
- e. Health status
- f. Perceived side-effects
- g. Perceived changes to the body
- h. Additional variables, such as depression and drug use (optional)

a. Demographic variables

Demographic variables, such as the respondent's sex, age, education level and marital status, are clearly important for understanding the broader context that may influence adherence, as are variables such as socioeconomic status, income-generating activities and food security. Questions for gathering information on these types of variables can be found in the Sociodemographic Module of the Client Instrument.

b. Social support

The following questions on social support appear in the Adherence Module of the Client Instrument. Many of these close-ended questions are followed by the question: "Please tell me about this". These questions are closely related to disclosure, which is discussed at more length in the previous chapter on HIV Stigma.

Researchers with a particular interest in social support may wish to add another question about social support that is not included in the Client Instrument: "If you were sick in bed, is there anyone who would bring you food?" If the answer is yes, then the interview can ask: "Please tell me about this person".

EXAMPLES OF SURVEY QUESTIONS ON SOCIAL SUPPORT

- Does your partner/spouse know that you are taking antiretroviral therapy?
- Is there any other adult in your household who does not know you are taking antiretroviral therapy?
- Is it ever difficult for you to take your medications when someone from your family can see you?
- Is it ever difficult for you to take your medications when someone from your community or your workplace can see you?
- Is there anyone who regularly reminds you to take your antiretroviral therapy?
- During the past month, have you ever not taken your antiretroviral therapy because you did not want someone to find out?

c. Access to the clinic

The Adherence Module of the Client Instrument contains two core questions on access to the clinic, including a question about whether respondents have ever been unable to get to the clinic and a question about whether cost has ever been a barrier to adherence. Researchers who have a particular interest in access to care may want to gather more detailed information about how often respondents are supposed to go to the clinic, what form of transportation they use, how long it takes to reach the clinic and how much it costs to get there. It may also be possible to find out some of this information from a key informant, such as how often most patients are supposed to come to the health facility. Examples of more detailed questions about access that are not included in the Adherence Module but may be useful include the following:

EXAMPLES OF SURVEY QUESTIONS ABOUT ACCESS

SURVEY QUESTIONS ON ACCESS IN THE CLIENT INSTRUMENT

- In the past year, have you ever had problems getting your antiretroviral therapy on time because you were not able to reach the clinic? *If yes: Please tell me about this.*
- During the past year, has the cost of medications or the cost of clinic care ever interfered with your ability to get your antiretroviral therapy or take your medications on time? *If yes: Please tell me about this.*

EXAMPLES OF OTHER POSSIBLE SURVEY QUESTIONS ON ACCESS

- How often do you need to get to the clinic to obtain your medications or meet with a health care worker regarding your treatment?
- What form of transportation do you use to get from your home to the place where you get your antiretroviral therapy? (response options should be adapted for the setting)
- How long does it normally take you to get from your residence to the place where you get your antiretroviral therapy?
- How much does it cost you to get from your residence to the place where you get your antiretroviral therapy?

d. Food security

The Adherence Module of the Client Instrument contains one closed-ended and one open-ended question about food security, as follows: “During the past month, have you missed a dose of your antiretroviral therapy because you did not have enough food?” If the respondent says yes, then the interviewer can ask: “Please tell me about this”. Researchers who want more information about the relationship between food security and adherence may use the questions about food security from the Sociodemographic Module of the Client Instrument (noted below) or add additional items on this topic.

During the past month, how often have you had problems getting the food you need?

- never
- sometimes
- often
- always

If yes: Please tell me about this.

e. Health status

Questions about how respondent rate their health before and after they began antiretroviral therapy make it possible to measure the effect of antiretroviral therapy on patients’ lives. The two questions below appear in the Adherence Module. They are designed to obtain this information efficiently. More developed scales are available, however, for researchers who want more detailed information on this topic, including, for example, the SF-12v2(TM) Health Survey (Ware et al. 2002).

How would you rate your health before starting antiretroviral therapy?

- excellent
- very good
- good
- fair
- poor

And now that you are on antiretroviral therapy, how would you rate your health?

- excellent
- very good
- good
- fair
- poor

f. Perceived side-effects

To understand adherence, it is important to ask about both patients’ experienced side-effects and the influence that side-effects have had on patients’ daily lives, as illustrated by the questions in the next box. The Adherence Module contains a list of symptoms to be read to respondents. This list was adapted from the AIDS Clinical Trials Group (ACTG) baseline questionnaire (Chesney et al. 2000), from the Justice checklist (Justice et al. 2001) and from other sources of information about side-effects related to antiretroviral therapy such as lipodystrophies (Duran et al. 2001). Researchers may want to modify this list of side-effects based on the results of formative research.

SURVEY QUESTIONS ABOUT SIDE-EFFECTS

- **Some people experience side-effects when they take antiretroviral therapy. This varies a great deal – some people have a few, while others have more. Have you experienced any side-effects since you started taking ART?**
- *If yes, Which side-effects have been the most bothersome?*
- **Can you please tell me more about these side-effects?**
- **I’m going to read you a list of side-effects. Please tell me whether you have experienced any of these side-effects in the past month.**
Read list.
- **For each side-effect that the respondent reports: Has this side-effect been very bothersome, somewhat bothersome or not at all bothersome?**

g. Perceived changes to the body

In addition to the side effects, it is also important to ask respondents about changes in the appearance of the body. The Adherence Module contains questions about body changes that have a similar structure to the questions about side-effects. The instrument provides a list of commonly reported body changes. Researchers may want to modify that list based on the results of formative research.

SURVEY QUESTIONS ABOUT PERCEIVED CHANGES TO THE BODY

- **Since you started taking ART, have you experienced a change in the way your body looks? *If yes: Can you tell me what changes you have experienced?***
- **In the past month, have you experienced any of the following.**
Read list.
- **For each change that the respondent reports: Has it been very bothersome, somewhat bothersome or not at all bothersome?**
- **Of all the body changes that we have just discussed, please tell me more about the changes that are the most bothersome for you?**
Probe for the top 2 or 3.

h. Additional variables

Researchers may consider investigating other variables in addition to those that are included in the Adherence Module, depending on their particular interest and the context where their studies are being carried out. Possible variables of interest may include the following:

- ▶ **Depression.** Depressive symptoms can be assessed by self-report measurement tools such as the CES-D scale (Radloff 1977).

► **Drug use.** In settings where drug use represents an important route of HIV transmission, modules can be added to measure the extent to which respondents are injecting drugs or involved in related types of high-risk behaviours. More information on asking about drug use can be found in the Prevention chapter in this volume and in the Alcohol and Drug Module of the Client Instrument.

5.3 Variables and survey questions for key informants working in the health facility

Researchers may want to gather information on possible factors that influence adherence by reviewing records or interviewing key informants in health care facilities that provide HIV treatment and related care.

ADDITIONAL VARIABLES RELATED TO ADHERENCE TO BE GATHERED FROM KEY INFORMANTS OR CLINICAL OR PHARMACY RECORDS

- a. Reliability of the antiretroviral therapy supply
- b. Cost of treatment
- c. Frequency that patients need to come to the clinic for medication and other care

a. Reliability of antiretroviral therapy supply

To investigate the reliability of antiretroviral therapy supply, researchers can ask clinic administrators or pharmacists whether the first-line or second-line antiretroviral therapy regimens prescribed in the clinic have ever been out of stock or unavailable for any reasons when patients needed them during the past year. If respondents say yes, then researchers can follow up with a question such as: “Please tell me about this”.

b. Cost of treatment

To investigate the cost of treatment, researchers may ask clinic administrators, providers or other key informants in the facility: “What is the typical cost of antiretroviral therapy per month at this clinic?” In addition, researchers may want to ask about additional costs that antiretroviral therapy patients must incur in order to receive treatment at the facility.

c. Frequency that patients need to come to the clinic

When antiretroviral therapy regimens are fairly standard, it may be possible to ask a key informant in the health care facility how frequently patients need to come in to receive their medications. This variable may add to an understanding of barriers to access as a factor that may influence adherence.

5.4 Variables and survey questions for providers

In addition to key informant interviews, researchers may want to interview health workers who provide services to patients taking antiretroviral therapy. The Provider Instrument in this volume contains an Adherence Module for that purpose. The key variables addressed by this module are presented in the box below:

KEY VARIABLES IN THE ADHERENCE MODULE OF THE PROVIDER INSTRUMENT

- a. Type of interaction with ART patients
- b. Perceived effectiveness of adherence counselling
- c. Provider practices related to ART service delivery
- d. Perceptions about how well ART patients manage to take their medication
- e. Perceptions of difficulties experienced by patients in taking pills on time

The Adherence Module of the Provider Instrument contains some detailed questions about provider practices, including whether the provider is involved in adherence counselling, the type of information they give to patients and the frequency and methods used to assess adherence. The module also contains questions about how many of their patients report problems with adherence (of different types), and what the providers perceive to be the underlying reasons why their patients sometimes have problems adhering to treatment.

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CHAPTER 4

HIV PREVENTION IN THE CONTEXT OF SCALED-UP ACCESS TO HIV TREATMENT

1. BACKGROUND

1.1 Rationale: why research is needed on HIV prevention among those receiving ART

As HIV treatment programmes scale up across countries, more attention is being directed to the implications of greater access to antiretroviral therapy for HIV prevention, and it is important to assess the potential for both positive and negative consequences. New antiretroviral therapy regimens improve longevity and the quality of life of individuals with HIV, and they have the potential to reduce HIV transmission by suppressing viral loads among people living with HIV (Granich et al. 2008). Greater access to treatment can also lower stigma and raise awareness of HIV, thereby encouraging people to seek testing and adopt preventive behaviours. But greater access to treatment may also increase the number of sexually active individuals infected with HIV, as antiretroviral therapy restores health and extends lifespans, leading to a growing pool of individuals who could potentially transmit HIV. In addition, some evidence suggests that the availability of effective treatment in some settings has reduced concerns about HIV transmission and contributed to an increase in high-risk sexual practices, such as unprotected sex or multiple partners (Cohen 2005; Cassell et al. 2006). Documenting and studying the complex links between treatment and prevention has, therefore, become a priority issue for antiretroviral therapy programmes.

Research on HIV prevention typically relies on behavioural surveillance surveys, Reproductive Health Surveys and Demographic and Health Surveys that focus on the general population or key populations at higher risk of HIV, such as men who have sex with men. A small but growing number of population-based surveys have gathered data to analyse behaviours in relation to respondents' serostatus, such as the 2004–2005 Uganda HIV/AIDS Sero-Behavioral Survey (Bunnell et al. 2008). Such research designs are key to monitoring trends at the population level. By contrast, this chapter focuses on groups whose behaviours may be influenced by the scaling up of HIV treatment. These groups include: patients receiving antiretroviral therapy and HIV-positive individuals who are not receiving treatment (e.g. those who are ineligible to initiate treatment or who are on waiting lists). Other populations of interest to operational research projects may include partners of individuals receiving treatment or users of testing and counselling services who test negative.

The primary objective of research proposed in this chapter is to document sexual risk behaviours among HIV-positive individuals receiving health services in order to: a) learn from comparisons across programmes, countries, regions or time periods about the factors that influence high- or low-risk behaviours; b) gather information to inform behaviour change communication strategies; and c) identify gaps in service delivery. Researchers who want to track changes in sexual behaviours among individuals receiving treatment or to evaluate the effectiveness of prevention interventions may be able to use the tools in this volume for that purpose with some adaptation.

2. FACTORS AND PROGRAMME STRATEGIES

2.1 Factors that influence HIV prevention in the context of scaling up treatment

The implications of treatment for HIV prevention is a complex issue that involves biomedical, demographic and behavioural factors, some of which are summarized below.

Biomedical factors that influence prevention

Antiretroviral therapy may influence sexual transmission of HIV in a number of ways. First, treatment that suppresses viral loads to undetectable levels may reduce but not necessarily eliminate the risk of sexual transmission of HIV infection (Quinn et al. 2000). Shedding of HIV continues in some patients, possibly related to a separate reservoir of infection (Kovacs et al. 2001; Barroso et al. 2003; Fiore et al. 2003; Zuckerman et al. 2004) or to the type of antiretroviral therapy regimen (Neely et al. 2007), and the risk of HIV transmission or re-infection remains.

Moreover, as discussed in the Adherence chapter, inappropriate treatment or poor adherence may result in incomplete viral suppression and the development and transmission of drug resistant viral strains (Paterson et al. 2000; Bangsberg and Deeks 2002). In fact, several studies suggest a relationship between poor adherence and higher risk sexual behaviours (Wilson et al. 2002; Flaks et al. 2003; Kozal et al. 2004), which underscores the need to document sexual risk behaviour among HIV-positive individuals receiving treatment.

Another biomedical factor that may influence HIV transmission is the eligibility criteria used to determine who receives antiretroviral

therapy. In general, while HIV infectivity in a community may decline as antiretroviral therapy programmes scale up (Fang et al. 2004; Porco et al. 2004), some researchers argue that increased access to treatment is unlikely to reduce HIV incidence if eligibility criteria substantially limit the proportion of HIV-positive individuals who can initiate treatment (Auvert et al. 2004; McClelland et al. 2006). Mathematical models suggest that universal testing could drastically cut HIV incidence, but only if treatment were given to all who test positive, not just those who meet strict clinical or immunological eligibility requirements (Granich et al. 2008). These analyses underscore the need to strengthen behaviour change prevention efforts among individuals who are HIV-positive but not receiving antiretroviral therapy.

Sexual risk behaviour among those receiving antiretroviral therapy

Individuals receiving treatment may resume sexual activity as they recover their health and normal functioning. Some researchers and policy makers have raised concerns that wider access to antiretroviral therapy might lead to increased high-risk sexual behaviour — a phenomenon sometimes called “behavioural disinhibition” or “risk compensation” (Cohen 2005; Cassell et al. 2006). Many studies from Europe and the United States have examined whether HIV treatment leads to increased sexual risk behaviours among individuals receiving antiretroviral therapy. A few studies have reported an association between immunological or virological improvements and sexual risk behaviours (or proxy measures such as STI rates) among men who have sex with men and injecting drug users (Martin et al. 2001; Scheer et al. 2001; Tun et al. 2004). However, most research has not found a consistent or significant association with risk behaviour, even when patients achieve an undetectable viral load (Dukers et al. 2001; Bouhnik et al. 2002; Vanable et al. 2003; Wolf et al. 2003; Crepaz et al. 2004; Diamond et al. 2005).

Nevertheless, studies suggest that a substantial minority of patients receiving treatment are sexually active, and some engage in unprotected sex. Even if receiving treatment does not increase levels of unprotected sex, antiretroviral therapy may still increase the risk that those patients who do engage in unprotected sex will transmit a drug resistant strain of the virus. Surveillance data from the United Kingdom suggest that the proportion of new HIV infections that involve a drug resistant strain has increased between 1994 and 2000, accounting for an estimated 27% of new infections in 2000 (Fidler et al. 2001; Cassell et al. 2006).

Only limited evidence is available from low- and middle-income countries, but a number of studies from Côte d'Ivoire, Kenya, South Africa and Uganda have generally failed to find significant increases in high-risk sexual behaviour among individuals receiving antiretroviral therapy (Moatti et al. 2003; Bateganya et al. 2005; Bunnell et al. 2006a; Kennedy et al. 2007; Eisele et al. 2008a; Eisele et al. 2008b; Luchters et al. 2008; Sarna et al. 2008). Thus, while existing research does not support the notion of disinhibition, the limited evidence suggests that measuring behaviour change and HIV prevention efforts among those receiving treatment remains a high priority.

The influence of treatment availability on risk perceptions and sexual behaviour

At the community or population level, there are various hypotheses regarding the effects of treatment availability on risk perceptions, attitudes and behaviours related to HIV transmission. On the one hand, expanding treatment availability may increase knowledge and awareness of HIV and give people a greater sense of control over their lives, resulting in risk avoidance and reduced HIV transmission. On the other hand, increased access to treatment may reduce concerns about unprotected sex, if people believe that treatment lowers the risk of transmission or the negative consequences of HIV infection (Valdiserri 2004).

While research does not support the notion of ‘behavioural disinhibition’ among individuals receiving treatment, evidence from high-income settings does suggest that expanded access to treatment may be associated with increased sexual risk taking. For example, studies among men who have sex with men in Australia, the Netherlands, the United Kingdom and the United States found that unprotected sex increased in those populations after antiretroviral therapy became widely available (CDC 1999; Dodds et al. 2000; Stolte et al. 2001; Wolitski et al. 2001; Chen et al. 2002; Katz et al. 2002; Van de Ven et al. 2002). High-risk sex may have increased in those settings because treatment availability lowered concerns about the risk of HIV transmission and the negative consequences of contracting the virus. For example, rates of multiple partners, unprotected sex and inconsistent condom use were found to be significantly higher among those who believed that antiretroviral therapy lowers infectivity (Van de Ven et al. 1999; Herlitz and Steel 2001; Suarez et al. 2001; Wilson and Minkoff 2001; Elford et al. 2002; Ostrow et al. 2002; Stolte et al. 2004). Similarly, a meta-analysis by Crepaz et al. (2004) found that rates of unprotected sex were significantly higher among respondents who believed that treatment availability had reduced the risk of HIV transmission or the seriousness of contracting the virus — regardless of their treatment or serostatus.

Research is currently underway to examine whether treatment availability is linked to behavioural disinhibition in low- and middle-income countries. Little has been published at the time this volume is going to press, but one study suggests that this is not the case (Bunnell et al. 2006b).

Other factors that influence sexual behaviour among those living with HIV

Based on the vast literature on sexual behaviour and its determinants, this section summarizes other key factors that should be considered when investigating high-risk sexual behaviour in the context of scaling up treatment for HIV. These include:

- ▶ **Number and type of partners.** Some studies suggest that the number of partners, the number of recent sexual encounters and the types of sexual partners are associated with unprotected sex (Wenger et al. 1994; Hays et al. 1997; Grulich et al. 1998; Heckman et al. 1998; Wilson et al. 1999; Semple et al. 2000; Crepaz and Marks 2002). Many prevention programmes

have considered sex worker and casual partnerships to be higher risk than regular partnerships. In the context of HIV prevention among people living with HIV, however, regular partnerships pose a particular risk when the regular partner is HIV-negative and when condom use is low. Evidence from sub-Saharan Africa suggests that many HIV-positive individuals are married to or living with HIV-negative partners (Dunkle et al. 2008). In addition, unprotected sex is common in regular partnerships, even when couples are serodiscordant or the partner's serostatus is unknown (Bunnell et al. 2006a).

- ▶ **Concurrent partners.** There is evidence that sexual concurrency (having more than one sexual relationship at the same time) is a more important predictor of STI transmission than the number of partners. This has been shown in theoretical sexual network models (Watts and May 1992; Kretzschmar 2000) and confirmed in epidemiological studies (Morris and Kretzschmar 1997; Potterat et al. 1999; Rosenberg et al. 1999; Koumans et al. 2001).
- ▶ **Partner serostatus and viral load.** Partner serostatus also influences sexual risk behaviour. HIV-positive men and women were significantly more likely to engage in unprotected sex with seroconcordant partners in studies from both developed and developing countries (Crepaz and Marks 2002; Hong et al. 2006; Kiene et al. 2006; Kiene et al. 2008). Similarly, research from the United States found that HIV-negative men who have sex with men were more likely to engage in unprotected sex with an HIV-positive partner if that partner had an undetectable viral load (Guzman et al. 2006). It is noteworthy, however, that a number of recent studies from sub-Saharan Africa suggest that a substantial proportion of patients receiving treatment do not know the serostatus of their partner (Bunnell et al. 2006a; Simbayi et al. 2007; Luchters et al. 2008; Sarna et al. 2008).
- ▶ **Knowledge and attitudes about HIV and AIDS.** Unprotected sex among HIV-positive individuals has been found to be associated with less knowledge about HIV and transmission (Wenger et al. 1994; Muller et al. 1995; Huszti et al. 1998; Derlega et al. 2006), with beliefs that condoms decrease sexual pleasure (Kline and VanLandingham 1994; Hays et al. 1997), with little commitment to self or others (Godin et al. 1996; Kalichman et al. 1997), and with perceived lack of control and lower confidence in one's ability to negotiate condom use (Crepaz and Marks 2002).
- ▶ **Disclosure.** While Crepaz et al. (2002) did not find an association between disclosing HIV status and lower condom use, recent studies have found an association between non-disclosure and rates of multiple partners and unprotected sex in some settings (Olley et al. 2004; Carballo-Diequez et al. 2006; Derlega et al. 2006; Kiene et al. 2006; Simbayi et al. 2007). More research may be needed to sort out these inconsistent findings.
- ▶ **Desire for children.** Living with a sexual partner and a male partner's desire for children were found to be factors that

increased the likelihood of unprotected sex among HIV-positive women in studies from Brazil (Kerrigan et al. 2006), India (Sri Krishnan et al. 2007), Togo (Moore and Oppong 2007), Uganda (Nakayiwa et al. 2006) and the United States (Crepaz and Marks 2002).

The evidence for some of these associations is somewhat circular, in that the outcome variable — high-risk behaviour — is not always clearly separate from independent variables, such as number of partners or lack of control. Nevertheless, these factors need to be taken into account in operational research on the links between sexual behaviour and HIV treatment.

2.2 Programme strategies related to HIV prevention in the context of treatment

While most HIV programmes include some information on prevention when counselling clients who are tested for HIV or who receive treatment, prevention is not always systematically integrated into HIV treatment services. Messages about prevention are typically delivered at the initiation of treatment and infrequently thereafter; and follow-up visits typically focus on adherence and management of side-effects with little emphasis on preventing transmission. Some observers have noted that this represents a missed opportunity for providers to encourage safer behaviours and to empower people living with HIV to persuade others to avoid risks.

A number of studies in the United States have found that individual or small group counselling was associated with reports of reduced unprotected sex among those living with HIV (Kalichman et al. 2001; Rotheram-Borus et al. 2001; Patterson et al. 2003; Sorensen et al. 2003; Richardson et al. 2004; Wingood et al. 2004; Kalichman et al. 2005; Wolitski et al. 2005). In most cases, these programmes were designed to provide skills, to raise awareness of the risks of HIV transmission and to address behavioural issues related to treatment and prevention. A meta-analysis of controlled trials in the United States found 14 interventions that significantly reduced unprotected sex (Crepaz et al. 2006). Most were based on behavioural theory and addressed a range of issues (coping, adherence, etc.) but focused extensively on specific skills and behaviours. In addition, most were delivered on a one-to-one basis by health care providers or professional counsellors and involved at least 10 sessions over three months.

A meta-analysis of studies from developing countries between 1990 and 2005 found evidence that client-initiated testing (commonly called VCT) may have a moderate but significant positive effect on prevention (Denison et al. 2008). Specifically, individuals who had received VCT were significantly less likely to engage in unprotected sex after being tested, compared with their behaviour before testing and compared with participants who had not received client-initiated testing; however, the meta-analysis found no significant effect on the number of sex partners (Denison et al. 2008). This review underscores the potential for client-initiated testing as a prevention strategy, but also the need for more evidence. For example, as mentioned in the chapter on

Testing and Counselling in this volume, recent studies from the United States and Zimbabwe (neither of which was included in the meta-analysis mentioned above) reported that high-risk sex increased following rapid HIV testing among men who tested negative (Metcalf et al. 2005; Corbett et al. 2007).

Since 2005, there have been a few additional studies in sub-Saharan Africa that have examined efforts to integrate HIV prevention into services for people living with HIV (Kalichman 2007). For example, prevention efforts by the TASO programme in Uganda significantly reduced levels of unprotected sex among those living with HIV (Bunnell et al. 2006a; Were et al. 2006). Community health workers developed individualized risk reduction plans with goal setting, encouraged and facilitated disclosure and partner testing, and in some places provided HIV tests at home for family members. (These results are similar to an earlier study in Zambia where home-based services, partner HIV testing and couple counselling among patients receiving antiretroviral therapy were found to reduce high-risk sexual behaviours (Allen et al. 2003).) A recent study from South Africa reported that a brief risk reduction intervention delivered by counsellors during routine clinical care visits led to a significant decline in unprotected sex among those receiving the service compared with those in the control group (Cornman et al. 2008). And, a large HIV prevention trial has begun among discordant couples in eastern and southern Africa (Lingappa et al. 2008). More research is needed to examine the extent to which these prevention services

can be successfully integrated into treatment services and which strategies are most effective in different settings.

3. RESEARCH OBJECTIVES AND QUESTIONS

As noted earlier, the objective of the research proposed in this chapter is to document sexual risk behaviours among specific HIV-positive populations, with the goal of identifying gaps in service delivery, designing prevention programmes or behaviour change communications strategies and/or comparing programmes. Possible research questions and hypotheses relevant to sexual risk behaviours in the context of scaling up HIV treatment are given in the box below.

The first two research questions require comparisons of HIV-positive individuals who are receiving treatment with those who are not, or before-and-after comparisons of the same individuals over time. (Note, however, that the former design presents a challenge, as researchers must ensure that control and study groups are comparable and that they do not compare healthy controls with symptomatic study group participants.) The third research question applies to a broader study population, including individuals who are HIV-positive but are not yet receiving treatment. The fourth research question can be investigated by asking health workers about their practices and by asking users of health services about their experiences. The fifth research

OPERATIONAL RESEARCH QUESTIONS ABOUT HIV PREVENTION IN THE CONTEXT OF SCALING UP TREATMENT

1. To what extent is receiving antiretroviral therapy associated with a change in levels of sexual activity (a resumption, an increase, an interruption or a reduction of sexual activity)?

Hypotheses:

- Sexual activity among HIV-positive individuals increases/decreases/stays the same after *initiating* antiretroviral therapy.
- Sexual activity among HIV-positive individuals increases/decreases/stays the same *with increased duration* of antiretroviral therapy.

2. To what extent is receiving antiretroviral therapy associated with high-risk sexual behaviour (such as unprotected sex)?

Hypotheses:

- High-risk sexual behaviour increases/decreases/stays the same after *initiating* antiretroviral therapy.
- High-risk sexual behaviour increases/decreases/stays the same *with increased duration* of antiretroviral therapy.

3. To what extent are knowledge, perceptions or attitudes about HIV and HIV treatment associated with high-risk sexual behaviours?

Hypotheses:

- Individuals who have limited knowledge of HIV transmission are more likely to report high-risk sexual behaviours, such as unprotected sex.
- Individuals who believe that receiving treatment or achieving undetectable viral loads reduces or eliminates the risk of HIV transmission are more likely to report high-risk sexual behaviours.
- Individuals who are excessively optimistic about antiretroviral therapy or who express lower concern about HIV in light of treatment availability are more likely to report high-risk sexual behaviours.

4. To what extent are prevention services integrated into HIV treatment services?

5. To what extent do prevention services (delivered in the context of treatment) reduce high-risk sexual behaviours among HIV-positive clients?

Hypotheses:

- Patients receiving prevention services in the context of HIV treatment will report fewer high-risk sexual behaviours than those who do not receive these services.

question would be relevant when seeking to evaluate the effects of prevention strategies integrated into treatment services; however, investigating this question may require more complex study designs than those proposed in this volume.

4. METHODS

4.1 Study populations and study design

The primary population groups to be studied for prevention studies in the context of scaling up HIV treatment may include:

- ▶ patients with a diagnosis of HIV who are receiving antiretroviral therapy;
- ▶ people living with HIV who are not on treatment but are accessing services or are on waiting lists;
- ▶ individuals who have used HIV testing and counselling services may be used as a comparison group, depending on the design of the study; and
- ▶ health care providers and administrators working in HIV testing, counselling and treatment programmes.

Ideally, prevention research should integrate both quantitative and qualitative data collection methods in order to monitor changes in behaviour as well as to gather an in-depth understanding of the context in which these behaviours take place. Possible study designs may include repeated cross-sectional surveys among different study populations at different points in time. For example, researchers may conduct cross-sectional surveys among HIV-positive individuals before and after initiating treatment and at different points in time thereafter. They may also compare treated versus untreated HIV-positive individuals. With some adaptation of the instrument, researchers could compare individuals who have been tested with those who have not, or with general population groups according to treatment availability and coverage in different settings.

4.2 Measuring sexual risk behaviour

Sexual risk behaviour has been documented through many behavioural surveys conducted among general populations, as well key populations at higher risk. Reviews of validity and reliability of such research have found that sexual behaviour data are fairly consistent (Aral and Peterman 1996; Crosby 1998; Fenton et al. 2001; Wellings and Cleland 2001), and that self-reported data from partners about sexual acts and condom use are reasonably congruent, especially for infrequent acts and short recall periods (Elish et al. 1996; Shew et al. 1997; Stone et al. 1999; Weir et al. 1999; Obermeyer 2005). Quantitative indicators of risk behaviours may indicate the magnitude or direction of changes over time, but they provide limited information on the context of or reasons for high-risk behaviours. Qualitative data can improve the quality of self-reports by providing information on the context in which sexual risk behaviour takes place (Amon et al. 2000). The variables in the box below have been used widely to measure sexual risk behaviour in prevention studies because they have a direct influence on sexual HIV transmission.

In addition, researchers may need to gather information about knowledge of HIV infection and its transmission, attitudes about condom use, personal risk perceptions, relationships with partners and respondents' ability to negotiate condom use. For such variables, both quantitative and qualitative data are recommended.

Operationalizing variables, populations of interest and recall periods

Researchers studying HIV prevention in the context of treatment may need to consider the following methodological points:

- ▶ **Asking respondents to categorize their sexual partners presents important methodological challenges.** Many studies have used categories such as regular, casual and commercial sexual partners. Regular partners are often defined as spouses or

WIDELY USED VARIABLES FOR MEASURING SEXUAL RISK BEHAVIOUR

- **Multiple partners.** Multiple partners can be measured by asking about the number of sexual partners during a defined reference period.
- **Concurrent partners.** Concurrent partners are overlapping sexual partners. Concurrency can be measured by asking for the dates that partnerships began and ended or, less specifically, by asking about multiple partnerships over a short but defined reference period.
- **Type of sexual partners.** Partners may be categorized in different ways, such as regular, non-regular (casual) and sex workers. Categories of male and female partners can be explored separately or together, depending on the study objectives and the extent to which men have sex with men in the community being studied.
- **Condom use.** Condom use is the key variable when studying sexual risk behaviour. Information on condom use is most often elicited with regard to condom use during the last sexual act (for which recall is expected to be accurate for a realistic time frame) and consistent condom use (use of condoms every time during the reference period). This information can be asked with respect to a particular partner or all partners depending on study objectives and design.
- **Proportion of unprotected sexual acts.** The proportion of penetrative sexual acts (anal and vaginal) in which neither partner used a condom can be sought for different sexual partners and various sexual acts.

co-habiting partners, but in some cultural contexts, researchers may want to use a broader definition that includes long-term partners, even if the couple is not married or cohabiting. Sex worker partners are generally defined as sexual partners who are paid in exchange for sex, but patterns of exchange of sex for money or gifts are complex and the definition is not easy to operationalize. Some researchers classify sex workers as casual partners for convenience, however, this may lead to a loss of information. Non-regular or casual partners are often defined as those who are not regular partners and are not sex workers. The categories of sexual partnerships commonly used by researchers are complex and pose a major measurement challenge, since they may not match local understanding and may not translate well into different languages (UNAIDS 2007). To avoid confusion, researchers may want to explore local categories and terms for different types of partnerships before finalizing the wording of their questionnaires. They will also need to carefully explain these categories to respondents.

► **Researchers can gather information on each sexual partner individually, or by asking about all partners of a specific type during a certain time period.**

There are two approaches to collecting data on sexual partners in prevention studies. One approach is to collect information about each individual sexual partner in the order that the sexual encounters occurred during a specified reference period. Researchers can decide how many partners are to be included depending on the study objectives. For example, sexual network studies often focus on the last three sexual partners (Laumann et al. 2004; Morris et al. 2004), while studies examining the risk of HIV transmission may focus on all sexual partners during a fixed reference period (Bunnell et al. 2006a). The other approach is to collect information on each category of sexual partner, for example regular partners, casual partners and sex worker partners, in a given reference period (Amon et al. 2000; Horizons 2006). This method is widely used in behavioural surveillance surveys in most countries and can allow comparisons within and across countries and geographic regions. It is also the method used in the Client Instrument in this volume.

► **Recall periods may be 3, 6 or 12 months long.** Different recall periods have been used to document sexual behaviours. Behavioral Surveillance Surveys conducted by Family Health International (Amon et al. 2000), National Family Health Surveys (IIPS and Macro International 2007) and monitoring and evaluation indicators developed by the UNAIDS Monitoring and Evaluation Reference Group (MERG) use a 12-month reference period, while Centers for Disease Control and Prevention studies, such as Reproductive Health Surveys, have used a 3-month reference period (Morris et al. 2005; Bunnell et al. 2006a). Demographic and Health Surveys have used a 6-month reference period (Bateganya et al. 2005; Sarna et al. 2008). There are advantages and disadvantages to each of these recall periods. Shorter recall periods provide more reliable responses, but if few respondents report sexual activity, researchers may need to lengthen the recall period or increase the sample size. In this volume, the Prevention Module of the Client Instrument uses a recall period of

3 months, but researchers can modify this to 6 or 12 months, depending on the needs of the particular study.

► **Separate research instruments or questionnaire sections may be needed for men and women.**

It may sometimes be appropriate to divide the data collection instrument into different sections for men and women respondents to make it easier to seek responses related to same sex sexual partners (men who have sex with men). If the same instrument is used for both men and women, careful skip patterns may be needed.

► **Interviewers need special training to gather data on sexual behaviour.**

Training is necessary to ensure that interviewers can build rapport with respondents, conduct interviews in a non-judgemental manner and elicit accurate responses on sensitive subjects. Training on other ways to collect sensitive data such as ACASI (audio computer-assisted self-interviewing) may also be desirable.

► **Studies of sexual behaviour among HIV-positive respondents may need to address slightly different variables than those carried out among the general population.**

Although prevention studies among HIV-positive populations may address many of the same questions as those among the general population, researchers may want to gather more detailed information about factors that influence sexual behaviour, depending on the scope of the study. In addition, researchers may need to add questions pertaining to stigma or disclosure, depending on the study population.

5. VARIABLES AND SURVEY QUESTIONS

The following section lists questions that can be used in surveys among HIV-positive respondents or health professionals who provide HIV-related care. Most but not all these variables are included in the Prevention Modules of the Client and Provider Instruments in this volume. As noted earlier, the Prevention Module uses a reference period of 3 months, but researchers can modify this to 6 or 12 months, depending on the study design and the preference of the researcher. “Don’t know”, “Don’t remember” and “No Response” categories can be added as appropriate.

KEY VARIABLES RELATED TO PREVENTION AMONG INDIVIDUALS LIVING WITH HIV

- a. Sociodemographic variables (e.g. educational, employment and marital status)
- b. Length of time since HIV diagnosis and initiation of antiretroviral therapy
- c. Sexual activity
- d. Type and number of sexual partners
- e. Sexual activity and condom use with regular/casual/sex worker partners
- f. Knowledge of partner’s HIV status/disclosure of own status to partner
- g. Sexual activity and condom use among men who have sex with men
- h. Concurrent sexual partners

- i. Knowledge and attitudes related to HIV infection and treatment
- j. Attitudes and treatment optimism related to antiretroviral therapy
- k. Fertility desires and family planning methods

5.1 Variables and survey questions related to prevention among individuals living with HIV

a. Sociodemographic variables

Sociodemographic variables should include age, sex, education, employment, living conditions and socioeconomic status. Marital status is a particularly important sociodemographic variable to be included in sexual behaviour studies. In countries where polygamy is common, survey instruments should ask married individuals about more than one spouse. Researchers may also need to disaggregate findings by sex and age in order to identify findings that can inform the design of effective programmes for women and men, as well as for young people (e.g. aged 15 to 24 years) versus older adults.

b. Length of time since HIV diagnosis and initiation of antiretroviral therapy

Researchers may want to examine how sexual behaviour changes over time among HIV-positive individuals receiving antiretroviral therapy. Therefore, asking about the length of time that has passed since the respondent received the HIV-positive diagnosis or initiated antiretroviral therapy provides important information about reference periods. Time on antiretroviral therapy is also a key variable for comparing behaviour before and after starting treatment and at different points in time over the course of treatment, as well as for comparing patient groups.

c. Sexual activity and behaviours

Asking respondents whether they have had sexual intercourse in a recent reference period allows researchers to determine the number and proportion of patients on antiretroviral therapy who are sexually active. This in turn provides the denominator for the proportion of sexually active patients who engage in high-risk sexual behaviours.

VARIABLE	SUGGESTED WORDING OF SURVEY QUESTION
Proportion of respondents who are sexually active	Have you had sexual intercourse (meaning penetrative vaginal or anal sex) during the last 3 months?
Number of sexual partners in last 3 months	How many different partners have you had sexual intercourse with during the last 3 months?
Reasons for sexual inactivity in last 3 months	<i>If sexually inactive: What are the reasons why you have not had sex in the last 3 months?</i>

d. Type (and number of each type) of sexual partners

The Client Instrument includes numerous variables and survey questions related to the type and number of sexual partners, including the total number of partners and the number of regular partners, casual partners, sex worker partners and — for male

respondents — the number of male partners (whether regular, casual or sex workers). Depending on the study objectives, researchers might want to include additional questions about the lifetime number of sexual partners (which has been found to be associated with an increased risk of unprotected sex), the age at first sexual intercourse and whether sexual initiation was forced or voluntary.

e. Sexual activity and condom use with regular partners/casual partners/sex workers

It is expected that the best recall of condom use would be for the most recent period, so it is common to enquire about condom use at the respondent's most recent sexual contact. But since successful prevention strategies require condoms to be used consistently, surveys on prevention should also ask about consistent condom use over a specific reference period. Consistent condom use is typically assessed on a categorical scale for the reference period (e.g. always, almost always, sometimes, rarely and never). If researchers need a quantitative measure to calculate the proportion of unprotected sexual acts, they may want to use a shorter reference period and include more detailed questions. Researchers may also want to ask about reasons for using or not using condoms.

VARIABLE	SUGGESTED WORDING OF SURVEY QUESTION
Penetrative sex with each type of partner (regular, casual, sex worker) in the last 3 months	During the last 3 months, have you had sexual intercourse (meaning penetrative vaginal or anal sex) with a spouse or a live-in — what we call a regular partner? <i>The same question can be posed for casual partners, sex worker partners and male partners (for male respondents).</i>
Consistent condom use with all partners of each type (e.g. all regular, casual, sexual worker and male partners)	During the last 3 months, when you had sexual intercourse with your regular partner(s), how often did you and your partner(s) use a condom? <i>The same question can be posed for casual partners, sex worker partners and male partners (for male respondents).</i>
Consistent condom use with all partners	Thinking about all the times you had sex with any partner during the last 3 months, would you say that you and your partner(s) used a condom: <input type="checkbox"/> always (every time) <input type="checkbox"/> almost always <input type="checkbox"/> sometimes <input type="checkbox"/> rarely <input type="checkbox"/> never <input type="checkbox"/> declined to answer
Condom use at last sex with most recent partner, by type	The last time that you had sexual intercourse with your most recent regular partner, did you and your partner use a condom? <i>The same question can be posed for casual partners, sex worker partners and male partners (for male respondents).</i>
Reasons for not using a condom at last sex (optional)	Why didn't you or your partner use a condom the last time you had sex with a regular partner/non-regular or casual partner/sex worker?

f. Knowledge of regular partner's HIV status and disclosure of own status

Knowledge of regular partner's HIV status and disclosure of status to regular partner are core variables for all prevention studies, as they can influence condom use. More details about how to collect information on this variable are available in the Testing and Counselling chapter.

g. Sexual activity among men who have sex with men

Depending on the research objectives and the extent of same sex behaviour among men who have sex with men in the study sites, researchers may want to include a section on this type of sexual activity in the questionnaire. For studies exploring whether such behaviour exists in the community, this line of enquiry can be limited to a few survey questions. For more detailed information, researchers can ask survey questions similar to those for other types of partners. Variables may include: sexual intercourse ever with a male partner (for male respondents), sex with a male partner in the last 3 months, number and type of male partners in the last 3 months and condom use with male partners in the last 3 months.

h. Concurrent sexual partners

Researchers with a special interest in concurrent sexual partnerships may want to ask detailed questions about the duration of sexual relationships (including start and stop dates) with various partners over a fixed time frame. This requires a full set of partner related questions, however, which lengthens the questionnaire and may not always be feasible. A simpler global question is to ask: "During the last 3 months, did you have sexual intercourse with any partner during the same period of time that you were having an ongoing sexual relationship with someone else?"

i. Knowledge and attitudes related to HIV infection and treatment

In this volume, survey questions about knowledge and attitudes related to HIV and HIV treatment are included in the Testing and Counselling Module of the Client Instrument. Therefore, they are not repeated in the Prevention Module. Researchers who want to gather information on these variables without using the whole Client Instrument may want to extract survey questions from the Testing and Counselling Module on the following topics:

- ▶ **Knowledge of HIV transmission.** What are some ways that HIV can be transmitted?
- ▶ **Knowledge of ways to reduce the likelihood of sexual HIV transmission.** What are some ways that an HIV-positive person can reduce the likelihood that he or she might transmit the virus to another person through sexual contact?
- ▶ **Knowledge of people infected with HIV.** Does the respondent personally know anybody who is infected with HIV or who has died of HIV? Or, does the respondent have a close relative or close friend who is infected with HIV or who has died of HIV? If yes, who was this person in relation to the respondent?

- ▶ **Knowledge of HIV and HIV treatment.** Does the respondent believe that antiretroviral therapy can remove the virus from the body completely? Can HIV or AIDS be completely cured? Does the respondent think that a healthy looking person can be infected with HIV?

j. Attitudes and treatment optimism related to antiretroviral therapy

The items below have been adapted from questions developed and used in studies of treatment optimism (Van de Ven et al. 1999; Elford et al. 2002; Venable et al. 2003). These items can be analysed individually, or they can be combined to create a composite variable for optimism. Ideally they would be used with a 5-point scale (such as strongly agree, agree, undecided, disagree or strongly disagree), but a 3-point scale may be preferable in some settings.

Please indicate whether you agree, are undecided or disagree with each of the following statements:

- ▶ **I would feel safe having intercourse with someone who has an undetectable viral load (or who is receiving treatment).**
- ▶ **I am less worried about HIV infection now than I used to be.**
- ▶ **The new HIV treatments make me less anxious about having unprotected sex.**
- ▶ **I believe that HIV treatment makes people with HIV less infectious.**

k. Fertility desires and family planning methods

Given the limited availability of assisted reproduction techniques (such as sperm washing or in vitro fertilization) in most developing countries, HIV-positive individuals who want children may have no other choice but unprotected sex. Research on prevention should, therefore, include some survey questions about number of living children, desire for more children and use of family planning methods, such as:

- ▶ **Desire for children.** Does the respondent want to have a child/another child? If yes, in what timeframe? Does the respondent's spouse or partner want to have a child/another child?
- ▶ **Current use of family planning.** Does the respondent or his/her partner/spouse use any family planning method? If yes, which one?

5.2 Additional variables and questions for research on prevention

Depending on feasibility and relevance in particular settings, researchers may consider collecting data on the following topics in prevention studies.

a. Biomedical variables

If researchers can gather biomedical data, viral load and CD4 counts are key variables. Viral load may influence the risk of transmission and should be obtained where possible. CD4 cell

counts reflect the degree of immune suppression as a result of HIV infection. CD4 measures can be used as surrogate markers of improved health status, and they are more readily available than viral load tests in most resource-limited settings. Variables might include:

- ▶ **Viral load at start of treatment (if available)**
- ▶ **Viral Load – most recent/current**
- ▶ **CD4 at start of treatment (if available)**
- ▶ **CD4 – most recent/current**

b. Alcohol and Drug use

Depending upon the context, prevention strategies may need to consider addressing alcohol and drug use, either as a mode of HIV transmission (in the case of injecting drug users) or as a factor that may increase the risk of sexual HIV transmission. Alcohol use and drug use questions can be used individually or combined to develop index scores. Drug use questions are generally structured to ask about ever use, active drug use in a certain reference period and high-risk behaviours related to injecting drugs that are commonly available in the community.

The reference period used to define active drug use varies with surveys. The widely used Behavioral Surveillance Surveys (Amon et al. 2000) use 6 months as the reference period. This volume contains an optional module for the purpose of gathering data on respondents' use of alcohol and other types of drugs.

5.3 Variables and survey questions related to prevention for health care providers

There are a number of variables and survey questions related to prevention in the Provider Instrument in this volume. Single or composite variables on prevention services can be generated from the following types of questions for health care providers:

- ▶ **Are clients provided information on risk reduction and safer sex at clinics where they receive treatment?**
- ▶ **Are condoms available at and distributed by the clinic?**
- ▶ **Do health providers discuss disclosure of HIV status to partners?**
- ▶ **Do they recommend partner testing?**

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