Sustaining adherence to antiretroviral therapy among HIV/AIDS patients in Uganda
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2 Methodology

2.1 Introduction
The nature of the theoretical arguments outlined in Chapter 1 determined the nature of the methodology\(^5\), including the research design process. The pre-field theoretical arguments and the emergent empirical findings guided the prioritisation and sequencing of the research methods. It should be noted, however, that the primary objective of this research was not to saturate theoretical categories or theoretical density (which is the purpose of a grounded theory), but to exhaust the descriptions of and explanations for adherence to antiretroviral treatment. This adherence research adopted methodological triangulation drawing from both quantitative and qualitative research methodologies. This methodology chapter is comprised of six sections. The first section here is the introduction, and the second section presents the construction of the research design in the form of a planning process. The third section justifies the sampling procedures, while the fourth and fifth describe the process of data collection. The last two sections focus on the issues of validity and reliability and the ethical considerations.

2.2 Constructing the Research Design
The research design entailed two major components: planning and execution. This section describes the first phase in the form of constructing a design or plan. This phase involved both desk work and reconnaissance to validate the plans and assumptions.

2.2.1. Literature Review and Problem Formulation
As the previous Chapter has presented the problem definition, the focus here is on how the study problem emerged. This being an exploratory-explanatory research, the literature search and review was a continuous process, with the need to find theoretical and empirical answers to the emergent research questions guiding the literature review process. In other words, literature reviewed was used not only

\(^5\) Methodology is a research strategy that translates ontological and epistemological principles into guidelines that show how research is to be conducted (Sarantakos 2005).
to provisionally generate a research problem and research questions but also to illuminate the research path. The emergent research issues on which literature was reviewed included: the economic burden of illness (health economics); sustainable livelihoods (poverty); social capital and social support (sociology); counselling (psychology); health protection models (theory); and health project documents (practice). Consequently, each empirical Chapter contains its own literature.

This formative phase was punctuated by reconnaissance in Uganda in 2005, intended to substantiate and validate the initial research hypotheses generated from the literature review. Punctuating the literature review with reconnaissance shaped the conceptualisation process and methodological choices. My discussion with HIV/AIDS service providers in five newly accredited antiretroviral facilities\(^6\) and policy makers revealed that Uganda had not only achieved the international target of antiretroviral drug access for 3 million people in the developing world by 2005; but also, based on unprocessed pill-count data, had succeeded in achieving 95% adherence among a large number of patients. Since both private and public facilities manifested high adherence rates it was necessary to go beyond an analysis of barriers and focus on the facilitating factors as well. Second, given the fact that the causes of high adherence rates in Uganda's resource-poor settings remained unclear, it was necessary to begin with qualitative exploratory studies that would help make the social survey more focused. Third, in order to generate rich and/or generalisable data, it was necessary to include a mix of public and private treatment providers located in urban and rural settings respectively, whose treatment programmes had lasted for more than one year, and hosted a large number of clients. This is why, in all except one case (Mbuya Reach Out), the health facilities visited during the reconnaissance were left out of the main study.

### 2.2.2 Selecting the Research Framework

For any formal research, the researcher’s own underlying assumptions that locate the research problem within a body of knowledge should be explicitly stated using a research framework (Eisenhart 1991). A research framework provides a structure for conceptualising the phenomenon, designing the research study, interpreting data resulting from the study, and drawing conclusions. A research framework is the basic structure of the ideas (abstraction and relationship) that serve as the basis for a phenomenon that is to be investigated (Lester 2005).

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\(^6\) The five treatment sites selected were: Jinja Hospital (Mid-Eastern), Tororo Hospital (Eastern Region), Masaka Hospital and Kitovu Mobile Clinic (Central South-Western), and Mbuya Reach Out (Central Region). For pragmatic reasons, only Mbuya was selected from the original sampling list, and a new site was incorporated, Kayunga.
There are three research frameworks from which to select, and these are a theoretical framework, a conceptual framework, and/or a practical framework (Einsenhart 1991, in Lester 2003). A theoretical framework guides research activities by its reliance on a formal theory that already exists. The existing theories are used to explain observed events, predict the outcome of events and relationships, or systematically summarise existing knowledge. A conceptual framework is itself an argument based on selected concepts that are perceived by the researcher as relevant and appropriate to use for a given research problem. A conceptual framework is built upon a wide array of previous research, various theories, and the practitioner’s knowledge. It is therefore a skeletal structure of justification, rather than of explanation (Lester 2005). On the other hand, a practical framework guides research by using ‘what works’ in the experience of doing something by those directly involved. This framework is not guided by a formal theory but the accumulated practical knowledge of the practitioners and administrators.

This research did not rely on a theoretical or a practical framework but on a conceptual framework to guide the research process. A review of theory-based literature revealed that individual health models and the structural models had strong points and limitations. For instance, while psychologically-based models concentrated on the biomedical factors, they left out the structural factors. On the other hand, while anthropological and sociological models focused on the structural and institutional factors, they tended to be weak in explaining the biomedical factors. At this point, I will briefly highlight the strong and weak points of the main health models from psychology, anthropology, and sociology.

The Health Belief Model (HBM) by Rosenstock (1950, 1991) can be classified as an expectancy model of healthcare decision making because of its role in predicting preventive health behaviours or compliance (Walker et al. 1982; Greenfield et al. 1987; Kirn 1991). It focuses on self-efficacy and states that health behaviours depend mainly on two major factors: the desire to avoid illness (or to get well), and the belief that a particular action will relieve illness (Malcolm et al. 2003). Based on Sanzero (2008), if this theory were to be applied, the likelihood of adherence to Highly Active Antiretroviral Therapy (HAART) would be:

- **Perceived susceptibility**: the individual’s belief that a person is susceptible to HIV disease progression
- **Perceived severity**: the individual’s belief that HIV disease progression has serious consequences
- **Perceived benefits**: the individual’s belief that adherence to ART would reduce susceptibility to HIV disease progression or disease severity
- **Perceived barriers**: the individual’s belief that the materials, physical and psychological costs of adhering to ART outweigh the benefits
- **Cues to action**: the individual’s exposure to factors that prompt adherence to ART
- **Self-efficacy**: the individual’s confidence in his/her ability to successfully adhere to ART

In other words, the HBM is an individual-based cost-benefit analysis and, for change to occur, benefits must outweigh the costs (UNAIDS 1999). The major weakness with this health model is that it focuses on individuals’ personal beliefs, knowledge, and attitudes but lacks the research capacity to investigate the health system’s capacity and social response to the epidemic. To use Agar’s (1996:397) observation, it is not that material explanation is irrelevant but neither is it adequate. Host lives in a symbolic environment as well as material one.

Next, the psychologically-based *Health Compliance Model* (HCM) focuses on the operant conditions that interact with basic behavioural repertoires. These are physician variables, physician-patient variables, compliance promotion variables, quantity and frequency of prompts, and social-medical environment variables (Heiby & Carlson 1986; Heiby *et al.* 2005). This is also a social-cognitive theory that focuses on provider and patient characteristics and behaviour, reinforcement strategies, and the operant environment. There are other psychologically-based models not discussed here, including the *Theory of Reasoned Action* (advanced by Fisbein and Ajzen in the 1960s), *Information-Motivation-Behavioural Skills Model* (Fisher *et al.* 2006), all of which suffer from the major weakness of focusing on the host (rational human beings) and thus explaining important phenomena such as individual learning, memory, choice, and performance (also after Ewart 1991), but failing to explain the social processes (e.g. systemic and social support systems) that are crucial for adhering to ART.

Finally, there are the sociological and anthropological theories. Despite the UNAIDS (1999) article being primarily interested in the relevance of the health models for HIV prevention, it provides an adequate overview of the theoretical orientation of various sociological theories. It notes that any sociological theory ‘asserts that society is broken up into smaller sub-cultures and it is the members of one’s immediate surroundings, the peer group that someone identifies with, that has the most significant influence on individuals’ behaviour’ (UNAIDS 1999:8). Of particular interest here is the anthropologically-based *Healthcare System Model* (HSM) by Kleinman (1978), which is useful in identifying the role of support systems and sub-cultures (popular, folk, and professional), but it leaves out the biomedical factors and the social-contextual
barriers, including the economic burden. The sociological Behavioural Model of Health Service (BMHS) by Anderson (1968, 1995) is more inclusive, capturing predisposing factors (all patient characteristics), enabling factors (availability of services, financial resources, health insurance, social networks), and need (perception of severity, duration of illness, number of days missed from work). However, since its primary goal is to explain equitable access to healthcare, not adherence to a life-long regimen for chronic illnesses, it tends to emphasise the availability of healthcare services but not adherence factors, including the role of a regimen and the healthcare setting.

Given the fact that the existing psychologically- and sociologically-based health models lacked the working capacity (conceptual categories, dimensions, and meanings) to accommodate the theoretical argument, this research used a skeletal structure of justification (conceptual framework), rather than a skeletal structure of explanation (theory) (see Appendix Table A.1). This is because the conceptual framework would allow the incorporation of differing points of views. But even then, the conceptual framework was dropped after the preliminary phase of data collection because it also proved to be conceptually restrictive, especially in analysing the relationship of the key emerging concepts and the context. This was particularly evident in the preliminary survey results that revealed that adherence to ART was consistently high, regardless of patient socio-demographic characteristics, healthcare settings and capacity, and the level of affordability of access and adherence costs.

2.2.3. Conceptualisation and Operationalisation of Adherence

Conceptualisation and operationalisation involves refining and specifying abstract concepts (conceptualisation) and developing specific research procedures (operationalisation) that will result in empirical observation of things that represent those concepts (empirical referents) in the real world (Rubin et al. 2001; Sarantakos 2005:139). To put it simply, operationalisation deals with translating a concept or construct into functioning and operating reality7. Most of the literature implies that conceptualisation and operationalisation apply primarily to quantitative research, with some qualitative researchers arguing that the best form of operationalisation is no operationalisation at all (Sarantakos 2005:140); ‘because interpretive research implicitly assumes that every person conducting a research study will have [a] unique interpretation of the results’ (Labianca et al. 2000:24, in Sha et al. 2006). This explains why the way in which concepts are developed and employed in qualitative research is rather different from that implied in quantitative research strategy. Quantitative research tends to put emphasis on definitive concepts (with fixed dimensions and

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indicators) while qualitative research identifies sensitising concepts (providing a general sense of reference and guidance to what is being studied) (Bryman 2004:270, quoting Blumer 1954). In order to strike a balance between the two traditions, the important dimensions and indicators of 'adherence' as a core concept (or outcome variable) were defined prior to commencement of the study, and allowing the dimensions and meanings of the explanatory variables (independent variables) to emerge as the research progressed.

In practical terms, the definition of adherence which I present in the introductory Chapter is too general, as it is concerned with adherence to health products and plans and lacks specific parameters for measuring adherence to antiretroviral regimens. The operational definition8 for this research, therefore, was adopted from Osterberg et al. (2007), who stated that adherence is the extent to which patients take medication as prescribed by the healthcare providers. In this respect, adherence rates are used to measure the extent of adherence, calculated as the ratio of pills taken to pills prescribed, multiplied by 100. It should be noted; however, that the theoretical orientation for this research suggests that adherence to medication is an outcome of a complex process. The use of a single number to define adherence would, consequently, mask adherence activities that precede, culminate in, and follow the pill-taking event itself, and the attendant barriers. For that reason, five adherence activities were identified and used. These were: 1) adherence to initiation appointments; 2) adherence to medication refill; 3) adherence to meal/snack-taking; 4) adherence to medication time; and 5) adherence to the medication dose itself.

**Text Box 2.1: Adherence Activities**

- **Adherence to Initiation Appointments** – Refers to adherence to the initial treatment activities intended to prepare a client for life-long treatment;
- **Adherence to Refill Appointment** – Returning for a new prescription on the appointment date;
- **Adherence to Meal/Snack-Taking Advice** – Taking a meal or snack to avoid adverse metabolic effects associated with antiretroviral medication;
- **Adherence to Medication Time** – Taking the prescribed dose within one hour of the scheduled time;
- **Adherence to Medication Dose** – Taking the prescribed number of pills at each medication time.

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8 The ‘operational definition’ refers to the translation: the operations, or indicators, used to determine the quantity or quality of the category observed about a particular variable (Rubin et al. 2001).
The second operational assumption was that each of the adherence activities is associated with unique adherence barriers that act independently or interactively to affect the final outcome – adherence to medication dose.

2.2.4. Selection of Methods for Measuring Adherence to ARVs

So far, adherence to medication dose is the standard measure of adherence, and adherence to ART has been measured by two methods: objective and subjective (Farmer 1999; Osterberg et al. 2007). The subjective or indirect methods include self-reporting and self-administered questionnaires, electrical monitoring devices, pharmacy refill records, pill-count, keeping medication diaries, and assessing adherence through care-givers. The objective methods include drug assay of blood or urine, examination of the CD4 count, and direct observation of the patient taking/receiving medication. The strengths and weaknesses associated with direct and indirect methods are well documented in other work (see Farmer 1999; IOM 2008:124).

This research also reveals the weaknesses associated with using a single measure of adherence. The questionnaire included two consecutive questions: ‘According to the respondent has s/he ever skipped taking an ARV dose on any given day?’ and ‘According to pill-count records, has the patient ever skipped taking an ARV dose?’ The results indicated inconsistencies between self-reporting and pill-count information. Of the 142 patients whose clinical records indicated that they had missed pills during the past treatment time period, 41 cases (26%) denied ever missing pills through self-reporting. As a result, this research opted for pill-count data rather than self-reporting. The urban-based Mission Facility had a strong home care programme, permitting validation of the pill-count data through un-announced pill-count visits by the community volunteers known as Community AIDS and TB Treatment Supporters, or CATTS.

In order to minimise inaccuracies associated with using a single subjective measurement of adherence to ART, health indicators (CD4 cell count, weight, and functional status) were also extracted from clinical records in order to establish treatment response. Despite all these control measures, Chapter 3 shows that urban patients in particular still masked the actual adherence barriers, using the term ‘I forgot’ in order to avert punitive measures imposed as a result of non-adherence by health workers. At the time of this research, the normal refill interval was one to two months, but grossly non-adherent patients were asked to return after 2 weeks for close monitoring, which involves extra transport costs on the part of the non-adherent patient.
2.2.5. Selection of the Study Sites

Two study sites were selected to implement this research: Reach Out Mbuya, here referred to as the Urban-based Mission Facility (UMF), and Kayunga Public Hospital, referred to as the Rural-based Public Facility (RPF). Both treatment sites were running a main treatment centre and treatment outposts. For the RPF, fieldwork was carried out in the main hospital, while for the UMF fieldwork was carried out at Kinawataka, a treatment outpost located near the main facility, offering the same healthcare services.

The two sites shared certain common characteristics. In both facilities, ART treatment had been running for more than two years. Both the urban and rural sites were geographically situated in impoverished conditions and served a multi-ethnic group. In terms of healthcare arrangements, both facilities were under the overall supervision of the MOH, and both dispensed single and multiple pill regimens, with rapidly expanding enrolment for HIV/AIDS services coinciding with a shrinking number of professional staff. However, as the following table shows, there were also differences between the two facilities.

<table>
<thead>
<tr>
<th>Peri Urban Area Served by Mbuya Mission Facility</th>
<th>New Office Block for Mbuya Mission Facility</th>
</tr>
</thead>
<tbody>
<tr>
<td>Kayunga Hospital Block</td>
<td>Front View Kayunga Hospital</td>
</tr>
</tbody>
</table>

| Date: 22 |
Table 2.1: Differences between the Two Study Sites by September 2006

<table>
<thead>
<tr>
<th>Mbuya Reach Out (UMF)</th>
<th>Kayunga Hospital (RPF)</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Urban site located in the suburbs of Kampala city. Clientele come from the nearby suburb (Kinawataka), presumably not travelling long distances or incurring access costs.</td>
<td>• Rural site located 46 km from Kampala city. Clientele come from a wide catchment area, experiencing long distances and travel costs.</td>
</tr>
<tr>
<td>• The core values of faith, charity, and volunteering guided service delivery.</td>
<td>• The principles of equity and utilitarianism guided service delivery.</td>
</tr>
<tr>
<td>• Implements a holistic healthcare service (medical, psychosocial, socio-economic, community network of care) for patients and OVCs, with huge external funding (see Appendix Table A.7).</td>
<td>• Provides a minimal healthcare package (medical and psychosocial support) to rural patients, and is under-funded by the government.</td>
</tr>
<tr>
<td>• Accredited as an ART outlet in March 2004, with a large clientele of 1,833 patients, 27% male and 73% female (June 2005).</td>
<td>• Accredited as an ART facility in January 2005, with 250 patients by January 2007 (based on this survey, 37% male and 67% female).</td>
</tr>
<tr>
<td>• Small number of doctors (4), with a large (52) base of a community network of care, with a structure of home care-givers.</td>
<td>• A small number of professionals manage the HIV/AIDS clinic, with 1 doctor, 4 nurses, and few (6) health volunteers, but with a strong base of professional staff (Table A.6).</td>
</tr>
<tr>
<td>• As an NGO, the HIV facility lacked health infrastructure, and depended on external laboratory facilities (at the Mildmay Centre) to carry out all laboratory tests, and referrals for potential inpatients.</td>
<td>• Possessed a laboratory facility, with CD4 machine donated by the Walter Reed Project in 2008, and 8 outpatient departments.</td>
</tr>
<tr>
<td>• Served a multi-ethnic clientele speaking different languages, with some being mobile due to work and rural kinship ties.</td>
<td>• Multi-ethnic clientele but united by common language (Ganda), and rural permanent residence.</td>
</tr>
</tbody>
</table>

The inclusion criteria assumed that differences in healthcare services, resources endowment, and social environment were likely to have a substantial impact on adherence to ART.

2.2.6. Selection of the Unit of Analysis

Micro-based research can be implemented on three levels: individual, household, and community. Normally, the selection of the household as a unit of analysis is based on the premise that household members share resources and decision making processes (Seeley 1995). With adherence studies, taking the household as a unit of analysis proved unfeasible and conceptually limiting. It would be erroneous to assume that PLWHA benefited from intra-household resource allocation. In fact, results from this survey revealed that a high proportion of patients (44.3%, 116) were excluded from intra-household financial resources due to a combination of reasons, resulting from non-disclosure of their serostatus, lack of income earning opportunities in the home, or simply being a single-occupancy household. The second problem was
directly linked to logistical constraints. HIV patients, or ART clients for that matter, are not a horizontal but a vertical community. A horizontal community is a group of people within a geographically defined area, while a vertical community is a group of people living in different locations but with a common interest that they defend, e.g. the homosexual community, religious and ethnic-based groups (see James 1994, in Kofi 1999). Since HIV patients do not occupy a definable space in relation to other areas, selecting the household as the unit of analysis would pose logistical constraints to locating ART clients over a vast area without a proper address.

As a result, individual patients seeking services at the facility were taken as the unit of analysis, though household characteristics were still attributed to the individual patient. Theoretically, the patient served as the primary unit of analysis and observation (sampling unit), sampling element (subject), as well as the population (aggregate of study elements) within a broad ‘healthcare setting’ embracing the household, community, and facility. To that effect, the questionnaire included the household characteristics and social support system; while the qualitative interview guide included issues of healthcare capacity and treatment support systems (see Appendix Supplementary Material SM.1; SM.2; SM.3; SM.4). This extended unit of analysis would also allow the investigation of the major hypothesis that adherence to ART is the outcome of a complex process involving biomedical and environmental factors.

2.3 Sampling Procedure

Once the preliminary research design was completed, the next step was to decide how to systematically and objectively select a representative sample for the research purpose. On the basis of the theoretical argument, this research adopted methodological triangulation, hence the adoption of a combination of quantitative and qualitative sampling procedures.

2.3.1. Quantitative Sampling Procedure

A pseudo-random sampling technique was used to select the patients for the survey. I will describe what I mean by a ‘pseudo-random sampling technique’. The sampling frame was obtained during the exploratory phase, when research assistants extracted

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9 Sampling is the process of identifying, from a large population, a smaller group which not only shares the former’s characteristics but is more manageable for study (Shensul & Lecompte 1999).

10 A sampling frame is a comprehensive list of all members or units within a population from which samples are chosen (Shensul & Lecompte 1999).
pill-count data, and the clinical data from the patients’ files at the health facility. At the pre-selection stage, a minimum inclusion criterion of $\geq 6$ months of being on antiretroviral treatment was considered. Arguably, this biased the study sample because only those patients in their persistence phase were selected. However, the rationale for such a selection criterion was to obtain information-rich patients, as well as deriving adherence trends. Inherently, this involved an infusion of qualitative and quantitative sampling procedures. Based on the review of clinical records, the initial sampling frame included 300 patients.

However, pre-selection of patients for interview in routine healthcare settings was rendered useless because different patients come for monthly pharmacy refills on different dates, spanning over a two month period. Strict adherence to the 300-person sampling frame would slow down fieldwork and eventually increase fieldwork costs. As a result, the original sampling plan was discarded, and we resorted to interviewing patients who had come for pharmacy refill or medical consultation, provided they satisfied the 6 months’ persistence inclusion criterion. But also this meant re-extracting pill-count and clinical data for those patients who were readily available at pharmacy refill.

This is what is referred to as pseudo-random sampling, as opposed to the pure lottery method, or the convenience (or accidental) sampling procedure. A convenience (or accidental) sampling procedure, or ‘man-in-the-street’, involves selecting any group of people readily accessible to the researcher that might reasonably be assumed to possess characteristics relevant to the study. In this case, while the application of randomness was unsystematic, it was guided by a selection criterion of 6 or more months treatment duration (right subjects), seeking pharmacy refill on scheduled appointments (right time), from the ART accredited site (right place).

Finally, 262 patients were interviewed during the survey, with 142 in the Mission Facility and 120 in the Public Facility. Although there is no gold standard for ‘when a sample stops being too small and becomes large enough’ (Amin 2005), the sample size of 262 respondents was regarded to be large enough to permit generalisation of results. Furthermore, the repeated and intensive qualitative studies permitted collection of additional qualitative data (see 2.3.2 below). However, the ever increasing enrolment for HIV and ART services still makes it impractical to precisely determine a statistically acceptable sample size.

The table that follows presents the characteristics of the respondents that were included in the survey.
### Table 2.2: Socio-Demographic Characteristics of the Respondents: Survey Data (n=262)

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Urban Mission Facility</th>
<th>Rural Public Facility</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean Age</td>
<td>38 (142)</td>
<td>38 (120)</td>
<td>n=262</td>
</tr>
<tr>
<td>Gender</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>62% (88)</td>
<td>63% (76)</td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>38% (54)</td>
<td>37% (44)</td>
<td></td>
</tr>
<tr>
<td>Marital Status</td>
<td></td>
<td></td>
<td>n=262</td>
</tr>
<tr>
<td>Never Married</td>
<td>6% (8)</td>
<td>2% (2)</td>
<td></td>
</tr>
<tr>
<td>Married</td>
<td>48% (68)</td>
<td>36% (43)</td>
<td></td>
</tr>
<tr>
<td>Separated/Divorced</td>
<td>13% (19)</td>
<td>19% (31)</td>
<td></td>
</tr>
<tr>
<td>Widow/Widower</td>
<td>33% (47)</td>
<td>37% (44)</td>
<td></td>
</tr>
<tr>
<td>Place of Residence</td>
<td></td>
<td></td>
<td>n=262</td>
</tr>
<tr>
<td>Rural</td>
<td>2% (3)</td>
<td>62% (74)</td>
<td></td>
</tr>
<tr>
<td>Urban</td>
<td>98% (139)</td>
<td>38% (46)</td>
<td></td>
</tr>
<tr>
<td>Members of Household</td>
<td></td>
<td></td>
<td>n= 256</td>
</tr>
<tr>
<td>Having Access to Regular Sources of</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Income</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>76% (105)</td>
<td>75% (88)</td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>24% (33)</td>
<td>25% (30)</td>
<td></td>
</tr>
<tr>
<td>(Missing Cases = 6)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Number of Months on ART According to</td>
<td></td>
<td></td>
<td>n=259</td>
</tr>
<tr>
<td>Clinical Records</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>24 Months</td>
<td>9% (24)</td>
<td>16% (42)</td>
<td></td>
</tr>
<tr>
<td>24 Months</td>
<td>24% (62)</td>
<td>28% (72)</td>
<td></td>
</tr>
<tr>
<td>38 Months</td>
<td>22% (56)</td>
<td>1% (3)</td>
<td></td>
</tr>
<tr>
<td>(Missing Cases = 6)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Type of Regimen</td>
<td></td>
<td></td>
<td>n=262</td>
</tr>
<tr>
<td>Triomune-40 (simplified)</td>
<td>47% (68)</td>
<td>71% (85)</td>
<td></td>
</tr>
<tr>
<td>Multiple pills (PEPFAR)</td>
<td>52% (74)</td>
<td>29% (35)</td>
<td></td>
</tr>
</tbody>
</table>

Education attainment was evaluated at the household level rather than at the patient level. The statistical output reflected similar patterns of education attainment between the rural and urban households – 14% (199) never attended formal education, 56% (805) attended primary school, 25% (361) attended secondary school, 2% (25) obtained advanced level, 2% (24) certificate, 2% (21) obtained a diploma, 1% (13) obtained a degree. The household education characteristics reflect the patients’ level of education as other survey questions suggest that the respondents were the household head (cf. respondents marital status and age). For detailed analysis of patient profile see section 5.3.6).
2.3.2. Qualitative Sampling Procedure

A *purposive sampling technique* was used to select the study participants. This technique, also known as judgmental sampling, selects the sampling element based on the researchers’ knowledge of the population and its elements, and purpose of the study (Rubin & Babbie 2001:254). The inclusion criteria of the sampling element normally include diverse background, information-rich and contrasting cases (Hardon *et al.* 2001, 2004). In this case, the basic selection criterion was the participants’ ability to provide credible and/or contrasting information. Inclusion of information-rich participants was guided by background information available from patients’ medical files, the health staff, and the health volunteers who practically knew the patients on treatment.

In order to validate emergent data and hypotheses and understand the social context, the purposive sampling technique was applied sequentially during the explorative studies and the post-survey explanatory studies. In total, 37 qualitative studies were conducted, staggered over a period of three years. Table 2.3 below provides the breakdown of interviews held in the UMF and RPF.

**Table 2.3: Qualitative Sampling Elements**

<table>
<thead>
<tr>
<th>Type of Studies</th>
<th>Number of Participants</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Qualitative Exploratory Studies</strong></td>
<td>Mission Facility</td>
</tr>
<tr>
<td>Health Staff Key Informants</td>
<td>3</td>
</tr>
<tr>
<td>Individual Patient Interviews</td>
<td>5</td>
</tr>
<tr>
<td>Healthcare Volunteers</td>
<td>1</td>
</tr>
<tr>
<td>Observation of ART Counselling Sessions</td>
<td>2</td>
</tr>
<tr>
<td>Healthcare Volunteers FGD</td>
<td>1</td>
</tr>
<tr>
<td><strong>Qualitative Explanatory Studies</strong></td>
<td></td>
</tr>
<tr>
<td>Individual Interviews for Economic Burden Study</td>
<td>3</td>
</tr>
<tr>
<td>Survey Follow-up FGD</td>
<td>1</td>
</tr>
<tr>
<td>Social Support Recipients (Patients) FGD</td>
<td>1</td>
</tr>
<tr>
<td>Social Support Provider (Treatment Buddy) FGD</td>
<td>1</td>
</tr>
<tr>
<td>Healthcare Volunteers FGD</td>
<td>2</td>
</tr>
<tr>
<td><strong>Total Number of Participants</strong></td>
<td>20</td>
</tr>
</tbody>
</table>

Table 2.4 below singles out the FGDs and presents the composition of each FGD by gender. Like in the case of the survey, females formed the largest proportion.
Table 2.4: Number of Participants in Each FGD

<table>
<thead>
<tr>
<th>Type of FGD</th>
<th>Gender Composition</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Male</td>
<td>Female</td>
</tr>
<tr>
<td>Healthcare Volunteer FGD</td>
<td>5</td>
<td>6</td>
</tr>
<tr>
<td>Survey Follow-up (Mission Facility)</td>
<td>4</td>
<td>7</td>
</tr>
<tr>
<td>Survey Follow-up (Public Facility)</td>
<td>6</td>
<td>4</td>
</tr>
<tr>
<td>Social Support Beneficiaries (Mission Facility)</td>
<td>4</td>
<td>6</td>
</tr>
<tr>
<td>Social Support Beneficiaries (Public Facility)</td>
<td>4</td>
<td>6</td>
</tr>
<tr>
<td>Social Support Providers (Mission Facility)</td>
<td>2</td>
<td>6</td>
</tr>
<tr>
<td>Social Support Providers (Public Facility)</td>
<td>4</td>
<td>3</td>
</tr>
<tr>
<td>Healthcare Volunteers (Mission Facility)</td>
<td>3</td>
<td>8</td>
</tr>
<tr>
<td>Healthcare Volunteers (Public Facility)</td>
<td>1</td>
<td>4</td>
</tr>
<tr>
<td><strong>Total Number of Participants</strong></td>
<td>33</td>
<td>50</td>
</tr>
</tbody>
</table>

2.4 Data Collection

A methodological triangulation\(^{11}\) was used to implement this research study. An iterative process involving qualitative and quantitative methods was used to answer the central question and the emergent research questions and hypotheses. The quantitative method was mainly a survey intended to generate descriptive statistics. Since ‘qualitative methods are a set of data collection and analysis techniques that can be used to provide description, build theory, and to test theory’ (Van Maanen 1979, in Sha et al. 2006:1824), the major goal for implementing qualitative data was the ability to study, describe and interpret the medication patterns, processes and experiences.

Obviously, quantitative and qualitative research traditions consist of distinct methods for data collection and analysis. The following section will distinguish the data collection procedures between the two different traditions that were used. Three major studies were implemented: qualitative exploratory studies, a survey, and qualitative explanatory studies, each of which is described next.

2.4.1. Qualitative Exploratory Studies

The qualitative exploratory studies marked the beginning of the actual fieldwork. They are so described because, even after comprehensive review of the literature, there was still a need to clarify and verify the a priori hypotheses, discover new variables and questions, and establish a rapport with gatekeepers (patients, providers, and volunteers) in both sites. Instead of a hurried survey, three sub-studies were

\(^{11}\) Triangulation is the practice of using more than one methodology, method, sample, times, and/or researcher within the context of the same study (Sarantakos 2005).
implemented: 1) assessment of the healthcare services and settings (AHSS); 2) extraction of adherence and clinical data from patients’ files; and 3) gathering patients’ life stories.

1) Assessment of Healthcare Services and Settings
AHSS provided a means of understanding the physical settings, actors, resources, and social processes, and the impact they have on adherence to ART. The first activity targeted the health staff. A semi-structured interview guided the discussion with the health staff, focusing on seven themes (see Supplementary Material S.M. 3).

After the AHSS, the counselling trajectory was observed in both UMF and RPF. At the time of research, counselling involved five stages: 1) client enrolment (VCT/RCT\textsuperscript{12}); 2) ART education (clients and care-givers); 3) prescription counselling; 4) adherence counselling; and 5) client follow-up (facility or home visits). Since ART education is directly linked to adherence, I attended the ongoing ART counselling sessions twice between September 2006 and January 2008. This ‘time-point observation technique’ permitted verification of consistency in the counselling methods and content, and its implication for modelling adherence behaviour. A content analysis was used to analyse the information text collected from the ART counselling session (see section 2.5.2 below).

2) Review of Patient Files
In Uganda, all patient’s clinical and adherence data is recorded on the HIV CARE/ART CARD provided by the Ministry of Health. The rationale for undertaking this tedious exercise was that the existing database on patient assessment and drug refill forms was more likely to yield authentic data than self-reporting during interviews. This is because clinical and adherence data is technical in nature (at least within the Ugandan context) and patients would find it difficult to recall such data. The issues captured included the following:

- Client name (later tagged to the questionnaire as number and abbreviation);
- Date of ART initiation enrolment;
- Type of regimen and, if applicable, instances of switching regimen and reason for doing so;
- Whether client was ever suspended from ART treatment and reasons for such;

\textsuperscript{12} Routine Counselling and Testing (RCT) is provider-initiated for effective clinical management of the patient.
• Symptomatic illness at time of enrolment for HIV treatment;
• Adherence to treatment initiation appointments (CD4 test, picking CD4, 1st, 2nd, and 3rd counselling appointment, ART initiation), recorded as date expected and actual date reporting;
• Date being initiated on Cotrimoxazole and ARVs;
• Episodes of skipping pharmacy refill appointment and reasons recorded;
• Incidence of taking extra doses, or returning fewer pills in the pill bottle than expected, and reasons recorded;
• Episodes of non-adherence to ARVs, documented as date of recording, number of pills missed over prescribed, and reasons recorded;
• Quality of life indicators (WHO staging, CD4+ T cell count, functional status, weight) and dates of recording such indicators;
• Dates and types of opportunistic infections and side effects ever recorded;
• Number of people who are HIV positive in the household.

Significantly, extraction of the actual date (‘dd/mm/yy’) when the information was taken from the patient by the provider made it possible to derive a retrospective trend analysis for pill-count adherence, health indicators, and (re)occurrence of side effects and opportunistic infections. This clinical record data was integrated into the survey questionnaire before the actual interview, and verified them with the patient at the time of individual interview. The abbreviation that was used to mark that technical data on the questionnaire for subsequent verification was ‘CR’ (for clinical records). Integrating the clinical record-based data into the questionnaire well in advance of the survey meant that the survey dealt not with two separate datasets but one; it also permitted verification of such data with the patient, and with the adherence counsellors in the event of a patient’s denials.

3) Individual Patient Interviews

As stated, prior to the survey, 10 (5 at each site) Individual Patient Interviews were implemented, with informants selected on the basis of gender and the duration of treatment (2 years). The Individual Patient Interviews were intended to obtain a life history on personal (subjective) and social (objective) lives (see Supplementary Material S.M.2). A descriptive questioning technique was used, with patients asked to describe the key events in their life journey, for instance: growing up, moving to places, becoming engaged in a relationship, encountering and coping with HIV as a stigmatised illness, seeking medical attention, coping with treatment demands and obligations, people in their lives and illness, and the future.
Emergent data from the life stories illuminated core variables that should be taken seriously in subsequent research phases. The key issues that merited inquiry were: adherence as a process and outcome; adherence pre-conditioning factors, especially the shift from herbal to Western medication; the indirect costs of accessing and adhering to ART; the instrumentality of social support in the health seeking process; the role of information and education; and facilitating and constraining factors.

In addition, one FGD, consisting of 11 healthcare volunteers known as CATTS, who are PLWHA themselves, was implemented in the Mission Facility in order to identify consensus and different opinions about the perception of illness and treatment experiences.

2.4.2. The Survey

Once the explorative qualitative studies were complete and the questionnaire revised, the survey was implemented. Text Box 2.2 presents the key research questions included on the questionnaire (also see the Supplementary Material S.M. 4).

**Text Box 2.2: Key Questions Included in the Questionnaire**

- What are the patient’s characteristics and household characteristics?
- What is the level of household resource endowment (physical, natural, financial assets)?
- Specifically, what are the household income sources and expenditures on consumption items, including health?
- What is the social support stock (providers, relationships, assistance, and frequency)?
- What is the level of adherence to various adherence activities (treatment initiation appointment, pharmacy refill, food intake, dosing time, and medication dose) and what are the respective adherence barriers?
- What changes, over time, are there in the quality of life indicators (weight, CD4, function, WHO staging)?
- What is the effect on disease condition and side effects of commitment to ART?
- What individual and programmatic factors influence adherence?
- What are the costs involved in accessing and utilising ART services? What is the impact of economic burden on adherence, and what coping strategies are there?
- What is the level of satisfaction with healthcare services, including counselling?
2.4.3. Qualitative Explanatory Studies

The qualitative explanatory studies were implemented after the survey, and were staggered over a period of one year through the thesis writing process. They were intended to generate qualitative insights into the quantitative data, find answers to emergent hypotheses and questions, and seek unique explanations for unexpected results. Without pre-empting the empirical Chapters, it can be said that, in general terms, socio-demographic characteristics, locational factors, facility resource endowment, biomedical and adherence barriers, and so on, did not have a substantial negative effect on adherence to ART. Rather than using further computer-aided statistical analyses, it was better to seek explanations through qualitative studies.

A renewed search for answers resulted in phased and repeated implementation of qualitative explanatory studies. For instance, the first post-survey qualitative studies intended to discover how patients accommodated or navigated the economic burden in the two resource-scarce settings. Subsequently, FGDs were conducted in order to obtain consensus and differences in opinion about the perceived patterns and trends in adherence levels and barriers between the two accredited sites. Discoveries that weather conditions had a potential effect on adherence trends led to collecting rainfall performance data from the Makerere University Weather Station and comparing it with seasonal fluctuations in adherence to ART. Furthermore, since the survey findings pointed to the role of information in adherence to ART, the counselling information previously collected during the exploratory qualitative studies and set aside as secondary material was retrieved, and content analysis performed to assess the potential link between counselling and education with adherence to ART. Finally, because patients and health facilities survived amidst resource-scarcity, it became necessary to assess the instrumentality of social support systems. All these qualitative studies allowed a clear picture to emerge of how biomedical factors interact with environmental factors to create adherence to ART.
2.5 Data Analysis

2.5.1 Quantitative Data Analysis

After the survey, some of the open-ended questions whose responses could not be predicted in advance were coded. Once the coding process was complete, the questionnaire was entered onto the computer using EPI-INFO version 6 and the output data exported to SPSS version 12.0 for statistical analysis. During analysis, two types of adherence measuring were statistically derived, namely: adherence level and adherence status. The first is the traditional way of measuring adherence to medication dose, recorded as the number of tablets taken correctly, as a proportion of those prescribed. This is what is commonly presented as ‘mean’ and ‘median’ adherence in most of the background adherence studies. This form of measuring adherence is an important marker for the clinical evaluation of individual patients, as well as for counselling purposes. In my opinion, adherence level is a more precise way of measuring adherence itself because it gives the exact figure in the form of a mean (or median). However, the major limitation with establishing adherence through adherence level is that it does not reveal the proportion of patients within a given sample who achieve the 95% adherence, which is the optimal adherence required to suppress the HIV virus. Adherence status was, therefore, calculated as the percentage of patients who took at least 95% of their pills correctly. This is essential for programmatic or public health evaluation (Laing & Hodgkin 2006:28). However, as
there is no gold standard for measuring optimal adherence, four adherence thresholds were derived: optimal adherence (100%), near-optimal adherence (95-99%), sub-optimal adherence (80-94%), and non-adherence (<80%), indicating the proportion of patients under each threshold. The overall mean adherence was based on the 3-years’ pill-count data preceding the survey.

The analysis also focused on two kinds of adherence: global adherence and adherence trends. The global adherence reflected the overall adherence for all years combined. On the other hand, based on the date recordings as extracted from the patients’ files, the adherence trend was broken down into mean monthly and mean quarterly adherence for each year (from October 2004 to July 2007), as well as a pooled seasonal calendar adherence (January to December). The seasonal calendars adherence was intended to establish seasonal fluctuations in adherence, and the potential causes.

In a bivariate analysis, Pearson’s Chi-Square tests were carried out to measure the relationship between key independent variables and sub-optimal adherence (<95), with results indicating no statistically significant relationship.\(^\text{13}\) Such results do not necessarily imply that there are no predictors of adherence in the two settings. As my statistician noted, an association that is not statistically significant does not necessarily imply that it is not socially significant. Complicated statistical modelling has its limitations. As indicates Huwe (2005:4):

> Traditional statistical techniques (such as p-values or confidence intervals) can aid interpretation amongst the statistically literate, but are confusing to many and are open to significant pitfalls. Apparent differences across indicators may not in fact represent real underlying differences but may be the result of random variation. Conversely, real and important differences may go undetected when all measures fall within statistical limits (false reassurance). Assessing changes over time in indicators can also be difficult.

In this study, combining both quantitative and qualitative data helped in constructing the facilitating factors as the predictors of adherence (refer to Chapter 5).

In order to establish treatment response as a function of adherence to antiretroviral therapy, data on health indicators were analysed. These included CD4 count, weight,\(^\text{13}\) The Independent variables that were tested included gender, marriage, place of residence, previous exposure to risk/shocks, number of friends, access to care and support, number people who are HIV in a home, type of regimen (single-pill and multiple pills), evaluation of health conditions, orphans in a home, health expenditure a patient ever incurred, daily activity, disclosure, level of satisfaction with information and quality of care, role of treatment supporter, access to facility socio-economic services, health expenditure incurred in accessing and utilising ART services, travel time, distance, mode of transport.
function status, and WHO staging. The two facilities collected CD4+ T cell tests for individual patients once every six months. At the time of the survey, patients had undergone CD4 tests between 1 and 5 times. A paired Samples T-Test was used to assess the mean change in CD4 count over consecutive visits. The data for other health indicators other than CD4 count was also calculated in terms of the mean, on a monthly and/or quarterly basis, and compared with the ART adherence trends.

2.5.2. Qualitative Data Analysis

Given that qualitative data aided in providing plausible explanations for the emerging hypotheses and questions during the research process, the actual data analysis was not done after but between fieldwork phases. Analysing and reanalysing data, and writing while collecting the data, made it possible to collect more data to answer emergent questions and hypotheses before the data collection was over.

Analytical induction was used to analyse the qualitative data. In simple terms, analytical induction aims to produce complete and universal statements about social phenomena (Sarantakos 2005). This means moving from the specific to the general, that is, constructing abstract concepts from study specific data (ibid: 351). Here, analytical induction involved relating the data to the emerging hypotheses, confirming the hypotheses, or generating new hypotheses until saturation was achieved. The Chapter ‘Working with Data’ in Taylor et al. (1984) guided the analysis of qualitative data, which involved (re)reading field notes and qualitative data line-by-line and making notations in the margins. The key questions that guided this process were:

- What does this piece of evidence tell me?
- What is the participants’ major concern?
- What themes, concepts, and propositions emerge here?
- What meaning is assigned to the concepts by the participants?
- Within what setting and by which people is this being said or done?

In some cases, the patterns were less apparent or subtle, necessitating discovery of the deeper meaning of what was being said and done. This was the case while analysing the interaction of adherence barriers and facilitating factors.

A second set of qualitative data that was analysed was the counselling material. A content analysis (CA) was used to analyse the content of ART counselling material. A complete CA looked for the manifest and the latent content of counselling material14. With manifest content, descriptive content analysis was used to identify

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14 The manifest content refers to the visible, surface text, and the actual part of the text manifested on the document — the words, sentences, paragraphs and so on. The latent content is the underlying
the frequency of the appearance of a given message. In looking for latent content, *meaning-contextual analysis* was used to deconstruct and reconstruct the purpose of communication strategy, meanings encoded in the message, the context in which meanings are constructed, and the impact such messages may have had on health compliance. The second level contextual analysis involved a thorough (re)reading of the text to identify underlying meaning that may cause emotional and cognitive impact, as well as recalling the counsellors’ communication behaviour and motives, and the social context within which such counselling messages were created (see Chapter 6, section 6.4.3).

In the pursuit of accuracy, I shared the counselling material with the two counsellors who had previously conducted the counselling sessions. In addition, in order to have the reader participate in the interpretation of the counselling material, in Chapter 6 the counselling text is reproduced in its original form with the meaning labels that I personally developed during open coding (see Chapter 6, section 6.3).

### 2.6 A Note on Validity and Reliability

Validity refers to whether the instrument measures what it intends to, and reliability refers to whether the instrument is free of random error (Pequegnat *et al.* 2000, in IOM 2008). With validity, the major issue is whether the findings are in agreement with theoretical or conceptual values, while reliability is about whether the method produces the same results whenever it is repeated, and is not sensitive to the researcher, the research condition, or the respondents (Sarantakos 2005:83-92). The process of describing the methodology has highlighted the rigour with which this study was conducted, especially in terms of study design, the care taken to measure adherence itself, and the explanatory variables (*internal validity*). As already indicated in this Chapter, the research instruments included all key relevant variables for measuring the core argument (*content validity*), and the open-ended research design allowed additional explanatory concepts/variables to emerge.

In terms of *external validity*, the primary aim of this research was not to generate results that are generalisable or transferable to other resource-poor settings, but to provide a *reasonably* complete explanation of adherence to ART and the desired best practices. This is because Uganda’s HIV treatment programme, in terms of history, policy direction, and implementation process, would differ from other resource-poor settings. Even with intra-country experience, the results would not be comparable because this study included pioneer ART sites and an early majority of patients with meaning conveyed through the document. Here, the researcher identifies the hidden meaning (Sarantakos 2005:301).
a wealth of coping experiences, strong social support systems, in routine healthcare settings. It is possible that adherence results and barriers would have been different if this study had been conducted in hard-to-reach areas, in a conflict situation, or somewhere without regular antiretroviral supplies.

In terms of reliability for this research, firstly the accuracy of the measuring instruments and procedure lay not in pre-determination of the methodology path but in the flexibility of the research design. Secondly, in order to overcome inaccuracies associated with adherence methods, a combination of self-report and pill-count (subjective methods) and health indicators (objective methods) were used in order to reduce the errors associated with measuring adherence methods using a single tool. Third, the survey was conducted by six social scientist enumerators (3 male and 3 female), adequately trained in the techniques of administering the questionnaire and facilitating a field relationship. Fourth, the questionnaire was pre-tested in order to assess the relevance of the questions and the completed pilot questionnaire was passed on to the statistician for a trial analysis. Fifth, as exit interviews were conducted on pharmacy refill visits, the questionnaires were immediately edited for accuracy by the principal researcher before the respondent left for a one-month refill recess.

Since, with interpretive research, the traditional notions of validity and reliability do not apply in the same fashion as in the positivist tradition, alternative criteria have to be employed to judge the rigour of qualitative research. The alternative criteria for evaluating qualitative research are trustworthiness and authenticity\(^\text{15}\) (Bryman 2004:273). In this case, the reliability of qualitative methods can be judged by the inclusion of multiple individuals and groups, therefore generating multiple accounts (credibility); inclusion of two comparative study sites and implementing fieldwork for an extended duration (transferability); and sharing the research process and outcomes with peers (dependability).

### 2.7 Ethical Considerations

This research was cleared by the Uganda National Council of Science and Technology (NCST), the supreme body vested with power and authority to review and grant permission to conduct research that requires such permission. The NCST verifies whether the proposed research complies with ethical standards before permission is granted. At the level of implementation, permission was sought from the Project Director of the Mission Facility and the Medical Superintendent of the Public Facility.

\(^{15}\) Trustworthiness is made up of four criteria, each of which has an equivalent criterion in quantitative research – credibility, transferability, dependability, confirmability. Authenticity refers to the wider impact of the research, for instance action research (Byman 2004:273).
Although the clinical records were reviewed without patients’ direct permission, permission was granted by the provider, who equally reserved the right to use the patient data provided such usage posed no harm to the provider or the patient. The questionnaire itself had an informed consent statement which was read out before the commencement of the interview. In terms of anonymity, the name of the respondent did not appear on the research instrument. Instead, the questionnaire bore respondents’ initials and number, with the actual names kept separate from the questionnaire. Finally, for confidentiality, direct quotes presented in this thesis do not bear respondents’ names, nor has the raw data been made public.

2.8 Discussion

The fundamental conclusion is that even with adherence to medication, quantitative and qualitative methodologies are not mutually exclusive. The methodology section presented above provides systematic guidance to how the two methodologies can be infused in a single adherence study, and the benefits associated with such methodological triangulation.

The major issue, however, is not whether it is possible to have combined methodologies, but the reasons for desiring and adopting methodological triangulation. Here, the intrinsic purpose of implementing a combined methodology was to explicate and thus to prove or disprove the theoretical argument. However, the implementation strategy was not determined by the researchers’ underlying belief about the methodology but by the emergent data. As a result, the two methodologies were approached with caution, thus adopting an ‘open and flexible’ strategy in the quest for valid and reliable results within overall ethical concerns. In other words, the emergent results and attendant assumptions determined what data would be sought and from whom, using which appropriate research methods and techniques. In summary, in this case, the quest for plausible and accurate explanations (outcome) determined the methodological fit and path, but not the research object (adherence), theoretical perspectives (health models), or the researcher’s belief in a given methodology (subjective conviction).