How to investigate access to care for chronic noncommunicable diseases in low- and middle-income countries

A survey manual based on a Rapid Assessment Protocol

Draft for field testing, May 2012

David Beran
International Insulin Foundation
University College London
London, United Kingdom
Université de Genève
Geneva, Switzerland

Michiyo Higuchi
Nagoya University School of Medicine
Nagoya, Japan

Acknowledgements

This manual is based on the Rapid Assessment Protocol for Insulin Access designed by the International Insulin Foundation and implemented in Kyrgyzstan, Mali, Mozambique, Nicaragua, Zambia and Viet Nam. The Foundation would like to recognize the support of Dr Hans Hogerzeil, former Director, Essential Medicines and Pharmaceutical Policies Department, World Health Organization, for his initial support in the development of this tool. The pilot of the Protocol in Mozambique was made possible by a generous grant from the World Diabetes Foundation. Funding for other projects was also received from the Diabetes Foundation, International Diabetes Federation, Diabetes UK and the other benefactors of the International Insulin Foundation.

The authors would also like to thank the past and present Trustees of the International Insulin Foundation: Professor Robert Beaglehole, Mr John Bowis MEP, Dr John Day, Professor Maximilian de Courten, Professor Geoffrey Gill, Professor Jak Jervell, Professor Harry Keen, Professor Jean-Claude Mbanya, Professor Ayesha Motala, Dr Kaushik Ramaiya, Professor Solomon Tesfaye, Professor Stephen Tomlinson, Professor Nigel Unwin, Dr Peter Watkins and Professor John S. Yudkin for their support and dedication throughout the development of this tool as well as its in-country implementation.

Without the hard work of in-country partners, the implementation of the Rapid Assessment Protocol would not have been possible. The lessons learnt as a result of this work has contributed greatly to the preparation of this document. Our appreciation to:

- Mrs Aida Abdraimova, Ms Baktygul Akkazieva, Dr Melitta Jakab and the whole Health Policy Analysis Centre Team (Kyrgyzstan)
- Mr Stéphane Besançon (Mali)
- Professor Aires Fernandes, Mrs Rosalina Machatine and Dr Carla Silva-Matos (Mozambique)
- Dr Catherine Atlan-Corea, Mrs Aura Cuadra and Dr Adilia Guadamuz, Mrs Ana-Julia Martinez and Dr Brenda Tapia (Nicaragua)
- Dr Socorro Escalante, Dr Dennis S. Quiambao, Dr Soe Nyuntu, Dr Budiono Santoso and Dr Robert L.P. So (Philippines)
- Professor Nguyen Thy Khue, Professor Ta Van Binh, Dr Hoang Kim Uoc, Dr Le Quang Toan, Dr Nguyen Bich Phuong, Dr. Dong Tran and Miss Kieu Thi Thu (Viet Nam)
- Dr Chishimba Lumbwe, Dr Susan Zimba-Tembo and the Diabetes Association of Zambia (Zambia).

The work in the Philippines was supported by the Foundation for Advanced Studies on International Development and Health Action International Global. Logistical support from the World Health Organization Representative Office in the Philippines is also gratefully recognized.

In helping to prepare this document the International Insulin Foundation would like to acknowledge the assistance of Dr Jonny Currie, Dr Zoe Rutter-Locher and Dr Angelika Siapkara.

To the staff of Health Action International Global and the World Health Organization Departments of Essential Medicines and Pharmaceutical Policies, and Noncommunicable Diseases and Mental Health, many thanks for your constructive comments throughout this process.

Our sincere gratitude to Dr Richard Laing, Essential Medicines and Pharmaceutical Policies Department, World Health Organization, for his unwavering support and guidance throughout this process. His experience and knowledge of the area of access to medicines and care has truly influenced the preparation of this manual, as well as our overall understanding of the challenges of delivering care for noncommunicable diseases (NCDs) in low- and middle-income countries.

Lastly, we would like to thank all the respondents from the seven countries for their time and for sharing their experience. The field work legitimated this tool as it is based on a true understanding of the challenges of people with diabetes and is hopefully helpful in addressing the growing burden of NCDs in low- and middle-income countries.

However, while acknowledging all of the support and assistance provided, the responsibility for the content of this manual is ours alone.

David Beran
International Insulin Foundation
University College London
London, United Kingdom
Université de Genève
Geneva, Switzerland

Michiyo Higuchi
Nagoya University School of Medicine
Nagoya, Japan

May 2012

Foreword

The global burden of noncommunicable diseases (NCDs) now contributes to greater loss of quality life-years than does that of all infectious diseases. This is the case for each individual region of the World Health Organization except Africa, but here, too, the burden of NCDs continues to rise. Health services in many low- and middle-income countries have evolved for the management of patients with acute infections, the constraining factors usually being poor availability of antibiotics or antimalarials, or of trained health workers. But the transition of disease burden from mainly acute to mainly chronic illness brings with it a series of different challenges for the health-care system.

This challenge has been recognized by the global community with the United Nations High-Level Meeting on NCDs and the First Global Ministerial Conference on "Healthy Lifestyles and Noncommunicable Disease Control" in Moscow. The World Health Organization's response has been the development and publication of an "Action Plan for the Global Strategy for the Prevention and Control of Noncommunicable Diseases" and a "Prioritized Research Agenda for the Prevention and Control of Noncommunicable Diseases". These two documents highlight the importance of health systems, health system research and researching issues around access to care in addressing the challenge of NCDs. In parallel, the Essential Medicines and Pharmaceutical Policies Department, World Health Organization, has carried out in-depth analyses of the affordability and availability of medicines for NCDs.

The International Insulin Foundation (IIF) was established in 2002 with the aim of prolonging the life and promoting the health of people with diabetes in resource-poor countries by improving access to diabetes care. In order to achieve this, it was felt necessary to undertake a clear analysis of the constraints to insulin access and diabetes care. This led the Foundation to develop the Rapid Assessment Protocol for Insulin Access (RAPIA). The purpose of a rapid assessment protocol is to gather information quickly, in situations where resources or logistical constraints make conventional research techniques impractical, and where assessments need to be tightly linked with developing interventions.

The RAPIA has been implemented by the IIF in six countries with a further assessment carried out in the Philippines to test the Protocol and help in the development of this manual. Assessments using the RAPIA have addressed areas including organization of the health-care system, diagnostic tools, drug procurement and affordability, accessibility of care, health-care worker training, community involvement, and the policy environment. In all cases, the conduct and reporting of the RAPIA have enabled the development of targeted projects and/or national diabetes plans with measurable improvements in care resulting.

This manual will allow different stakeholders involved in NCDs in low- and middle-income countries to plan and conduct surveys to explore current patterns of, and barriers to, good management, and to make recommendations in a short timescale and with limited resources. While the guidelines for good management of people with NCDs may differ to only a small extent between different countries, approaches to improving care will depend heavily on the existing patterns of care, resources and the barriers that exist in different countries. This manual is designed to support the development of country-specific plans by providing a practical tool that enables "research for action" in the area of NCDs.

After successful field testing and revision in the light of experience gained, the intention is to publish the manual as an official World Health Organization publication.

Table of contents

Abbreviations

AIDS	Autoimmune deficiency syndrome
CAQDAS	Computer assisted qualitative data analysis software
COPD	Chronic obstructive pulmonary disease
DALY	Disability adjusted life year
DHS	Demographic and Health Surveys
HAI	Health Action International
HIV	Human immunodeficiency virus
ICCC	Innovative Care for Chronic Conditions
IDF	International Diabetes Federation
IIF	International Insulin Foundation
INRUD	International Network for Rational Use of Drugs
M&E	Monitoring and evaluation
MDGs	Millennium Development Goals
MPR	Median price ratio
NCDs	Noncommunicable diseases
NDP	National Development Plan
NGO	Nongovernmental organization
PEN	Package of Essential Noncommunicable Disease Interventions
RAP	Rapid Assessment Protocol
RAPIA	Rapid Assessment Protocol for Insulin Access
UNDP	United Nations Development Programme
UNFPA	United Nations Population Fund
UNICEF	United Nations Children's Fund
WHF	World Heart Federation
WHO	World Health Organization
WHOSIS	WHO Statistical Information System

Chapter 1. Introduction

This chapter highlights the importance of a tool to investigate access to care for chronic noncommunicable diseases (NCDs). It also summarizes the current situation of NCDs, in particular, cardiovascular diseases and diabetes. Definitions of 'access to care' are then reviewed.

1.1 Aims of this manual

This manual presents how to investigate access to care for NCDs, including necessary medicines and supplies. The manual will allow different stakeholders involved in NCDs in low- and middle-income countries to plan and conduct surveys to explore current patterns of, and barriers to, effective management, and to make recommendations in a short timescale and with limited resources.

Such a survey is required in many low- and middle-income countries to describe the present situation of single or multiple NCD(s) as well as to identify possible barriers to access care since effective strategies have not yet been established to tackle the rapid increase of NCDs. The survey will be the initial step in a series of further actions. The process is expected to raise awareness of the disease and to increase the availability of data on these conditions in countries where this is often lacking. This manual presents methods that are suited to such objectives. The methods are standardized at some level. Applicable standardized methods will be useful in particular for countries that cannot afford to devote much time and/or resources to conducting research. In addition, standardized methods will be helpful for cross-country comparison to contribute to broader global and regional policy issues, since control of a disease often needs wider strategies that go beyond the national level.

1.2 Noncommunicable diseases

NCDs[i] such as cardiovascular diseases, diabetes, cancer and chronic respiratory diseases have human and economic impact through impaired quality of life, premature death and other adverse effects. NCDs are the leading cause of mortality. It is estimated that NCDs accounted for 60% of all deaths or 35 million deaths in 2005.(1)

The burden of NCDs is now increasing in low- and middle-income countries where 80% of global deaths caused by NCDs occur.(1) In resource-limited countries, however, less attention has been paid to these diseases by policy-makers, aid donors and academics than to acute, communicable diseases.(2) The need for management of NCDs at the primary healthcare level is becoming recognized.(3)

The rise of these diseases in low- and middle-income countries involves more serious issues than the epidemiological transition: the current rise of NCDs in these countries is being compressed into a short timeframe, and the burden of NCDs has increased where the burden

[i] 'NCDs', 'chronic diseases', and 'life-style diseases' are overlapping concepts although the diseases covered are not exactly the same. The conditions that this manual will focus on are 'Chronic Noncommunicable Diseases' to focus on the fact that the diseases are long-lasting and require life-long care, and are not transmissible between individuals.

of acute communicable diseases still exists, which imposes a double burden on such countries. Historical experience shows that rapid increases in diseases are likely to have a disproportionate effect on the developing world, and poor and disadvantaged populations, which leads to wider health gaps between and within countries.(4-7) There is a need to address the potential impact of the rising trends of NCDs, which may overburden both the health system and the household and thus impact on development.

1.3 Recognition of the challenge of NCDs

This challenge of NCDs has been recognized by the global community with the United Nations High-Level Meeting on Noncommunicable Diseases and the First Global Ministerial Conference on Healthy Lifestyles and Noncommunicable Disease Control in Moscow. The World Health Organization's (WHO's) response has been the development of an "Action Plan for the Global Strategy for the Prevention and Control of Noncommunicable Diseases"(8) and a "Prioritized Research Agenda for Prevention and Control of Noncommunicable Diseases".(9)

The Action Plan was endorsed at the Sixty-first World Health Assembly in May 2008 and seeks to build on existing WHO strategies, such as the Global Strategy for the Prevention and Control of Noncommunicable Diseases, endorsed at the Fifty-third World Health Assembly in May 2000, the WHO Framework Convention on Tobacco Control and the WHO Global Strategy on Diet, Physical Activity and Health. This Action Plan aims to direct Member States, WHO, and the international community in establishing and strengthening initiatives for the surveillance, prevention and management of NCDs.

Highlighting that "research is fundamental to generate knowledge and information for formulating evidence-informed policies and practices in support of global public health and health equity"(9), the Sixty-third World Health Assembly, in May 2010, in resolution WHA63.21, endorsed the WHO Strategy on Research for Health and established the role and responsibilities of WHO in health research. Within this strategy, the 'Prioritized Research Agenda for Prevention and Control of Noncommunicable Diseases' was developed to align this global research agenda with the '2008–2013 Global Strategy Action Plan'. Within this 'NCD research agenda' the focus is on low- and middle-income countries with research targeted at prevention and control of NCDs. The guiding principles of the NCD research agenda are:(9)

- Ensuring that decisions and actions for addressing NCDs are grounded in evidence from research
- Identifying knowledge gaps and strengthening research required for public health action, prevention of NCDs, priority health needs and health equity
- Strengthening the capacity of low- and middle-income countries to conduct research on priority NCD issues.

These two documents highlight the importance of health systems, health system research and researching issues around access to care in addressing the challenge of NCDs. In parallel, the WHO Essential Medicines and Pharmaceutical Policies Department has carried out in-depth analyses of the affordability and availability of medicines for NCDs.(10-11)

WHO strategies on NCDs focus on cardiovascular diseases, diabetes, chronic respiratory diseases and cancer. Due to the similar health-system factors required for the first three conditions, this manual will only focus on these diseases. Many of the tools and methods presented have some relevance to cancer treatment and other chronic diseases, such as depression.

1.4 Cardiovascular disease and hypertension

Cardiovascular diseases, which include ischaemic heart disease, cerebrovascular disease, hypertensive heart disease, and some other diseases, are caused by disorders of the heart and blood vessels and are the major cause of deaths in the world.(12) Hypertension is known to play a major etiologic role in the development of these diseases.(13)

Cardiovascular diseases were responsible for the mortality of 17.1 million people in 2004 in the world, representing 29% of global deaths. Of these deaths, an estimated 7.2 million were due to ischaemic heart disease and 5.7 million were due to cerebrovascular disease. Currently, 82% of deaths from cardiovascular diseases take place in low- and middle-income countries. Global mortality from cardiovascular diseases is increasing; it is projected that 23.6 million people will die from cardiovascular diseases in 2030.(12,14)

Globally, 51% of cerebrovasucular disease deaths and 45% of ischaemic health disease deaths are attributable of high systolic blood pressure.(15) Although the treatment of hypertension has been shown to prevent cardiovascular diseases, it remains inadequately managed everywhere.(13) The global annual cost attributed to suboptimal blood pressure was estimated at US$ 370 billion in 2001, which consumed 10% of all health expenditures in the world. Furthermore, the direct cost to the health-care system over a 10-year period would be nearly US$ 1000 billion if blood pressure remained the same.(16)

Annually 15 million people throughout the world suffer a stroke.(17) Of this total 5 million die and another 5 million are left with a permanent disability. The main causative factor of strokes is hypertension. It is projected that the burden of stroke will reach 61 million DALYs in 2020. Stroke affects women more than men and mortality rates in some low-income countries can be 10 times higher than in high-income countries.(17-18) The main factor for this is untreated hypertension.

Treatment strategies for hypertension are lifestyle modification, including exercise and diet, and pharmacological therapy.(13) In the most recent WHO Model List of Essential Medicines, four medicines are listed for the treatment of essential hypertension: amlodipine (calcium channel blocker), bisoprodol (β blocker), enalapril (angiotensin converting enzyme inhibitor) and hydrochlorothiazide (diuretic).(19)

1.5 Diabetes

Diabetes mellitus describes a metabolic disorder characterized by chronic hyperglycaemia with disturbances of carbohydrate, fat and protein metabolism. The current WHO diagnostic criterion for diabetes is fasting plasma glucose of over 7.0 mmol/l (126 mg/dl) or 2-hour plasma glucose of over 11.1 mmol/l (200 mg/dl). WHO now recognises the use of HbA1c as a diagnostic tool for diabetes.(20) Chronic elevation of blood glucose results from defects in insulin secretion, insulin action, or both, and will eventually lead to tissue damage, with

consequent disease in many organ systems, such as kidneys, eyes, peripheral nerves and blood vessels. These complications can lead to renal failure, blindness, lower extremity amputation and cardiovascular diseases.(21-22)

Prevalence of diabetes is also increasing. It is estimated that the total world population with diabetes was 285 million in 2010, and this will increase 1.5-fold by 2030. Almost 80% of current diabetes deaths occur in low- and middle-income countries. It is known that complications from diabetes result in human suffering and disability, and huge socio-economic costs are generated through premature morbidity and mortality. The IDF estimated that diabetes caused at least US$465 billion in health-care expenditures in 2011.(23) However, many people with diabetes are reportedly poorly controlled. For example, in a multi-centre survey in the secondary and tertiary health-care setting in 12 Asian countries, mean HbA1c was 8.6% and 55% had values in excess of 8% of the HbA1c, which is indicative of poor glycaemic control.(24)

While patients with type 1 diabetes, which is characterized by a lack of insulin production, need insulin therapy to survive, patients with type 2 diabetes are treated by lifestyle modification and pharmacological therapy. Pharmacological therapy for type 2 requires oral hypoglycaemic agents and/or insulin. In the latest version of the WHO Model List of Essential Medicines, two oral hypoglycaemic agents and two types of insulin are listed for the treatment of diabetes: glibenclamide (sulfonylureas), metformin (biguanide), soluble insulin and intermediate-acting insulin. Soluble insulin is short-acting. Compound insulin zinc suspension and isophane insulin are known as intermediate-acting insulin.(19, 25) Glucagon, a hormone injection, is also included in the latest Model List of Essential Medicines.

1.6 Chronic respiratory diseases

Chronic respiratory diseases are diseases that affect the airways and lungs, which include asthma and chronic obstructive pulmonary disease (COPD), they cause more than 4 million deaths every year and affect the lives of many more.(26) Women and children are especially vulnerable to these conditions. Prevalence of these diseases is increasing dramatically throughout the world, especially in children and elderly people.

Three hundred million people throughout the world have asthma and it causes 250,000 deaths annually. These deaths are purely due to lack of access to appropriate treatment.(26) COPD was the fifth cause of death worldwide in 2002 and is projected to be the fourth cause by 2030.(27)

In many low- and middle-income countries, the main barrier to proper management of chronic respiratory diseases is the poor availability and affordability of essential medicines. This is particularly true for the inhaled corticosteroids (e.g. beclometasone) which are necessary for the long-term management of asthma.(28) Research from 40 developing countries showed a mean availability of anti-asthmatic inhalers of 30.1% in the public sector and of 43.1% in the private sector.(29) Monthly treatment of a combination therapy made of inhaled bronchodilator and corticosteroids costs from 1.3 days' wage of the lowest paid government worker in Bangladesh to more than 9 days' wage in Malawi.(11)

In addition to these essential medicines, evidence-based national guidelines and proper training of health professionals are also necessary to provide quality care.

1.7 Access to care

Although the management of NCDs is well established, many patients, particularly those in low- and middle-income countries, do not have access to established treatment measures. Consequently, they are poorly controlled due to constraints in accessing continuous care.

Access to care is a complex concept.(30) Part of this arises from its definition. The term 'health service accessibility' was introduced in MeSH in 1978 and defined as 'the degree to which individuals are inhibited or facilitated in their ability to gain entry to and to receive care and services from the health-care system'.(31) Although proximity to health-care services and/or effective transportation are essential factors, it is also clear that fulfilling such physical accessibility is not enough to ensure actual access to care.

In an early discussion of access to care, Aday and Andersen(32) suggested that 'having access' be the potential to utilize a service and is influenced by the characteristics of the health delivery system and the characteristics of the population at risk. 'Gaining access' is measured by health-care outputs and outcomes, such as health service utilization and consumer satisfaction.(32) The Institute of Medicine defined access to care as 'the timely use of personal health services to achieve the best possible health outcomes'. In its model of access to care, potential barriers were categorized into structural, financial and personal barriers.(33) Gulliford et al.(30) identified four aspects of access to care: service availability, utilization of services, health outcome and equity. According to the authors, service utilization is dependent on affordability, physical accessibility and acceptability. In discussion of access to essential medicines, four dimensions, such as accessibility, availability, acceptability and affordability, are suggested.(34) Recently, health insurance coverage is often considered as an important component of access to care.(35-37) The term 'access' has not yet been concretely defined and each author implies slightly different meanings by using the term. In addition, what complicates the situation with regard to accessing NCDs care is that treatment is life-long. This fact influences linkage between NCDs and poverty. Poverty is a known barrier to access to care for NCDs, in addition to NCDs leading to impoverishment of individuals, households and society.(1)

In this manual, access to care will include the following components: 1) physical accessibility, whether a patient can easily reach health-care providers, such as hospitals, clinics, laboratories and pharmacies; 2) availability of resources, whether human and material resources at health-care providers actually exist in a functioning or valid condition; 3) affordability, whether a patient's expenditure is within his/her ability to pay; and 4) acceptability, whether a patient understands how to seek for care and whether he/she is willing to do so.

1.8 WHO's Innovative Care for Chronic Conditions (ICCC) Framework

As NCDs are now the leading cause of death in the world, health systems need a "paradigm shift" from an acute to a chronic care model.(1, 3, 38-39) Nolte and McKee (40) state that the management of chronic NCDs is one of the largest challenges that health systems throughout the world currently face and that each system needs to find a locally adapted solution. The

management of all NCDs has common factors mainly linked to the fact that care needs to be provided over a long period of time, which requires the input from a multidisciplinary team of health-care workers, access to medicines and diagnostic tools, patient empowerment, coordination of different elements of the health system.(41)

WHO has developed the Innovative Care for Chronic Conditions (ICCC)[ii] Framework that provides a model for care of NCDs, which is particularly relevant to primary health-care settings in low- and middle-income countries. The framework intends to present health-care solutions for effective management of long-term health problems. Patients and families, health-care teams and community partners are centred as a triad in the framework so that all parties are informed, motivated and prepared to manage chronic conditions. The framework evaluates along the micro- or local-level (patients and families, community partners and the health-care team), the meso- or intermediate-level (health-care organization and community), and macro- or high-level (health policy and financing) of the health-care system. It also helps in taking action by using 'building blocks' at each level.(42) The model tries to comprehensively understand the situation at these multi-levels in order to take action, which is useful for investigating access to chronic NCD care.

1.9 WHO's Package of Essential Noncommunicable Disease Interventions for Primary Health Care

Building on the ICCC Framework for organizing health systems to effectively deliver care for NCDs, WHO has also developed the 'WHO Package of Essential Noncommunicable Disease Interventions' (WHO PEN).(43) The focus of the WHO PEN is to provide a series of cost-effective interventions that can be delivered to an acceptable quality of care, even in resource-poor settings. It can be viewed as describing the minimum standard for NCDs to strengthen national capacity to integrate and scale up care of heart disease, stroke, cardiovascular risk, diabetes, cancer, asthma and COPD in primary health care in low-resource settings. These interventions include early detection using affordable technology, non-pharmacological and pharmacological approaches for addressing the risk factors of NCDs and affordable medicines for prevention and treatment of cardiovascular disease, diabetes, cancer and asthma.

The focus is also on devolving NCD care to the primary level. This 'package' of interventions aims to provide 'best buys' for low-income settings. These include 'technologies', such as blood pressure machines, blood glucose machines and blood and urine glucose test strips and 'essential medicines' based on the WHO Model List of Essential Medicines.

A framework for implementation is also proposed including the need to assess the capacity of primary health care to deliver the requirements detailed in the WHO PEN.

[ii] The term 'chronic conditions', not 'chronic diseases', is used in the ICCC Framework. 'Chronic conditions' in the Framework is defined as 'health problems that persist across time and require some degree of health care management', including noncommunicable diseases, mental disorders, certain communicable diseases such as HIV/AIDS, and ongoing physical impairments.

1.10 Putting this into the global context – the link with the Millennium Development Goals

The Millennium Development Goals (MDGs) were adopted by world leaders in the year 2000 in order to provide targets for tackling extreme poverty and the wide scope of its causes.(44-45) They serve as a common goal for the international community to strive for. The eight MDGs are:

1. Eradicate extreme poverty and hunger
2. Achieve universal primary education
3. Promote gender equality and empower women
4. Reduce child mortality
5. Improve maternal health
6. Combat HIV/AIDS, malaria and other diseases
7. Ensure environmental sustainability
8. Develop a Global Partnership for development

MDG 8 focuses on developing a global partnership for development and includes a variety of issues such as debt relief, overseas development aid and market access for products from developing countries to developed markets. Target 8.E states that "in collaboration with pharmaceutical companies, provide access to affordable essential drugs in developing countries." Indicator 8.13 is "the proportion of population with access to affordable, essential drugs on a sustainable basis."

Studies have highlighted poor accessibility and affordability to essential NCD medicines in many settings.(10-11, 29, 46-49) Most medicines needed for the treatment of NCDs are included on the WHO Model List of Essential Medicines, available in generic form and at low cost. For example, a one month supply of metformin (a medicine to treat diabetes) costs US$ 0.63 (procurement price with no duties, taxes or mark-ups.(50) A study by Cameron et al.(29) found that access to medicines for NCDs was lower than that for acute conditions in both the public and private sectors. This problem highlights the fact that before the review of the MDGs in 2015 much work still needs to be done in achieving MDG 8, and without ensuring access to affordable essential NCD medicines this milestone will not be met.

Box 1.1

"Governments, in collaboration with the private sector, should give greater priority to treating chronic diseases and improving the accessibility of medicines to treat them." MDG Gap Task Force Report 2009.(51)

Chapter 2. Background

This chapter introduces three important survey methods referred to in this manual.

2.1 Overview of the Rapid Assessment Protocol for Insulin Access[iii]

The establishment of the International Insulin Foundation (IIF), by leading academics and physicians in the field of diabetes in 2002, was intended to mark embarkation on a concerted effort to improve the prospects of people with Type 1 diabetes in the world's poorest countries. The IIF was established with the aim of prolonging the life and promoting the health of people with diabetes in low- and middle-income countries by improving the supply of insulin and education on its use. The rationale for this was that Leonard Thompson was given his first injection of insulin on 11 January 1922 in Canada. He was the first patient to be treated with insulin for type 1 diabetes. Having survived some two and a half years from his diagnosis, he had survived for a longer period than most children with Type 1 diabetes in the pre-insulin era. Access to insulin saved Leonard from near certain death.

With the discovery of insulin in 1921, many thought that this meant the end of the complications and suffering for those with Type 1 diabetes. This discovery meant that Type 1 diabetes went from being a death sentence to a disease that could be managed and therefore life-expectancy of children with this condition significantly increased.(52-53) For people in low- and middle-income countries access to insulin is still problematic due to issues of both affordability and availability.(54-58) However, it is relevant to note that other health system factors apart from availability and affordability, such as health-care worker training, availability of diagnostics and government policies for diabetes and NCDs, also add to the challenge of diabetes care in resource poor settings, leading to decreased life expectancy.(48-49)

The IIF developed the Rapid Assessment Protocol for Insulin Access (RAPIA) recognizing the fact that merely increasing the insulin supply would not improve the prognosis for people needing insulin, and the root of the problems needed to be assessed. The RAPIA's framework studies the path of insulin to the point where it reaches or fails to reach the individual. Although it initially focused on insulin and patients with insulin-dependent diabetes, it now also includes oral diabetes medicines and patients with non-insulin-dependent diabetes.

The aim of the RAPIA is to provide a practical field guide to assist teams in the collection, analysis and presentation of data to evaluate and inform the development of health-care services for diabetes management in low- and middle-income countries. It is structured as a multi-level assessment of the different elements that influence the access patients have to insulin in a given country through multiple data sources. The data collection process is expected to provide a situation analysis regarding the supply of medicines and diabetes care, which highlights the strengths and weaknesses of the health system and proposes concrete actions.(47, 59-60)

[iii] Reports on previous studies and other related resources are available at: http://www.access2insulin.org/

Rapid Assessment Protocols (RAPs) have been used extensively to assess services for communicable diseases, including malaria, tuberculosis and sexually transmitted diseases, for the purpose of developing interventions.(61-67) The approach chosen here was to adapt existing protocols to suit the assessment of access to insulin. The main principles of the RAPs are:

- Speed – the methods are intended to provide relevant information quickly, upon which decisions about health-care interventions can be made.
- Use of multiple data sources – different methods are used to access different sources of data to obtain a balanced overview.
- Pragmatism – the methods should provide adequate information, without necessarily being 'scientifically perfect'. Triangulation or cross-checking between different sources of data is used to establish the validity and reliability of the data collected.
- Cost-effectiveness – the focus is on research instruments that provide information cheaply, and are not labour and time intensive. Where possible, use is made of existing data.

The RAPIA has three components: macro-level, meso-level, and micro-level. The RAPIA built on the ICCC Framework, presented in section 1.8 ,by studying three levels of the health system, as detailed in the table below. This ensures that an issue is observed from different viewpoints. Fifteen kinds of semi-structured, open-ended questionnaires are used to target interviewees at these three levels, as shown below.(47, 59-60)

Table 2.1: Questionnaires that make up the RAPIA

Macro-level	Ministry of Finance Ministry of Trade Ministry of Health Private sector (e.g. pharmaceutical wholesalers) Diabetes organizations Central medical stores Educators (e.g. Professors at Faculty of Medicine)
Meso-level	Regional health office Regional central medical stores Hospitals, clinics, health centres, etc. Laboratories Pharmacies
Micro-level	Health workers Traditional healers Patients

For meso- and micro-level data collection, three sites are purposively selected: the capital city, one urban area and one rural area. Selection of facilities at meso-level (e.g. hospitals, laboratories, pharmacies) does not rely on random sampling but uses a convenience sample. Sampling facilities purposively includes both public and private sectors. Micro-level sampling is also purposive, and usually uses 'snowball' sampling. The sample size is not fixed and recruiting respondents stops at 'theoretical saturation'. Data collected from different viewpoints are synthesized and analysed.

To date the RAPIA has been implemented in six countries (representing four WHO Regions) by the IIF: Kyrgyzstan, Mali, Mozambique, Zambia, Nicaragua and Viet Nam. Reports are available on the IIF web site: http://www.access2insulin.org/.

From these studies, 11 key elements for tackling problems linked to diabetes care have been identified and are used in reporting the findings.(48, 68) These elements are:

1. Organization of the health system
2. Data collection
3. Prevention
4. Diagnostic tools and infrastructure
5. Medicines procurement and supply
6. Accessibility and affordability of medicines and care
7. Health-care workers
8. Adherence issues
9. Patient education and empowerment
10. Community involvement and diabetes associations
11. Positive policy environment

Using these 11 elements helps focus the findings and recommendations from the country studies. These have produced in-country reports and presentations to help shape diabetes projects, diabetes action plans and national NCD policies. In addition, results from the RAPIA have been presented in a variety of conferences, as well as being published in peer reviewed publications, such as the Asia Pacific Journal of Public Health, BMC Health Systems Research, the Bulletin of the World Health Organization, Diabetes Care, Diabetes Research in Clinical Practice, Diabetic Medicine, Diabetologia and the Lancet. A list of these articles is attached in Appendix 1.

As shown in Chapter 11, use of the 11 elements also provides a framework for comparison between countries and as a means to monitor and evaluate the development of projects and policies following an initial RAPIA assessment.

2.1.1 Adaptation of RAPIA in the Philippines

A survey on diabetes care was planned in the Philippines, applying the RAPIA methods.(69-70) Questions were adapted to make them suitable for the highly decentralized health system. Reflecting the country's diversity of health situations, more health

professionals and patients in the community were interviewed than in the original RAPIA and each questionnaire was simplified.

Modifying the RAPIA's data collection tools, three-stage sampling was applied in the Philippine survey: five sites were selected, including the capital city and four provinces; six anchor hospitals were then selected in each site; and health professionals and patients were identified from anchor hospitals for the third stage sampling. In total, 359 respondents were purposively and systematically obtained. Different questionnaires/checklists were prepared for various target groups in order to collect quantitative and qualitative data. Another major modification from the RAPIA was that a structured questionnaire for patients was separately developed to collect quantitative data on a patient's situation in a systematic manner.

The Philippine survey was conducted by a different investigator from the researcher who developed the RAPIA. It was intended to test future possibilities for wider application of the methods to other chronic NCDs in other countries, so that the methods can be widely used by researchers in their own situations.(69-70)

2.2 How to investigate drug use in health facilities

To simplify and standardize the study of medicine use, WHO and the International Network for Rational Use of Drugs (INRUD) produced a manual to investigate medicines use in health facilities. Consisting of 12 core indicators and 13 complementary indicators, the intended objectives of a drug use study by these indicators are: 1) describing current practices, 2) comparing the performance of facilities or prescribers, 3) monitoring and supervising specific behaviours, and 4) assessing the impact of an intervention.(71)

Although only simple indicators were measured in the INRUD/WHO method, results were important where no objective data on this issue were available. In addition, the INRUD/WHO indicators were developed as first-line measures to stimulate further questioning and to guide subsequent action.(71) In 1993, the use of medicines in 12 developing countries was assessed by using these standardized indicators.(72) By 2006, WHO had collected more than 800 studies using the method.(73)

2.3 Overview of the WHO/HAI price survey[iv]

In 2001, WHO and Health Action International (HAI) developed a standard method to survey price and availability of medicines. The objectives of this method are to obtain information on the prices of selected medicines, the price components, the availability of the medicines, and the affordability of the medicines. The results can be compared between brands and generics, and by sector (e.g. public versus private). The survey also measures the mark-ups and other charges applied as a medicine moves through the supply chain. It can be used to investigate variations between different geographical areas in a country, and also to make cross-country comparison. The manual is also available online.(74-75)

[iv] The manual, data collection forms, and computerized workbook as well as data and reports of previous studies are available at: http://www.haiweb.org/medicineprices/

In the survey, data are collected on the availability and price of a selection of important medicines from a sample of medicine outlets in the public, private and 'other' sectors (e.g. NGOs). Apart from data collection for procurement prices that is generally conducted at the central level, data are collected from six geographic or administrative areas: the major urban centre plus five additional areas selected at random. Then, in each area, five public facilities, including the main hospital in the area, are selected to form the public sector sample. For each public facility, the nearest private pharmacy is chosen as a paired sample. Therefore, a total of 30 public health facilities and 30 private pharmacies are investigated. In addition, five 'other sector' medicine outlets, for example mission hospitals or dispensing doctors, are sampled in each area if these represent a significant medicine distribution point in the country.

Data are collected using structured 'medicine price data collection forms', and entered into a computerized Excel workbook which is pre-programmed to consolidate and summarize results. Median medicine prices found during the survey are expressed as ratios relative to a standard set of international reference prices (median price ratio or MPR). The most commonly used international reference prices are from Management Sciences for Health, which represent median prices of high quality, multi-source medicines offered to low- and middle-income countries by different suppliers. Availability is reported as the percentage of medicine outlets in which a medicine was found on the day of data collection. Affordability is expressed as the number of days' wages the lowest-paid government worker would need to purchase a standard course of treatment for an episode of illness (e.g., the monthly treatment cost for diabetes). Variations across outlets are analysed, and results are compared across product types (originator brand versus lowest-priced generic) and sectors. Mark-ups and price composition are also computed.(75)

Comprehensive analysis of the data from 36 countries was reported in 2009.(10) The results of over 50 surveys are currently available on the database at the HAI web site, along with survey reports and other information. Results that focus on NCD medicines were also published: a summary report of the results from 30 surveys (24 countries) on medicines for five NCDs was published in 2005,(76) and a comparative study on availability and affordability of 32 chronic NCDs medicines in six low- and middle-income countries was published in 2007.(11) Availability of medicines for chronic and acute conditions in the public and private sectors in developing countries was reported in 2011.(29)

Chapter 3. Survey overview

This chapter provides an overview of the planned survey: the aims and objectives, components, methods and process.

3.1 Aims and objectives

This manual provides multiple methods that aim to describe the present situation surrounding a single or multiple NCDs, such as cardiovascular diseases, diabetes and chronic respiratory diseases. The manual also identifies possible barriers to access to care for the target disease(s) in a given country or region.

The survey will help decision-makers in the development of projects, programmes, or policies. In addition, the survey might be utilized for cross-country comparison to contribute to broader policy issues such as regional strategies. Another aspect is stimulating interaction among people involved in the survey. The survey process is expected to raise awareness of the target disease and to increase the availability of the data that are required for this survey. The survey team may be able to act as a catalyst to induce discussion between different stakeholders.

3.2 Principal investigator

A government official in a relevant section (e.g. Department of NCD Control in the Ministry of Health) may be the most suitable principal investigator, as this should make it easier for survey findings to be translated into policy actions. If it is difficult for the head of the NCD Department to be fully involved in the research process, he/she may designate a senior officer in the department as an acting principal investigator. A researcher in an academic institute in the surveyed country or an internal or external consultant who is working for an NCD control programme could be an alternative.

The most critical role of the principal investigator is to involve all the relevant sections and people. This does not merely mean possible target institutions and informants of the survey (see 3.3.2) but also the target audience of the future report (see 10.4).

3.3 Components and structure of the survey

The survey consists of 3 key components: i) 11 **themes**, ii) 11 **target institutions/informants** (4 levels), and iii) 4 types of **data sources**. **Data collection tools** are also important parts of the approach. They are developed for each target group. Details of each component and how to develop data collection tools and a sampling scheme are explained in Chapter 6.

3.3.1 Themes

Survey topics comprehensively cover subjects related to the target disease(s) being studied (e.g. diabetes and/or cardiovascular disease). They include background information on the health system in the surveyed country or region and issues of care, including necessary medicines and supplies.

The 11 themes are:

1. General information
2. Health-care structure
3. Financial issues
4. Health insurance and other social security provisions
5. Disease-related policies, programmes and activities
6. Supply/procurement systems
7. Resource allocation/availability for care
8. Price/affordability of care
9. Disease management and treatment issues
10. Referral issues
11. Patient issues

While themes 1 to 3 describe the general environment in the health system beyond the target disease(s), themes 4 to 11 focus on the target disease(s).

The same topic questions are asked to each target group, as far as is relevant, so that cross-checking can be done from different viewpoints. For example, regarding medicines prices, while pricing policies are checked using the national price list at the national level, purchasing prices and selling prices at medical stores and pharmacies are verified as well. Information is also collected on how much a patient actually pays. This enables mark-ups to be calculated at each point. The terms used in actual questions may need to be changed depending on the target group (see Chapter 6).

Themes 7 'Resource allocation/availability for care' and 8 'Prices/affordability of care' should cover all aspects of health services (both activities and products) as listed below:

Activities

(a) Consultations
(b) Dispensing
(c) Laboratory tests
(d) Inpatient care

Products

(e) Injectable medicines, in particular, insulin
(f) Oral medicines
(g) Other types of medicines, in particular, inhalers
(h) Medical supplies (syringes, needles, inhalation medicine, etc.)
(i) Equipment (laboratory machines, glucometer, spectrophotometer, etc.)
(j) Consumables for laboratory tests (reagents, test strips, syringes, etc.)

Theme (6) 'Supply/procurement systems' also needs to cover the products mentioned above. All items to be included in each aspect of health services (activities and products) for the target disease(s) need to be identified before the start of the study. For example, if diabetes is being researched, medication should include oral hypoglycaemic agents, other oral medicines, insulin, and insulin-related materials like syringes and needles and glucometers and their strips. Laboratory tests should include at least urine glucose, blood glucose, ketones and HbA1c, based on the national essential medicines list, the national standard treatment guidelines, the WHO Model List of Essential Medicines and the Package of Essential Noncommunicable Disease Interventions for Primary Health Care.

3.3.2 Target institutions/informants

Eleven core target groups are categorized into four levels: the national level, intermediate level, local level, and patients and carers. Most of the institutions and informants, in particular those at the local level, can be characterized as public or private.

National level
(1) Ministry of Health (or equivalent)
(2) Central Medical Stores
(3) Disease-related associations (e.g. patient organizations, health professional associations, academic associations, etc.)

Intermediate level
(4) Health offices at the different levels (e.g. provincial health office, district health office, municipal health office, etc.)
(5) Regional medical stores (e.g. regional medicines store, provincial medicines store, district medicines store, etc.)

Local level
(6) Hospitals
(7) Health centres/clinics (or other health facilities without inpatient wards)
(8) Laboratories
(9) Pharmacies
(10) Health-care workers
* Respondents for 6–9 may be administrators/managers or health-care workers.

Individual level
(11) Patients and carers

In a highly decentralized health system, central and regional medical stores might not exist since every hospital would procure medicines individually. In some countries, a regional medicine store may be one section of the local health office.

The same person may be questioned as a respondent in different target groups; the director of a small health centre, who is practicing as the only physician in the same centre can be a respondent for (7) and (10); a governmental officer in the Ministry of Health who is working for a hospital can be a respondent for (1) and (6); a doctor for a public hospital who is

running a private clinic in the evening can be a respondent (10) for both the public sector and for the private sector.
If relevant in the study country and sites, complementary target groups may be added, as follows:

National level
– The Ministry of Trade
– The Ministry of Finance
– Importers (governmental and private)
– Pharmaceutical manufacturers
– Distributors
– Educators

Intermediate level
– Local distributors

Local level
– Traditional healers
–

3.3.3 Types of data sources

The following are the main data sources for the survey:

– Secondary documents (e.g. annual reports of health offices, statistics, policy papers, hospital records, academic publications, etc.)
– Primary data
  - Observations
  - Interviews

For example, a policy paper obtained at the Ministry of Health and a report of the provincial strategic plan for NCDs are documents that should be collected when available. Statistics about demographic data, epidemiological data and health utilization data should be gathered at each health office, and medicines and laboratory price lists should be observed at each hospital visited. Relevant data sources are identified in advance by theme and target, and then data collection tools are developed.

3.4 Methods and process

To achieve the aims and objectives described in 3.1, the principles of RAP are applied to the survey, which targets people in multiple groups and relies on multiple data sources. Data from each source are collected and analysed quantitatively and qualitatively. Pragmatism, speed and cost-effectiveness are the main principles of the RAP.(59) This means that the

survey requires gathering as much useful information as possible within a limited time and with limited resources.

In general, the survey proceeds as shown in Table 3.1. As an initial step, investigators need to know about the disease(s) to be surveyed. After obtaining information available online and accessible in a written form, preparatory fieldwork is conducted. The purposes of this preparatory fieldwork are to obtain further information needed to develop concrete survey plans, to make arrangements with relevant sections, and to identify key informants. It is advisable to organize survey committees in the country at this stage.

Table 3.1: Process of the survey

Process		Details in:
Start-up (Initial preparation)	• Literature review • First contact • Meetings with key informants and organizing survey committees • Preliminary data collection at the national level, if possible	CHAPTER 4
Sampling	• Development of a sampling scheme	CHAPTER 5
Adaptation of methods	• Development of data collection tools	CHAPTER 6
Preparation	• Proposal writing • Ethical and scientific reviews • Fieldworker training • Administrative arrangement to visit sites	CHAPTER 7
Data collection and entry		CHAPTER 8
Data analysis		CHAPTER 9
Reporting and dissemination	• Various types of report generation • Dissemination strategies	CHAPTER 10
Follow-on activities	• Follow-on questions • Comparisons • Monitoring and evaluation • Development of policy actions	CHAPTER 11

The next step is to develop a sampling scheme and data collection tools. Then, if necessary, the research proposal should be submitted to relevant sections, for example, the health authority, principal investigator's institute (when the principal investigator is a person outside the health authority) and research sponsors. When appropriate, ethical and scientific reviews should be completed before the main fieldwork starts, and the research team should be aware that this may take time.

At the beginning of the main fieldwork, one or two weeks may be needed to prepare for data collection, such as fieldworker training, administrative arrangements and logistic preparations to visit sites. The survey team, the principal investigator and fieldworkers, then move to sites to collect data. It is strongly recommended that available data be inputted as soon as possible, just after the data are obtained. At the initial stage, quantitative data and qualitative data may be analysed separately; however, findings from both analyses will be integrated in interpretation and discussion.

Based on the analysis, several kinds of reports, such as a full report, short summary, policy briefing paper, brochure, journal articles, etc. and presentations are prepared. A summary report should be submitted to every respondent. Merely submitting reports is not enough. If the principal investigator prepares the report outside the surveyed country, it is suggested that the principal investigator visit the surveyed country again, and then the survey team and relevant sections jointly hold a workshop to disseminate findings and to develop further plans with stakeholders.

More detailed information on the research process is described in Chapters 5–11.

Chapter 4. Initial preparation

This chapter explains how to collect necessary information and what to do before the start of the main fieldwork. These steps are important even if the researcher has in-depth knowledge of the target disease(s) and the country to be surveyed. It is still important to review literature, describe the research objective, and make the necessary preparatory arrangements.

4.1 Collecting information

Before conducting the survey, basic knowledge of the survey country and the target disease(s) are needed. It is useful for this objective to search for information provided by the government and relevant organizations, as well as related academic journals.

4.1.1 Country information

The Ministry of Health or the equivalent in the survey country probably has a web site and provides related information through the Internet. United Nations agencies, programmes and funds that work on health, such as WHO, the World Bank, the United Nations Children's Fund, (UNICEF), the United Nations Population Fund (UNFPA), the United Nations Development Programme (UNDP) and others, provide country profiles in relation to health issues. A list of web sites is attached in Appendix 1.

In many countries, the Ministry of Health and the Statistics Bureau (or the equivalent) release their country's health indexes and population data. Web sites of the organizations in the United Nations system mentioned above are also helpful to obtain country profiles and related statistics. The United Nations Statistics Division and WHO Statistical Information System (WHOSIS) provide useful databases of indicators. Population, health and nutrition indicators from the Demographic and Health Surveys (DHS) Project, which have been implemented in many countries, are accessible, and the datasets and reports can be obtained on request. Country's health-related laws and regulations and relevant sections of the national development plan (NDP) may also be accessible online.

Table 4.1 lists country information that is necessary for preliminary collection in advance of the main fieldwork.

Table 4.1: List of country information that is necessary for preliminary collection

Country information needed	Possible source
Country profile (health-related)	• Ministry of Health • UN agencies, programmes and funds - WHO - World Bank - UNICEF - UNFPA - UNDP etc.
Statistics and health indicators	• Ministry of Health • National Statistics Bureau • United Nations Statistics Division • WHOSIS • DHS etc.
Health-related laws and regulations and health-related sections of the NDP	• Ministry of Health etc.

4.1.2 Information on the target disease(s) from related organizations

There are useful resources for finding out about the target disease(s) on WHO's topic pages such as 'chronic diseases', 'diabetes' and 'cardiovascular diseases'. For example, global situations and major concerns about chronic NCDs can be found in WHO's World Health Report 2005, which is downloadable via WHO's web site.(1) Appendix 1 also provides lists of key web sites and references.

International NGOs for health professionals, academics, and/or patients also provide related information. The International Diabetes Federation (IDF) is one such example. It is an umbrella organization of over 200 national diabetes associations in over 160 countries, and published the 'Diabetes Atlas 5th edition in 2011.(23) A local counterpart organization of IDF in the survey country will be a survey target, and it is useful to obtain information about the organization in advance. Information from the World Heart Federation (WHF), the International Union Against Tuberculosis and Lung Disease, and other international disease-related organizations will be useful. It is also important to check whether any governmental and/or NGO donor implements or funds activities related to the target disease(s).

Table 4.2 lists disease information that is necessary for preliminary collection in advance of the main fieldwork.

Table 4.2: Disease information that is necessary for preliminary collection

Disease information needed	Possible sources
Global trends and concerns	• WHO's topic pages • International disease-related organizations/associations e.g. IDF, WHF, etc.
Country-specific problems and programmes	• Ministry of Health • Disease-related national organizations/associations - Health professionals - Academic researchers - Patients • Governmental and nongovernmental donors to support disease-related programmes etc.

4.1.3 Literature search

To understand current knowledge of the topic, literature search methods will be useful. 'Noncommunicable diseases' (or each specific name of the diseases), 'access', 'adherence', 'health system', 'low-income country' (or 'middle-income country') may be possible search terms in addition to the country name. However, such conventional literature review may not lead to the discovery of the academic literature from local institutions, since the intended articles may not be indexed in major databases and/or are written in the local language. Such information can be physically collected together with the country information when the investigators visit relevant offices and organizations (see 4.3). If a WHO/HAI survey has been conducted in the country where this survey is planned, the data and report on price and availability should be reviewed in advance. As explained in 2.2, WHO/HAI web site provides a database for results from previous surveys on medicines price and availability. The WHO Medicines Documentation System is also helpful to search the literature (see Appendix 1).

4.2 First contact

In parallel to searching for information, key reports for the target disease in the survey country may be found. Contact with the report author or the organization that produced the report may identify a potential collaborator or a useful link to other individuals and organizations that may be able to assist in the implementation of this research. Possible first contact sections are: a national association for the target disease, either a patient or professional association, a specialized hospital, such as a diabetes centre or heart centre, an academic institute of a health-related subject, such as medical, public health or nursing college, or an individual researcher who has published related research, the WHO country office, a relevant section in the Ministry of Health, such as a Department of Chronic NCDs Control, and others.

The first meeting with relevant stakeholders should be viewed as an opportunity to introduce the project team and the actual project. Depending on the situation, a formal research proposal may need to be submitted. A tentative plan can be presented while a more concrete proposal is being developed with local partners.

4.3 Preparatory fieldwork

The most important aim of the preparatory fieldwork is to identify country-specific situations for the further development of the research proposal. Key informants for the informal meetings at this stage will be future research respondents at the national level, who are listed in section 3.2.2, country offices of health-related UN agencies/programmes, such as WHO and UNICEF, and other sections that are identified by the 'snowball' method, in which respondents introduce the investigators to others who meet the sample criteria. At this stage, general information is more useful, although specific questions will be asked later during the main fieldwork. However, part of key informant interviews may be used as data at the national level.

Table 4.3: List of topics for the informal meetings with key informants

General information	• Health system structure (corresponding to the administrative structure) - Levels of health offices - Levels of health service provision - Administration of public hospitals and health centres (owned by the Ministry of Health, local government or autonomous?) • Resource allocation - Human resources - Material resources/facilities • National essential medicines list, national formulary, and standard treatment and/or management guidelines • Procurement/supply system for medicines and medical supplies • Pricing system for medicines and medical supplies • Payment system for health services (health insurance coverage and patient co-payment) • Referral system
Disease-related information	• Policies and national plans • Associations/organizations - Health professionals - Academic - Patients

Additional information which is locally available should be obtained, and information already gathered online and in an accessible written form (see section 4.1) should be verified and updated during the preparatory fieldwork.

Another important purpose of the preparatory fieldwork is to make arrangements with a future counterpart. If one has already been identified, it may be helpful to make an administrative agreement at this stage. This should include the overall schedule, fieldworker requirements, including their salaries, and arrangements for collaboration with local authorities, etc.

If data collection tools need to be translated, it is recommended that arrangements for this be made in the preparatory fieldwork. Obtaining information on living expenses, such as the cost of food, accommodation and transport, will be helpful to make a budget plan in a research proposal.

Chapter 5. Sampling

This chapter explains how to sample study participants. Sampling is necessary, as it is impossible to interview every person with diabetes or to visit every facility. Sampling is always a balance between convenience and accuracy. For example, it may be convenient only to visit facilities or interview patients in the capital but this will not give an accurate impression of the true situation throughout a country. By extending sampling out of the capital and including people that may not have been easy to contact, a more accurate representation of the true situation can be obtained. In a RAP method of research, quantitative (numbers) and qualitative (text data) methods are jointly used to collect data from the same respondents. This creates a tension, as quantitative studies require larger numbers of respondents to be "representative" while qualitative methods require in-depth information from a lesser number of respondents. The sample size used is a pragmatic compromise to meet the needs of both methods.

Simple random sampling is not recommended. Respondents should be purposively selected so that the selected respondents are as informative as possible. Purposive sampling means that the individuals included in the study have specific characteristics that are of interest. At national, intermediate and local levels, this is because the people targeted can be described as “key opinion leaders” due to their role within a given organization or their experience in NCDs. For individuals with NCDs the study aims to obtain a range of experiences to compare why people in the same country, province, city, etc. may have varying experiences of care.

To undertake a RAP survey as described in this manual, the sampling method will need to be adapted to the national situation, the resources and time available, and the purpose of the appraisal.

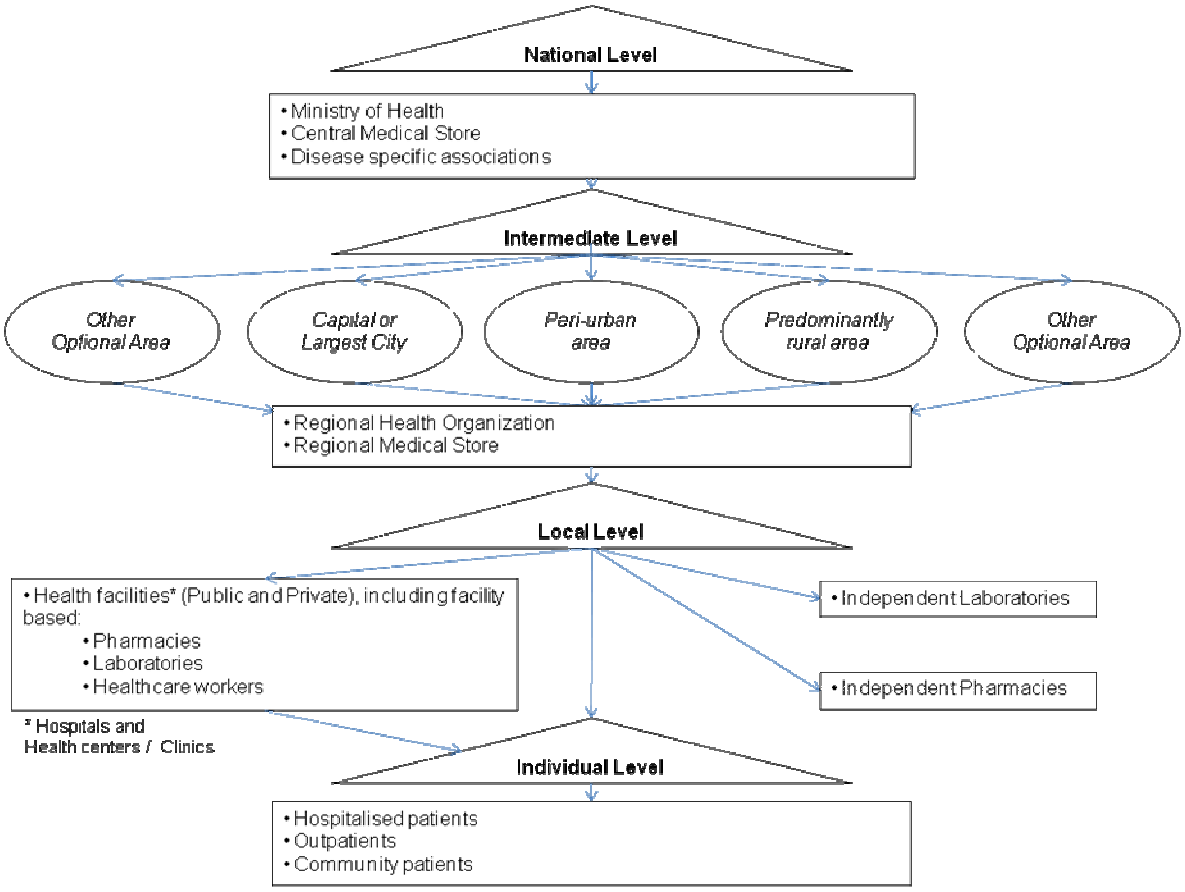
5.1 Sampling framework

As described in Chapter 3, this methodology aims to study 11 themes in order to gain insight into the barriers to care for NCDs in a given country or area of a country. In order to attain a full understanding of the breadth and depth of factors that may limit access to optimal care a variety of stakeholders will need to be interviewed. These range from government officials within the Ministry of Health to individuals with the target condition.

In some settings multiple individuals may need to be interviewed. For example, in the Ministry of Health the person responsible for NCDs, the person responsible for medicine procurement and supply as well as others may need to be interviewed. At facilities, administrators, doctors responsible for NCD care, nurses, pharmacists and laboratory technicians will need to be questioned.

The overall sampling by different levels is detailed in Figure 5.1.

Figure 5.1: The sampling strategy



5.2 Study locations and definitions

The sampling will need to be done in at least three areas of the country. Usually this is the capital city, a large urban area and a predominantly rural area. These three categories of areas can be applied at a national level or at a sub-national level, such as a state or province.

5.2.1 National level

The first level of the study is the national level. This includes the:

- Ministry of Health (or equivalent)
- Central Medical Stores
- Disease-related organizations

The **Ministry of Health** is the government organization, agency or department that is responsible for health at a national level.

Central Medical Stores are organizations, agencies or departments that are responsible for supply and procurement of medicines and medical supplies at a national level. They might be under the Ministry of Health of the country, independent administrative institutions or private organizations.

Disease-related organizations represent the voice of people with a given condition at a national level. They may have more of a patient or professional focus. The role of these associations can be: advocacy, training for patients and health-care workers about a given disease, support group for patients and carers, and provider of care.

5.2.2 Intermediate level

For the next level, the intermediate level, the unit of sampling is an administrative area in the survey country such as the province or district. It is recommended that at least three locations are selected: the capital city, one peri-urban area and one predominantly rural area.

Where administrative areas are stratified, for example, as province, district, municipality and village, decisions need to be made as to what the most appropriate sampling unit is. When a 'state' or a 'province', instead of a country, is targeted for a study, an administrative area under the state or the province will be chosen. At this level the following stakeholders are interviewed:

- Health offices
- Regional medicines store

Health offices are public organizations, agencies or departments that are responsible for health administration in the area. They might be under the Ministry of Health of the country in some settings, while they might be under the local government in other settings. They are called differently from country to country; for example at the provincial level, such an organization might be a provincial office of the Ministry of Health or a health department of the provincial government. Any relevant administrative body should be considered as a 'provincial health office'. There are health offices at a different level, which administer larger or smaller areas, such as a regional health office and/or district health offices or even city offices and/or municipal offices, and any of these can be included if necessary and appropriate.

Medical stores are organizations, agencies or departments that are responsible for supply and procurement of medicines and medical supplies in the area. They might be under the Ministry of Health of the country, under the local government, independent administrative institutions, or private organizations.

5.2.3 Local level

Health facilities will be visited in each intermediate level area studied. Depending on the organization of the health system and local terminology used, these will include:

- Hospitals
- Health centres/Clinics
- Pharmacies
- Laboratories

Hospitals are health-care facilities that provide both outpatient and inpatient services. Any facility that provides inpatient services can be categorized as a hospital even though it is called differently, for example, a medical centre.

Health centres/Clinics are health-care facilities that provide mainly outpatient services but no curative inpatient services. Such a facility might be called differently in different settings, for example, infirmaries, dispensaries, medical offices etc. Some governmental health centres may take both clinical and public health tasks, however, any facility that provides ambulatory clinical services but does not provide care for hospitalized patients can be categorized as a clinic.

Pharmacies are places where patients obtain medicines. Some may be on-site pharmacies and only fill prescriptions and dispense medicines (e.g. pharmacy department of a hospital and hospital dispensary), while others may be stand-alone or independent pharmacies and commercially sell medicines. The latter may be called drug stores or chemist's shops. Any facility that deals with medicines can be categorized as a pharmacy for the purposes of the survey.

Laboratories are places where patients take clinical laboratory tests. As with pharmacies, some may be on-site laboratories while others may be stand-alone or independent laboratories.

Both **public** and **private** facilities need to be covered. If health-care facilities are categorized by **level of services** (e.g. primary, secondary and tertiary), the level of identified facilities should be considered. If it is likely that **on-site** pharmacies (or laboratories) and **stand-alone** pharmacies (or laboratories) can provide different information, both types should be targeted.

Administrators and/or managers are supposed respondents for hospital, clinic, pharmacy and laboratory questionnaires. In some facilities, health-care workers also take administrative and/or managerial tasks. In such cases, the same person is interviewed for a facility questionnaire and a health-care worker questionnaire. For example, the head of a clinic who responds to the clinic questionnaire may be a physician who also responds to the health-care worker questionnaire. Respondents for the professional questionnaire include:

- Specialized doctors
- General doctors
- Nurses
- Pharmacists
- Laboratory technologists
- Dieticians

It should be noted that some health professionals work both for the public sector and for the private sector, e.g. they work for a general hospital during office hours and run a private clinic after office hours. In such a case, the same person may respond as a separate informant.

Specialized doctors are physicians who are specialists in the target disease (e.g. endocrinologists, diabetologists or internists for diabetes) and who are specialized for related conditions (e.g. ophthalmologists, nephrologists, vascular surgeons or orthopaedic surgeons for diabetic complications). Follow the professional categories in the survey country.

General doctors are physicians who are responsible for primary medical care. In some settings, they may be called family doctors or general practitioners. In either case, they are the ones likely to diagnose the disease for the first time. Some may screen the target disease and refer detected patients to a specialized doctor while others may continue to see such patients by themselves.

Nurses targeted in this survey are those involved in inpatient care, outpatient care or public health activities in relation to the target disease. Public health nurses are included in the survey where they exist.

Pharmacists are those who deal with medicines. They may fill prescriptions and dispense medicines and/or sell medicines. In some settings, non-pharmacists, for example, pharmacy assistants or dispensers may work at pharmacies. These people can be included in this category, and their professional criteria, such as the educational level, licence type and scope of work should be defined.

Laboratory technologists are those who conduct clinical laboratory tests. As is the case with pharmacists, non-technologists, such as laboratory technicians and laboratory assistants can be included in this category, and their professional criteria should be defined.

Dieticians are those who are involved in diet therapy. They may make menus for hospital meals, provide individual dietary counselling and/or work on public health activities in relation to diet and/or nutrition. Nutritionists can be included in this category, and their professional criteria should be defined.

In addition, other specialities can be included where appropriate.

5.2.4 Individual level

Patients should be recruited from various channels in order to hear the views of those in different situations. Health facilities identified in the intermediate level can be used. However, to identify those who do not present regularly at facilities, sampling outside of health facilities is also important. Patient respondents are categorized into the following three groups:

- Hospitalized patients
- Outpatients
- Community patients

Hospital patients are those who are identified in inpatient wards of the sampled hospitals. Many of them are likely to be severe cases, such as patients with a complication.

Outpatients are those who are identified in the sampled outpatient units. It is assumed that many of them are receiving care on a regular basis.

Community patients are identified outside the health facilities sampled in the second-stage. Collaboration with a key person in the community, such as a community health worker, will be helpful. Records for screening tests kept by such health workers could be used to find potential patients; however, ethical considerations, in particular issues regarding personal information protection, should be noted when using this method. Another possible way to approach potential patients is 'snowball sampling'. Find a possible respondent as the first respondent and ask him/her to introduce somebody else who is in a similar situation. And then continue this until enough information is obtained.

5.3 An example of a typical sampling scheme

For this methodology the sample size is flexible and is not fixed in advance. Theoretically, continuous purposive sampling is required until no new information is obtained. Practically, however, sample size estimation is vital to plan a survey, in particular, to make a time schedule and a budget for data collection. The table below describes the sampling of each level and gives a guide as to how many interviews should be carried out. For the national, intermediate and local levels some sample sizes are hard to determine as this will depend on the organization of the system. Data collection checklists are provided in Appendix 2.

Table 5.1: Estimated sample sizes per level

Level	Sampling location	Target institutions/individuals	Suggested sample size
National	Capital City or location of these organizations	Ministry of Health	Dependent on local setting as to how many people need to be interviewed
		Central Medical Store	
		Disease-specific association	
Intermediate	Capital or Largest City	Regional Health Organization	Dependent on local setting as to how many people need to be interviewed
	Peri-urban area	Regional Medical Store	
	Predominantly rural area		
Local	Capital or Largest City	Health facilities (Hospitals, Health centres/Clinics) Within each facility sampled if present: Pharmacy Laboratory Health-care workers	8 representative One per facility One per facility At least 2 per health facility*
		Independent Pharmacies	≈ 6
		Independent Laboratories	≈ 6
	Peri-urban area	Health facilities (Hospitals, Health centres/Clinics) Within each facility sampled if present: Pharmacy Laboratory Health-care workers	6 representative One per facility One per facility At least 2 per health facility*
		Independent Pharmacies	≈ 4
		Independent Laboratories	≈ 4
	Predominantly rural area	Health facilities (Hospitals, Health centres/Clinics). Within each facility sampled if present: Pharmacy Laboratory Health-care workers	4 representative One per facility One per facility At least 2 per health facility*
		Independent Pharmacies	≈ 2
		Independent Laboratories	≈ 2
Individual	Capital or Largest City	Inpatients Outpatients Community patients	≈ 5 -10 ≈ 30 ≈ 20 - 30
	Peri-urban area	Inpatients Outpatients Community patients	≈ 5 - 10 ≈ 20 ≈ 15-20
	Predominantly rural area	Inpatients Outpatients Community patients	≈ 5 ≈ 5 - 10 ≈ 5 - 10

* In the largest hospital in each area, six types of health-care workers listed in section 5.2.3 (specialist doctor, general doctor, nurse, pharmacist, laboratory technologist, and dietician) may be identified.

Chapter 6. Data collection tools

To conduct a survey, specific tools for each target institution/individual group are needed based on local situations and needs. These should be adapted from the attached sample data collection tools (see Appendices 3-10). For the national, intermediate level and part of the local level (mainly hospitals), many parts of the data can be obtained by secondary document reviews, with interviews conducted to obtain the missing information from the document review. However, the major part of the data for health-care workers and patients/carers will be collected by interviews using semi-structured questionnaires. (Hereafter, only data collection tools for health-care workers and patients/carers, which fieldworkers may mainly use, are called 'questionnaires'). The literature reviews will also inform this process. This chapter explains important points to be considered when developing data collection tools.

6.1 Principles of development of data collection tools

Some important areas of concern when developing different data collection tools for different target groups are:

- Secondary document reviews and primary data collection are mixed. It is likely that the upper level will be more dependent on document reviews.
- It is not necessary to develop all data collection tools and questionnaires at the same time. Data collection at the national level will inform data collection tools for the lower levels, and data collection at the intermediate level will inform data collection tools for the local level and individual level.
- Relevant questions for each target group should be chosen (refer to the instructions).
- All the necessary items should be covered, based on the national essential medicines list, the national standard treatment guidelines, the WHO Model List of Essential Medicines, and the Package of Essential Noncommunicable (PEN) Disease Interventions.
- Secondary documents, quantitative data and qualitative data should be appropriately combined, although each type of data may be entered and analysed separately during the initial stage of analysis.
- Both objective information and personal opinions/experiences should be comprehensively gathered, although it is necessary to treat them differently.
- Words and terms used in interview questionnaires should be suitable for the survey-specific context and the target institutions/informants. Careful attention should be paid to the definition of a term, and in particular to the local definition.
- Questionnaires should be convenient to use for interviewers.
- If data collection requires more information from other institutions/individuals, additional data collection tools can be developed (see 3.3.2).

6.2 General issues on development of data collection tools

Samples in Appendix 3 – 10 can be used to systematically develop a set of data collection tools for each target institution/informant group. As far as is relevant, all of the 11 core themes (see 3.2.1) should be applied to every target institution/informant group (see 3.2.2.) so that information can be cross-checked from different viewpoints.

In addition to the 11 themes, some questions about the actual interview are needed, such as the date of the interview, the duration of the interview, the location of the interview, the language used, the name of the interviewer, etc. Some general information on the institution/informant is also necessary. A space for additional unexpected information will be useful. Therefore, there are 13 headings for each set of data collection tools as a maximum, as shown below:

A Interview
B General information
C Health-care structure
D Financial issues
E Health insurance and other social security
F Disease-related policies, programmes and activities
G Supply/procurement systems
H Resource allocation/availability for care
I Price/affordability of care
J Disease management/treatment issues
K Referral issues
L Patient issues
M Others

Questions in themes H (resource allocation/availability for care) and I (price/affordability of care) should systematically cover the following aspects:

Activities
(a) Consultations
(b) Dispensing of medicines
(c) Laboratory tests
(d) Inpatient care

Products
(e) Injectable medicines, in particular, insulin
(f) Oral medicines
(g) Other types of medicines, in particular, inhalators
(h) Medical supplies (syringes, needles, etc.)
(i) Equipment (laboratory machines, glucometer, spectrophotometer, etc.)
(j) Consumables for laboratory tests (reagents, test strips, syringes, etc.)

Theme G (supply/procurement systems) also needs to cover the above-mentioned products.

The national essential medicines list and the national standard treatment guidelines in the survey country should be referred to for the development of the questionnaires. It is suggested that a list is made of all the essential medicines and recommended laboratory tests indicated in these documents for the target disease(s). If there is no national essential medicines list or standard treatment guidelines in the country, refer to the WHO Model List of Essential Medicines, the WHO guidelines and PEN. For example, when diabetes is the target disease, questions should cover at least glibenclamide 2.5mg, glibenclamide 5mg, metformin 500mg, regular insulin and intermediate-acting insulin. Blood glucose, urine glucose and HbA1c should also be included in the questions regarding laboratory tests.

Obtaining information on prices may be the most difficult element in terms of the data collection tools, and is not the main purpose of the survey. Precise calculation is very complicated because so many components and factors can be involved. These include health insurance systems, payment systems, including self-pay ratio/amount, subsidy and/or exemption for specific patients, etc. However, based on information gained in advance, a feasible and practical way to estimate prices can be established. Before developing relevant questions, the following information may be necessary:

- Possible items that patients may need to pay for
- Potential components of the total costs

Potential items may be: consultation fees, laboratory tests, medicines, diagnostics and dispensing fees. However, such categories vary in different settings. For example, laboratory tests may be included in the consultation fees in one setting while part of medicines costs for patients is covered in the flat fees in another setting.

Potential components of the total costs may be covered by insurance benefits, other benefits (e.g. social security, special programmes, etc.) and patient's out-of-pocket expenses. A patient may be aware of the total cost if he/she must pay out-of-pocket before the insurer pays. Another patient may only know how much he/she actually pays at the counter.

6.3 Data to be collected

In a RAP, different types of data sources, such as secondary documents, observations and interviews, are mixed in one data collection tool. Interviews and observations are the primary data for this survey. As described in the beginning of this chapter, it is likely that the upper level will require more information for document reviews, and data from health-care workers and patients/carers will mainly rely on interviews. In the interviews, both quantitative questions and qualitative questions are asked. Although information from secondary documents and primary data (quantitative data and qualitative data) are collected at the same time, they will be entered and analysed separately, at least at the initial stage. In interviews, objective information and the respondent's personal opinion and experience are requested, but they will be distinguished during analysis.

6.3.1 Types of primary data

In general, data types are categorized into quantitative data and qualitative data. Usually, quantitative data are obtained by a structured questionnaire, and qualitative data are obtained by a semi-structured questionnaire or by a broad topic guide. In a RAP, however, each set of data collection tools is used to collect both sorts of data.

Quantitative data can be measured or counted. They are further divided into two sub-types. **Numerical data** are measured or identified on a numerical scale; while discrete data occur when the variable can only take integer values (e.g. age), continuous data occur when the variable can take any values without limitation on the values (e.g. blood glucose level). **Categorical data** occur when the variable takes one of a number of possible options. **Binary data**, such as yes/no answers, are a particular type of the categorical data, which has only two possible categories. Some categorical questions allow the choice of multiple answers from multiple answer choices. Such a question can be considered a collective form of binary variables. Examples of each type of question are shown in Table 6.1.

Table 6.1: Type of quantitative data and examples of questions

Type of data		Type of question	Example
numerical	Continuous	It asks for a continuous value that quantifies a size, price, duration, etc.	• What is the blood glucose level? • How much did you pay for one tablet of glibenclamide (2.5mg)?
	Discrete	It asks a certain whole numerical value, such as the number of visits, age, etc.	• How many times did you see a physician during the last 12 months? • How old are you?
categorical	Categorical	It requests a respondent to choose one from several answer options.	• What is your occupational category? → Answer options may be: 1) specialized physician, 2) primary care physician, 3) nurse, 4) pharmacist, 5) laboratory technician, 6) dietician, and 7) others.
	Binary	It requests a respondent to choose one of two options, in many cases, 'yes' or 'no'.	• Is glibenclamide (2.5mg) available now? → Answer options are 'yes' and 'no' • What is your sex? → Answer options are 'male' and 'female'.
	Categorical (multiple answers are allowed)	It requests a respondent to choose from several answer options but does not restrict them to selecting only one.	• What items were included in the hospital fee that you indicated? → Answer options may be: a) room, b) meals and board, c) nursing care, d) professional fees, e) medicines, f) laboratory tests, g) operations h) others, This can be considered as eight binary questions. When a), b), c), and g) are chosen by the respondent, values for a), b), c), and g) are 'yes' and values for d), e), and f) are 'no'.

Qualitative data usually cannot be measured or counted. Qualitative research is any kind of research that produces results that are not reached through statistics. It has as its aim an understanding of a situation, experiences and behaviours rather than causal determination, forecasts or generalization as in quantitative studies. Qualitative research is now viewed as important by policy-makers and those in health systems research.(77-78) Qualitative research in public health is needed to answer new research questions to help in public health research and practice.(79-81) The use of qualitative research allows the researcher to investigate the complex public health issues from the individual's perspective based on their experience.(77, 82-84)

Qualitative data are obtained by open-ended questions. An open-ended question does not provide the respondent with a predetermined choice of responses, but allows the respondent

to give any answer. Answers are transcribed in text verbatim or in a summarized form. The transcription will be treated as data. Too much summarization may ruin the richness of data, and it is suggested that responses are recorded verbatim as much as possible. A key function of the qualitative interviews is to identify 'quotable quotes' that can be used in the final report to highlight important points.

6.3.2 Type of information

A question in the interview may ask for objective information or the respondent's personal opinion/experience. Both are important and necessary. Different ways are needed to obtain each type of information.

Some **objective information** is **supported by written secondary data**, such as official or organizational reports, census and health statistics. When the answer is supported by written secondary data, the source and date should also be recorded.

Other **objective information** may be **answered by the interviewee**. Written secondary data may not be necessary or do not exist for such information. Since there are no supportive documents, additional questions will be needed to draw out more information from the respondent, as far as is applicable, for example, 'please describe further details of …….', please tell us any specific issues about …….'.

Some questions ask about the respondent's **personal opinion and experience**. They will provide rich qualitative data when appropriately and fully answered. A certain topic may start with a categorical question, however, do not finish with a 'yes/no' answer or an option from the answer choices, but draw out the background information behind. Follow the initial closed-ended question by further open-ended questions, for example, what…?, why…?, how...?, etc.

Types of information and examples of questions are shown in Table 6.2.

Table 6.2: Types of information and examples of questions

Type of information	Example questions
Objective information supported by written secondary data	• What are the top 10 causes of mortality in the area? • What is the total annual health budget?
Objective information answered by the respondent	• Are you involved in any diabetes-related programme/project/activity? • Have you received any special training in diabetes? • How does the hospital/clinic procure the oral hypoglycaemic agents?
Respondent's personal opinion and experience	• In your personal opinion, what is the hardest part of diabetes care for diabetes patients and their family members? • Please tell us about any difficulties that you have experienced in having consultations for diabetes? • What do you find the most difficult about managing and treating diabetes patients?

6.4 Choice of words/definition of a term

Designing answer choices requires knowledge of the survey-specific context. For example, for a question that asks about the respondent's educational background, information on the classification of the educational level in the survey country is necessary.

Definitions of administrative levels, health facilities and/or health professionals vary among countries. For example, primary health-care facilities that provide outpatient services might be called 'health centres' in one country while they might be called 'dispensaries' in another country. A definition of a professional category also depends on the setting. Moreover, official definitions might be different from terms commonly used by lay people. When answer choices are developed, words and terms should be used carefully. Local consultations and pre-tests are required to check whether expressions used are understandable and appropriate.

The same subject might be discussed in different terms by the provider side and the recipient side. For example, 'allocation of a medicine' for health providers and 'availability of the medicine' for patients may look at the same issue from different viewpoints. This means that the most appropriate expression should be used in each data collection tool. Both answers will be compared and verified with each other at the data analysis stage.

In addition, the quality of translation is also important. Translation-related problems can result from difficulties in gaining conceptual equivalence or comparability of meaning, or the difference of grammatical and syntactical structures in two languages. Back translation (translating a document that has already been translated into a foreign language back to the original language) is a technique to ensure translation quality.(85) It is recommended when data collection tools are translated.

6.5 Skip instructions

In some cases, the response to a question determines what the next question will be. For example, while a respondent who answers 'yes' needs to continue to the following questions, another respondent who answers 'no' can skip some of the following questions and go to the next segment. For the fieldworkers' convenience and quality control of the data collection, it is recommended to provide skip instructions, such as 'go to …', to indicate how to proceed with the interview. Figure 6-1 gives an example.

For question 5 (Q5) in the example below, the next question to be asked depends on the respondent's answer. Those who answer 'yes' to Q5 need to answer Q6, but those who answer 'no' to Q5 skip Q6 - Q10 and then answer Q11, which is the beginning of the next segment. Among respondents who answer 'yes' to Q5 and go to Q6, those who answer 'yes' to Q6 skip Q7 and jump to Q8, but those who answer 'no' to Q6 go to Q7 and Q8. Respondents in both groups are required to answer Q8, but the next question depends on the answer to Q8.

Figure 6.1: Example of an interview instruction

	Question	Answer	go to
5	Are you prescribed any diabetes-related oral medicine?	1. yes 2. no	6 11
6	If yes, do you regularly take all the oral medicines as prescribed?	1. yes 2. no	8 7
7	If no, what are your reasons for not adhering to the prescription?	1. I do so only when I have a symptom. 2. I cannot afford it. 3. I cannot manage time. 4. hospitals/clinics are very far. 5. other reason(s)	
8	Do you usually purchase/get all the prescribed oral medicines in the hospital/clinic where you have consultations?	1. yes 2. no	11 9
9	If no, where do you mainly purchase/get them?	1. I cannot say because I purchase/get oral medicines at different places. (I do not decide where to purchase them.) 2. public pharmacy (including hospital pharmacy) 3. private pharmacy (including hospital pharmacy) 4. other reason(s)	10 11 11 11

Chapter 7. Fieldwork preparations

This chapter provides practical guidance on fieldwork preparations. This includes scientific and ethical reviews, fieldworker recruitment and training, administrative arrangements and logistics preparation. Scientific and ethical reviews should be planned as early as possible. Other preparations will be made during the first 2-3 weeks of the main fieldwork in the survey country, region or province.

7.1 Scientific and ethical reviews

Scientific rigour and ethical considerations should be reviewed by others in advance. Clearance of ethical and/or scientific reviews, before conducting research, is mandatory in many countries. Technical issues regarding research methods should be checked before an ethical review, using the principal investigator's and/or others' research network. Researchers need to be aware that these review processes usually take time and may cause a delay in the planned research.

7.1.1 Scientific review

A concrete proposal leads to smooth implementation of the survey. The preliminary research proposal can be used as a framework for the survey proposal. However, more concrete plans, especially in terms of methods, timetable, and budget, are needed, based on information gained from discussions during the preparatory fieldwork. After the development of data collection tools and before starting data collection, a complete survey proposal should be submitted to relevant individuals and organizations to ask for a scientific review. Advice from national experts, especially on sampling methods and data collection tools, would be useful. It may be necessary to use a given format to submit a proposal to the review committee.

Usually the final version of a survey proposal is attached to the ethical review documents. It is therefore advisable to complete a scientific review of the proposal among the relevant sections at an early stage. Involving people in the review process can raise awareness of the disease and the survey. Another benefit of early scientific review is that the research team can involve end-users at an early stage and obtain their input.

7.1.2 Ethical review

The basic idea of research ethics is simple and commonsensical: the respondent's autonomy should be respected throughout the survey; the survey should not damage any respondent physically, emotionally or financially; the survey should benefit respondents directly and/or through the community that they belong to; and the survey should be fair. Survey procedures are based on these principles. For example, obtaining informed consent, protecting respondents' confidentiality, compensating respondents for their time and expenses, and giving feedback of the survey results to relevant sections are all essential.

Informed consent: Any respondent has the right to know about the survey and should not be forced to participate in the survey if he/she is unwilling. In this survey, different target institutions/individuals need different information. Examples of informed consent forms for

non-patients and patients are attached in Appendices 11 and 12. Local input is needed to modify these examples.

Confidentiality: To maintain confidentiality, anonymity is not enough; researchers also need to ensure that no readers of the survey report can guess the identity of a participant in the survey.

Gifts or payments to participants: Researchers are responsible for ensuring that respondents do not lose money by participating in the survey. This does not merely mean reimbursing travel expenses, but for example, it might sometimes be necessary to show gratitude for the sacrifice of their time with a small token gift. However, it is not allowed to lure somebody into the survey by offering a gift and/or money. Advance approval of an ethical review committee is needed regarding gifts and/or money to compensate for people's time and/or transportation fees. It is important to consider the value and type of gift to be given carefully. Consultation with local experts is required to make these arrangements.

Feedback of the survey results: Researchers have a moral obligation to present the survey findings where the survey has been carried out and to promote the use of the results to improve respondents' situations. If patients are unlikely to receive the findings directly, explain to them that the findings will be submitted to relevant health authorities, and that this is expected to improve their access to or quality of care. Instead of survey findings, an information sheet on the disease may be given to them when the interviews have finished. To distribute the information sheet, ask for advice from national experts about whether the information given meets national standards. Avoid using a commercial brochure, e.g. that of a pharmaceutical company, for this purpose.

The issues raised above are only part of a range of ethical considerations. A research institute usually has a checklist for ethical considerations. Follow the standard procedures of both the principal investigator's institution and/or local authorities in the survey country. Resources for research ethics are available on the WHO web site[v]. In general, the process of an ethical review takes time. It is important to take this into account when preparing the survey schedule.

7.2 Recruitment and training of fieldworkers

Recruiting appropriate fieldworkers and conducting comprehensive training for them is an essential part of survey planning. This is required to ensure data quality.

7.2.1 Possible fieldworkers

The minimum requirements of fieldworkers are:

- must have an interest in the topic.
- must be able to speak a common language with the principal investigator and in the local language(s) to be used in the interviews.
- must have basic computer skills, in particular knowledge of MS Word and Excel.

[v] http://www.who.int/rpc/research_ethics/en/

Local advice is needed in advance as to what language should be used for the interviews. If the majority of people speak a national language very fluently, fieldworkers can be recruited in the national capital, which will make the research process easier. However, if it is assumed that patient respondents are more comfortable speaking in their own local language, at least some of the fieldworkers at each site should be locally recruited. In such a case, fieldworker training should be conducted at each site. Be careful when seeking advice on this matter. Usually governmental officers "politically" believe that every citizen can speak the official language fluently, but it might not be true in some countries. The choice of language used for interviews influences data quality, especially the quality of responses from open-ended interviews with patients as these need to be translated.

An interest in the topic might be for personal or professional reasons. Recruitment can be attempted from groups such as:

- students in health professional schools (e.g. medical students, nursing students and pharmacy students)
- related health professionals (e.g. pharmacists)
- young researchers in topic areas (e.g. masters students who are studying the target disease)
- patient association members, both patients and family members

To conduct fieldworker training efficiently, it is advisable to keep the fieldworkers' background uniform. For example, it might be good to establish a long-term multidisciplinary team consisting of one patient, one medical student, one drugstore owner and one master of public health student. However, it may not work very well for a fieldworker team in this survey since it is difficult to make all the fieldworkers achieve the same training goals during a short period.

In a country where large numbers of brand name medicines exist, pharmacists who are currently employed might be suitable fieldworkers because they are familiar with complicated medicine names. Members of staff in health offices may not be suitable for participating in data collection in survey countries since respondents might mistake the survey for performance monitoring/evaluation by the office, which may skew the data.

The number of fieldworkers employed depends on the schedule for future site visits. If fieldworkers are sufficiently competent and the principal investigator does not always have to accompany them, data collection can be done in several sites simultaneously. In such a case, double (or triple) the number of fieldworkers will be required. Nevertheless, it is strongly recommended that data collection, at least at the first site, be conducted under the supervision of the principal investigator. This ensures the quality of data collection. If focus group discussions among patients are planned an even number of fieldworkers is appropriate since one focus group discussion needs two fieldworkers: one discussion facilitator and one note-taker.

7.2.2 Making a contract of employment

To make a contract of employment, local consultations are needed. The contents of any contracts and procedures should not contradict either common sense or local regulations. For example, if members of staff in a public hospital participate in data collection as part of their work, they may not be allowed to receive additional remuneration for their extra work but only reimbursement of actual expenses, such as transportation and lodging. Another important point is to have respect for the local market value.

The following issues should be considered when a contract with a fieldworker is made:

– who makes the contract
– salary level and payment mechanism
– contract period

An individual or organizational contract can be made. When the contract is made with an organization, members of its staff are assigned to the fieldwork by the person who contracts with the survey project, such as the head of department. In such a case, research fees are usually paid to the organization, but not directly to an individual fieldworker.

Individual remuneration may be paid daily, weekly or monthly. It can also be performance-based; for example, a certain amount is paid per questionnaire. Ask for local advice as to what method is appropriate in the local culture. Since unexpected events can occur during data collection, it is not advisable to make a rigid timetable in a contract. An advance contract with fieldworkers about a flexible research schedule is needed.

7.2.3 Fieldworker training

Data quality is the heart of every survey, since solid data supports conclusions and recommendations. If false evidence is generated in the survey, it may lead to misunderstandings by others as well as inappropriate policy decisions. Data problems may be caused by insufficient development of data collection tools (questionnaires). However, even if the questionnaires are well developed, the quality of the data will be impaired if fieldworkers either misunderstand or do not fully understand the survey aims and objectives, sampling methods, data collection methods, and data entry methods. To ensure reliability and accuracy of data, the fieldworkers' training is extremely important. Usually, the principal investigator will be the trainer.

Training aims and objectives: The principal aim of the training must be 'to collect and manage quality data'. To make specific objectives achievable, it is better to decide in advance who the fieldworkers will interview. For example, if it is planned that the fieldworkers will interview patients and health-care workers, the fieldworker training can focus on only those questionnaires that the fieldworkers will use.

Training plans: The following items are expected to be covered in the training:

(1) Training overview (aims and objectives of the training)
(2) Introduction (importance of the survey)
(3) Background + country's health system and health information related to the target disease(s)
(4) Survey overview
(5) Sampling methods
(6) Questionnaires
(7) Data collection
(8) Data entry

Active participation should be encouraged throughout the training. Lectures must be kept to the minimum, and more time should be spent on exercises and pre-tests. How to interview respondents, how to fill in questionnaires and how to enter data into datasets should be practised repeatedly until all the trainees master them, by demonstration, practise, role-playing and pre-tests.

Chapters 1 – 8 (except Chapter 4) of this manual can be used as a training module. Where an overhead projector is available, slide presentations (either transparent sheets or PowerPoint) of essential information from this manual could be helpful.

Training evaluation: Small tests like true/false questions or multiple choice questions after lecture-type lessons are helpful for checking participants' understanding of the lectures. Final evaluation of the fieldworker training will be by observation of trainees' performance during pre-tests to see if they can accurately collect and enter data. One option is to train potential candidates and to include this in the recruitment process. Employment contracts are made with the trainees who achieve a satisfactory level or perform the best.

Table 7-1 shows an example of a 3-day training plan. In this plan, each session lasts for 1.5 hours. Including wrap-up at the end of the day and a review of the previous day, on average training will take 6-7 hours a day.

Table 7.1: Example of 3-day training

Time		Training plan			Training evaluation
		Content	Methods	Materials	
1st day	am (1)	Training overview	lecture group discussion	---	---
	am (2)	Introduction	lecture group discussion	CHAPTER 1	mini-test
		Background	lecture group discussion	CHAPTER 2 Country-specific materials	
	pm (1)	Survey overview	lecture group discussion	CHAPTER 3	
	pm (2)	Sampling methods	lecture demonstration practise	CHAPTER 5 sampling forms (blank)	mini-test observation
		Questionnaires	lecture demonstration practise	CHAPTER 6	mini-test observation
2nd day	am (1) (2)	Data collection	lecture demonstration role-playing	CHAPTER 7 questionnaires (blank)	observation
	pm (1) (2)	Data entry	lecture demonstration practise	CHAPTER 8 questionnaires (filled) computers	observation
3rd day	am (1) (2) pm (1)	Pre-tests	practise	---	observation
	pm (2)	Review	group discussion	---	---

7.3 Administrative arrangements

In many countries, the survey team may be requested by possible respondents to prove that they have the approval of and/or support for the survey from local authorities. While approval from the ethical review committee may be enough in some places, other types of document may be necessary elsewhere. Documents that may be needed are:

- A permission letter for the survey from a relevant authority (e.g. Ministry of Health), if the principal investigator works outside the relevant authority
- Request letters to the possible respondents, which are endorsed by the local authorities
- An agreement (memorandum of understanding) with the relevant institutions, if necessary

In addition to these types of document, local procedures may be important in some places. For example, the head of a provincial office may request the survey team to submit a permission letter from the Ministry of Health, and then once he/she receives it, he/she can write a letter to all possible respondents in the province to request participation in the survey. Another office may request letters both from the principal investigator's institution and/or the Ministry of Health. In another case, a letter from the principal investigator, endorsed by the Ministry of Health may be requested. Ask for local advice about what kinds of

documents are needed and what procedures are appropriate. Note that views at the survey sites might be different from those at the central level. Therefore, it is advisable to contact key informants in every survey site in advance to ask what process is needed to visit the site. Nevertheless, support from authorities should not be over emphasized because it might invite the misunderstanding that the survey is part of monitoring conducted by the authorities.

7.4 Logistic preparations

Before visiting survey sites, the following issues should be checked in advance to prepare for site visits.

Table 7.2: Checklists for logistic preparations

Local transportation	• whether using public transportation or renting a car • when renting a car, how to employ a local driver • transportation fees or rental fees
Lodging	• in one site, whether staying in the main town and commuting to other places or staying at each town • whether there is safe and low-cost accommodation • accommodation fees
Food	• whether there is a safe and low-cost eating place, such as a cafeteria for lunch at survey sites • estimated expenses for lunch
Communication methods	• landline coverage and mobile phone coverage • reliability of mailing system • telephone fees and postal fees • telephone directories of key informants
Printing (making photocopies of data collection tools, including information sheets for patient respondents)	• whether bringing printed data collection tools or copying them at the survey site • whether there is a copy shop with reasonable prices • when copying locally, estimated expenses for photocopying • who checks information sheets
Gifts to respondents	• when giving gifts, what to buy and where • when reimbursing respondent's transportation fees, how much to pay and how to pay (payment criteria, how to get a receipt, direct or through agent, etc.) • an estimated cost and estimated numbers of gifts

Chapter 8. Data collection and data entry

This chapter describes how a survey team carries out data collection. While data collection at the national level is likely to be done by the principal investigator alone, data collection at selected survey sites is conducted by a team. The chapter explains, in more detail, how to collect data in the areas (e.g. provinces, districts, cities, etc.).

8.1 Data collection at the national level

National level data collection may partially overlap with preliminary information gathering (see Chapter 4). It can be planned during the preparatory fieldwork, before going to the area visit at the beginning of the main fieldwork, or after finishing the area visits, according to the schedule.

This data collection may be done by the principal investigator since it needs to be flexible and is not very suitable for adaptation to fieldworkers' training. As findings from the national level data collection at an earlier stage can inform development of data collection tools at the lower level, it is helpful for the person who will lead developing data collection tools to collect the national level information.

Data collection at the national level is an opportunity to promote the survey project to relevant sections.

8.2 Data collection at selected survey areas

Data collection at the intermediate level, local level and individual level is carried out by a survey team in each site selected. A survey team comprises the principal investigator and two to four fieldworkers. When the principal investigator does not accompany fieldworkers to a site, one person should be appointed as leader. As noted in 7.2, however, it is strongly recommended that data collection, at least at the first site, be conducted under supervision of the principal investigator.

8.2.1 Plans and preparations for site visits

The division of tasks among members of the survey team should be decided carefully. There are some important factors to be considered: if the principal investigator is a foreigner, local health-care workers and patients might be more comfortable being interviewed by national fieldworkers; if fieldworkers are relatively young, it is advisable that the principal investigator interviews health officers and hospital officers him/herself so that they trust the survey. Also, when involving the private sector seems to be difficult, the principal investigator should carry out the interviews.

It is very helpful for fieldworkers if they are introduced to the head of a facility (e.g. hospital director) by the principal investigator. It will make their access to sections easier. Sometimes bringing identification and a request letter from the principal investigator with endorsement by the Ministry of Health (or another appropriate institution) will be enough to gain access. In all cases, prior consultations and arrangements by the principal investigator are required, especially when he/she cannot accompany fieldworkers to visit facilities.

Table 8.1 shows estimated interview time. The actual time needed for an area depends on how many people are interviewed (refer to Table 5.2), how many fieldworkers are involved, the distance from the central town in the site to the remote groups, and whether the survey team will stay locally near each area or commute from the central town to each area.

Table 8.1: Recommended data collectors and estimated data collection time by target institutions/individuals

Level	Target institutions/individuals	Recommended data collector[1]	Estimated time per data collection	Data source[2]
National	Ministry of Health	PI	1 – 2 hr	Mainly D Complementary I & O
	Medical store	PI	1 – 2 hr	
Intermediate	Health office	PI	1 – 2 hr	Mixed of D, I, and O (D > I & O)
	Medicines store	PI	30 min	
D Local	Hospital	PI	1 – 2 hr	Mixed of D, I, and O (D < I & O)
	Clinic	PI and/or FW	30 min	
	Laboratory	PI and/or FW	30 min	
	Pharmacy	PI and/or FW	30 min	
	Health-care workers	FW	30 min	mainly I
Patients	Inpatients	FW	30 min	mainly I
	Outpatients	FW	30 min	
	Community patients	FW	30 min	

[1] PI = principal investigator, FW = fieldworker

[2] D = document reviews, I = interviews, O = observations

8.2.2 Tasks of the principal investigator

The principal investigator is responsible for:

Before going out to the site
- preparing documents (a request letter, endorsement, introduction letter, etc.)
- getting permission for the survey from local authorities and the selected facilities
- confirming appointments with the selected facilities
- having fieldworkers duplicate data collection tools and other documents
- having fieldworkers prepare materials

On arrival at the site
- confirming the overall plan at the site
- checking if fieldworkers have prepared documents and materials to be brought the following day

On arrival at the facility
- introducing fieldworkers to facilities

– conducting interviews as allocated (e.g. health offices, regional medicines stores, hospitals, etc.)

At the end of each day
– conducting meeting with the survey team and discussing any difficulties that have arisen during the day
– ensuring that fieldworkers complete and clean the data
– ensuring that fieldworkers keep the raw data properly
– checking the balance of gifts and reimbursement money for respondents
– confirming team member allocation and timetable for the following day
– checking if fieldworkers have prepared documents and materials to be brought the following day

The principal investigator may need to go to the site earlier than the other members of the survey team to make local arrangements and to conduct interviews at health offices. One fieldworker can go with him/her to act as translator.

8.2.3 Tasks of fieldworkers

The tasks of fieldworkers are:
Before going out to the site
– helping the principal investigator confirm appointments with the facilities selected
– duplicating data collection tools (questionnaires, sampling forms and informed consent forms) and other documents (letters, information sheets for patient respondents, etc.)
– preparing materials (stationery, gifts, reimbursement money for respondents, telephone directories, mobile phones, etc.)

On arrival at the site
– confirming the overall plan at the site
– preparing documents and materials to be brought the following day

On arrival at the facility
– introducing themselves to facilities when the principal investigator cannot accompany them
– conducting interviews as allocated

At the end of each day
– participating in the survey team meeting and solving any difficulties that have arisen during the day
– completing and cleaning the data
– keeping the raw data properly
– recording the balance of gifts and reimbursement money for respondents

– confirming team member allocation and timetable for the following day
– preparing documents and materials to be brought the following day

Besides having knowledge of, and skills in, data collection methods, appropriate attitudes to respondents are extremely important. The principles of research ethics should always be kept in mind: respecting respondents' rights and dignity, considering the need to produce the most good and to do the least harm to the respondents, and always being fair. In daily activities, the following issues should be remembered by the fieldworkers for successful data collection:

– to be neatly dressed and polite
– to be confident of the importance of the survey and able to explain it to respondents
– to carry identification and letter(s) authorizing the fieldworkers' activities
– to avoid making respondents uncomfortable for the survey team's convenience
– to conduct data collection as efficiently as possible so that the survey does not disturb respondents' work

8.3 Informed consent

Respondents should be asked for permission to include them in the survey after information about the survey has been provided. Informed consent should be based on the principles of research ethics (see 7.1.2) and information given to respondents needs to include:

– description of survey objectives
– survey risks and benefits
– voluntary participation and confidentiality

As long as a respondent is literate, providing written information and obtaining written consent is usually recommended by research ethics committees. However, it is dependent on the socio-cultural context of the research area and local consultation is required. Examples of informed consent forms are attached in Appendices 11 and 12. Although an informed consent form is given to a respondent, it is also necessary for every respondent to be given an oral explanation by a fieldworker. Excessive adherence to an informed consent form is not very meaningful; the most important thing is to make sure every respondent understands what they are participating in and that they have the right not to participate if they choose not to.

8.4 Data collection and entry by fieldworkers

A RAP as a whole might be categorized as qualitative research; however, quantitative data are also collected at the same time in the survey. Different techniques are required for quantitative interviews and qualitative interviews. Questions in example questionnaires are ordered by theme, regardless of whether they are a quantitative or a qualitative question. Below are instructions on data quality control when multiple fieldworkers are responsible for interviewing health-care workers and patients/carers.

8.4.1 Qualitative data collection

Qualitative interviews are open-ended and in-depth. They need to be interactive and flexible. If necessary, an interviewer (fieldworker) can change the order of the questions in a questionnaire or can return to the same question after moving on to other questions. It is not always necessary for the interviewer to use exactly the sentences in the questionnaire, but he/she can rephrase them by using vocabulary that is more familiar to both the respondent and the interviewer.

An interviewer should not be directive. Cues shown by a respondent should be carefully picked up and every respondent needs to be given enough time to explain what he/she means. Do not make the interview superficial. Avoid teaching or counselling a respondent. Moreover, an interviewer must not present his/her own perspective to the respondent.

Interviewers are expected to record what the respondent actually says. Since respondents' original voices are precious information, keep as much of the original conversation as possible. During an interview, an interviewer may not have enough time to take notes in detail and may just jot keywords in bullet points. However, he/she needs to expand the notes as soon as possible after finishing the interview; otherwise it will be impossible to recall what the respondent said and the data will be lost. It is advisable to take and expand notes in the interview language first unless the interviewer is a professional simultaneous translator.

Qualitative research follows a sequential research process, as in the next chapter (see 9.2): researchers begin data analysis while data collection is still ongoing. The interim analysis can feed into or shape the ongoing data collection. If several fieldworkers are involved in data collection, it is important that they all, including the principle investigator, meet periodically to discuss what is happening during the data collection; in particular, recurring themes and unusual, noteworthy or contradictory events or views. This discussion can also include next steps for data collection and potential revisions to the data collection tools. (Note that revisions to the data collection tools are likely to occur in the open-ended sections for qualitative data. Usually, questions for quantitative data are not changed once data collection is started.)

8.4.2 Qualitative data entry

Expanded interview notes should be transcribed in digital files within the day of the interview, preferably by the same person who interviewed and took notes. Word-processing software (e.g. Microsoft Word) may be used. Some rules shared by the fieldworkers will be helpful when data are analysed later: for example, one file is created for one interview; the interview ID is used for the filename; 'level 1 heading' is used for questions and 'body text' is used for answers; the same heading is put for the same question.

After finishing transcription, translate the data into the language used in the report. If the translator is different from the interviewer (transcriber), it is advisable that translation is completed while they can work together.

8.4.3 Quantitative data collection

Quantitative data may be obtained by structured observations and interviews. Standardized data collection methods will be useful to obtain indicative findings although it is unlikely

that purposively collected quantitative data will be analysed by sophisticated statistical methods. Standardized procedures will be also helpful for the interviewers so that they are not confused during the data collection. Data collection for availability and price may be the most difficult and complicated part. Define 'availability' and identify what part of cost will be identified for 'price', and share the definitions with all the fieldworkers in advance. Some considerations are as follows:

Availability

The principle of checking availability is to ascertain whether **resources actually exist in a functioning or valid condition** at the provider. Patients' awareness of the availability and whether items can actually be obtained are also checked.

Availability at health facilities
Assessment of availability of medicines and materials at the provider is always based on observation. Even if an interviewee reports that they are available, it is not recommended to record them as such without seeing them. Regarding availability of a laboratory test, a test that is functioning at the time of data collection is recorded as 'available'. If the reagent runs out or the measuring machine is out of order on the day, for example, the test should be recorded as 'unavailable'. Regarding availability of health professionals, it might be defined by how often or how long the health professional (e.g. specialist doctor, etc.) can provide services in the facility.

Availability for patients
To investigate availability from the patient viewpoint, questions cover whether a patient knows where the nearest medicine provider is and if this provider can dispense the medicine the patient needs. If the patient cannot obtain the medicine there where does he/she have to go to get that item? These question patterns can be revised according to the survey-specific situation.

Price
Various patterns of pricing may exist. The simplest one is when a provider only charges the patient. In this case, what the provider charges (selling price or provider's price) and what the patient pays (buying price or patient's price) are the same. However, the payment may be shared by the patient and other parties, as described in Chapter 6. The following are some considerations to take into account when recording provider's prices and patient's prices.

Provider's price
In some settings, no charge is required for health services, while charges are shared by the government, insurance and patient in other settings, or patients might pay for all aspects of their care. Possible information on provider's price may be:

- Only the total charge (regardless of who pays)
- Only patient's price
- The total charge + components of this total cost (how the total cost is shared between the government, health insurance and/or patient)

It is necessary to identify what information is important and can be collected based on the local need and situations. And share the identified definition with the fieldworkers.

Patient's price

Many patients pay for items of care at different places using different payment methods. In principle, record **the patient's share (out-of-pocket expenditure)** for each item. Do not include benefits from insurance and/or social security support or any other form of financial support. When a patient uses different payment schemes from time to time, record the unit price that is the most frequently and/or commonly paid. When it is difficult to know the patient's unit price, leave the unit price unanswered. Ask the patient to estimate his/her monthly or annual out-of-pocket costs for the item, if possible. Note that free services and cashless payment systems are different. If a patient uses a cashless payment system, check the unit prices calculated from the bill.

8.4.4 Quantitative data entry

Quantitative data are entered in a spreadsheet (e.g. Microsoft Excel) or a file for data management software (e.g. EpiData). One file may be used for one institution/informant group. When a spreadsheet is used, the first row is used for variable names and each column is used for one respondent (or the first column is used for variable names and each row is used for one respondent). How to define each variable name for each entry field, for example, 'age' for the question that asks 'how old are you?' is crucial. Simple and easy names are preferable and all variable names should be understood by all fieldworkers. Or EpiData may be more user-friendly, if data entry fields are well developed. The appearance of the data entry fields can be made to match with the questionnaire. A fieldworker can then enter the data as he/she sees answers in the questionnaire.

Double entry is needed for quantitative data entry. EpiData or other types of data management software support double entry.

Chapter 9. Data analysis

This chapter describes how to analyse collected data. It will deal predominantly with qualitative analysis. Quantitative data, such as price and availability, will first be summarized, the quantitative findings will be integrated into the whole analysis.

9.1 Document reviews

As described in Chapters 6 and 8, secondary documents, such as annual reports from health offices or health facilities, statistics and others, may give necessary information. It is unnecessary to wait until all the documents are collected to begin analysis. Analysis of document reviews can be done throughout the whole study process. It is advisable that the gained information collected is sorted according to the 11 themes listed in 3.3.1.

9.2 Quantitative data analysis

Quantifying data is not the primary purpose of the analysis. Although complex statistical analysis is not feasible due to the nature of purposive sampling applied in this survey, some quantitative summaries can be useful for itemizing important characteristics of the data. Quantitative data are usually summarized by central tendency and proportion. Numerical values are summarized by central tendency (mean and/or median) and range. Binary and categorical questions are summarized by proportion among all the answers.

9.2.1 General issues for quantitative data analysis

Central tendency (mean or median)

A numerical value of one question or a processed (calculated) value from multiple questions is summarized by mean or median. When values in a variable are normally distributed (distribution of values of all respondents is not skewed), mean and median are the same, and mean is commonly used. Price data, both provider price and patient price, and expenditure data are more likely to include some very extreme (expensive) values, which inappropriately increase the mean value and lead to misinterpretation. Median is, therefore, a more suitable way of representing price and expenditure than mean.

Sometimes, a variable is defined by answers to several questions. For example, a patient may take metformin and aspirin and inject mixed insulin. This patient's monthly expenditure on medicines is then processed (calculated) from separate variables of 'monthly expenditure for oral medicines', 'monthly expenditure for insulin', and 'monthly expenditure for insulin-related medical materials'. A variable newly added for each respondent (for example, a variable named 'monthly expenditure for medication') is the sum of these variables. 'Median expenditure for medication' among all patient respondents is then calculated to present results.

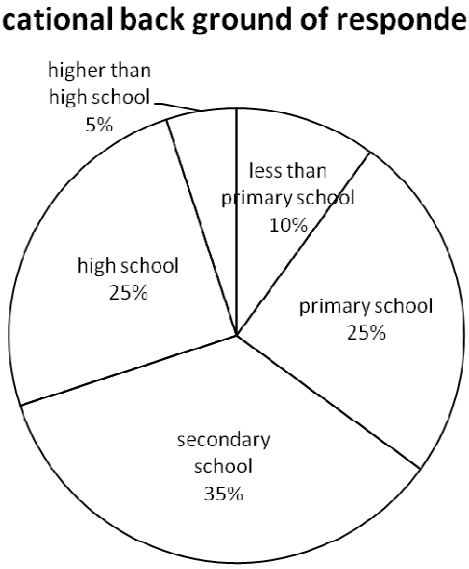
Proportion

The proportion of 'yes' answers can be obtained by dividing the number of 'yes' answers by the total number of valid answers (or proportion of 'no' answers can be obtained by dividing the number of 'no' answers by the total number of valid answers). Percentage, which multiplies proportion by 100, is commonly used. For binominal questions, usually the percentage of either 'yes' or 'no' is presented since if one answer is shown, the other is easily calculated.

In the calculation of a categorical question which allows only one choice, for example, the question in Figure 9-1 below, the sum of the proportions for all choices should be 100%. For this question, if there were 100 respondents and 10 of them had not completed primary school, 25 had completed primary school, 35 had completed secondary school, 25 had completed high school, and 5 had completed higher than high school level, the proportion for each choice is 10%, 25%, 35%, 25% and 5% respectively. The result is often displayed in a pie chart.

Figure 9.1: Example of a categorical question that allows only one choice

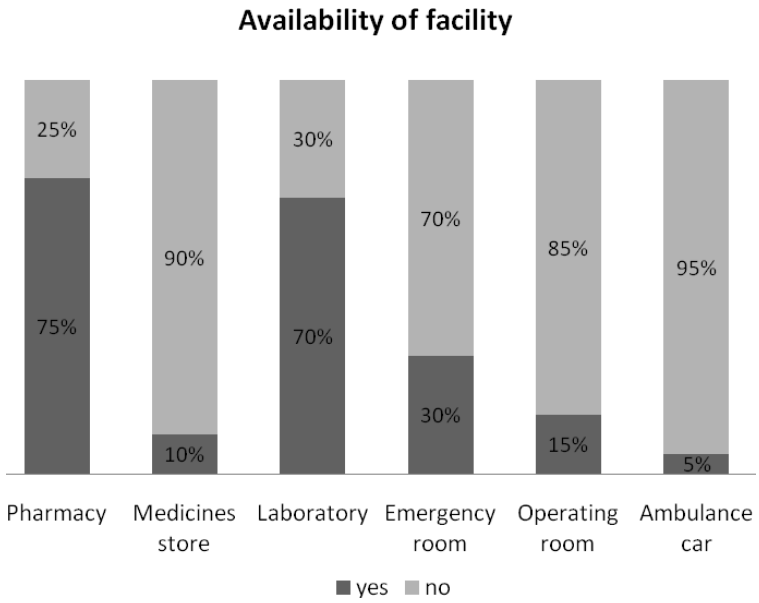
1. What is the highest level of schooling you have attended?
   a. Not completed primary school
   b. Completed primary school
   c. Completed secondary school
   d. Completed high school
   e. Completed higher than high school level



The type of categorical question that allows multiple choice answers is different. This type of question should be considered as a series of yes/no questions. For the question in Figure 9-2 below, which has multiple choice answers, while one health centre might have none of the listed facilities (none of the items a. to f. were chosen), another might have a pharmacy, medicine storage and laboratory (items a., b. and c. were chosen). Usually the percentage of people who chose a certain item, for example, what percentage of respondents chose item a, among the total valid responses, is presented. A sum of proportions is not meaningful. The results may be displayed in multiple 100% stacked columns/bar charts.

Figure 9.2: Example of a categorical question that allows multiple choice answers

2. Which of the following do you have in your hospital?
   a. Pharmacy
   b. Medicines store/stock room
   c. Laboratory
   d. Emergency room
   e. Operating room
   f. Ambulance car



9.2.2 Possible summary forms of quantitative data

Data obtained by the structured part of the questionnaires can be quantitatively summarized. Some examples are shown below. Some of them are calculated from one variable (e.g. percentage of facilities with a laboratory), while some of them uses multiple variables (e.g. median annual health expenditure). How to summarize data really depends on the local situations and needs. It is advisable to decide how to summarize data before data collection.

Results may be compared by respondent characteristics. Standardizing how to calculate each item will be helpful for future comparison within and/or across different studies.

Examples of summary forms for health facility data

- Availability of services and facilities (e.g. percentage of facilities with a laboratory)
- Availability of medicines, laboratory tests and medical materials (e.g. percentage of facilities where metformin (500mg) was available)
- Median unit price of medicines, laboratory tests and medical materials (e.g. median unit price of a test for blood glucose level)

Examples of summary forms for patient data

- Patients with regular care (e.g. percentage of patients with regular consultations)
- Patients who were hospitalized (e.g. percentage of patients who were hospitalized within the last 12 months)
- Percentage of current users of medicines and medical materials (e.g. percentage of current users of a self-monitoring device for blood glucose)
- Median unit price of medicines, laboratory tests and medical materials (e.g. median unit price of metformin (500mg))
- Median monthly/annual expenditure (e.g. median annual health expenditure)

9.3 Qualitative data analysis

Open-ended answers are qualitatively analysed. Interviews are transcribed into text, and the text is then 'indexed'[vi] for thematic analysis.(86-87) This section explains basic thematic analysis methods. For further information, refer to textbooks on qualitative data analysis.

9.3.1 Characteristics of qualitative data analysis

In principle, qualitative analysis does not count or measure, but deals with speech or words (text data). Data are preserved in their non-numeric form to interpret social phenomena, such as action, interactions, behaviours, attitudes, decisions, beliefs, values, preferences, etc. To start qualitative data analysis, it is not necessary to wait until all data collection has been completed. The data analysis usually begins during the data collection so that it can feed into the ongoing data collection. A researcher can go back to refine questions and to pursue emerging issues.

9.3.2 Initial stage

The first task in the analysis is to become familiar with the collected data while managing them. This data management stage entails reading and re-reading all the data. Researchers look for recurring themes and unusual, noteworthy or contradictory events or views.

A thematic framework[vii] is a list of themes (categories) and sub-themes (sub-categories) to be used for qualitative data analysis. These themes are identified at the early stage of data analysis. Or this may be carried out by drawing previously identified issues and questions derived from the aims and objectives of the study.(88) Since practical applicability and promptness are important factors of this survey, it is recommended that 11 core themes, which are indicated in Chapter 3, are used for a thematic index (framework) of analysis at the initial stage. However, this should always be flexible and should be modified based on data obtained when necessary. During the analysis, categories may be further refined and reduced in number by being grouped together.

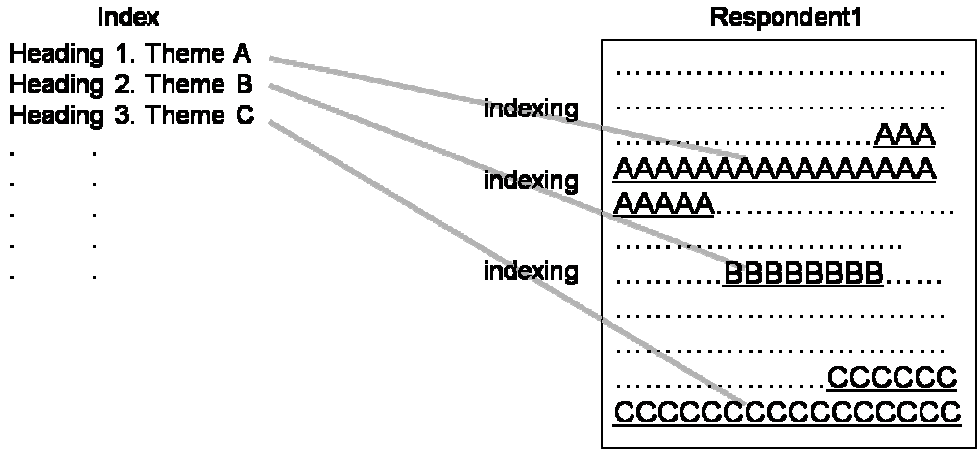
[vi] 'Indexing', 'coding' and 'labelling' may be used interchangeably. Some authors, however, may think of them differently. The use of these terms is dependent on the textbook and the author.

[vii] Terms such as 'thematic index' and 'coding scheme' can be considered similar to 'index'. The definition also depends on the textbook and the author.

9.3.3 Indexing

Applying the framework, text data are indexed. A researcher considers which themes are mentioned or referred to in a particular section of the data (e.g. a phrase, a sentence or a paragraph of the transcript), and then fits the section into one category or more than two categories in the index. Figure 9.3 shows how one piece of data is indexed with one theme; however, in real data analysis, a data item may fit into more than two themes. An indexing system needs to allow this duplicate indexing. Recording emerging themes during indexing is also important.

Figure 9.3: Indexing



Once the data are indexed, extracts from a number of cases in the same categories are located together so that a researcher can focus on each thematic category in turn. Data can be compared and contrasted during this process. Data are rearranged by using 'cut-and-paste' techniques (see Figure 9.4). This can be done manually using scissors, glue and sheets of blank paper. Or a word processor can digitally cut and paste extracts to a set of files; one file for each category. Then, sheets with cut-and-pasted data, or files created in a word-processing programme are sorted. Each of the sheets or files has a sheet name or a file name from the index. The data are now sorted, according to themes, on paper or in a word-processing programme (see Figure 9.5).

Figure 9.4: 'Cut & Paste'

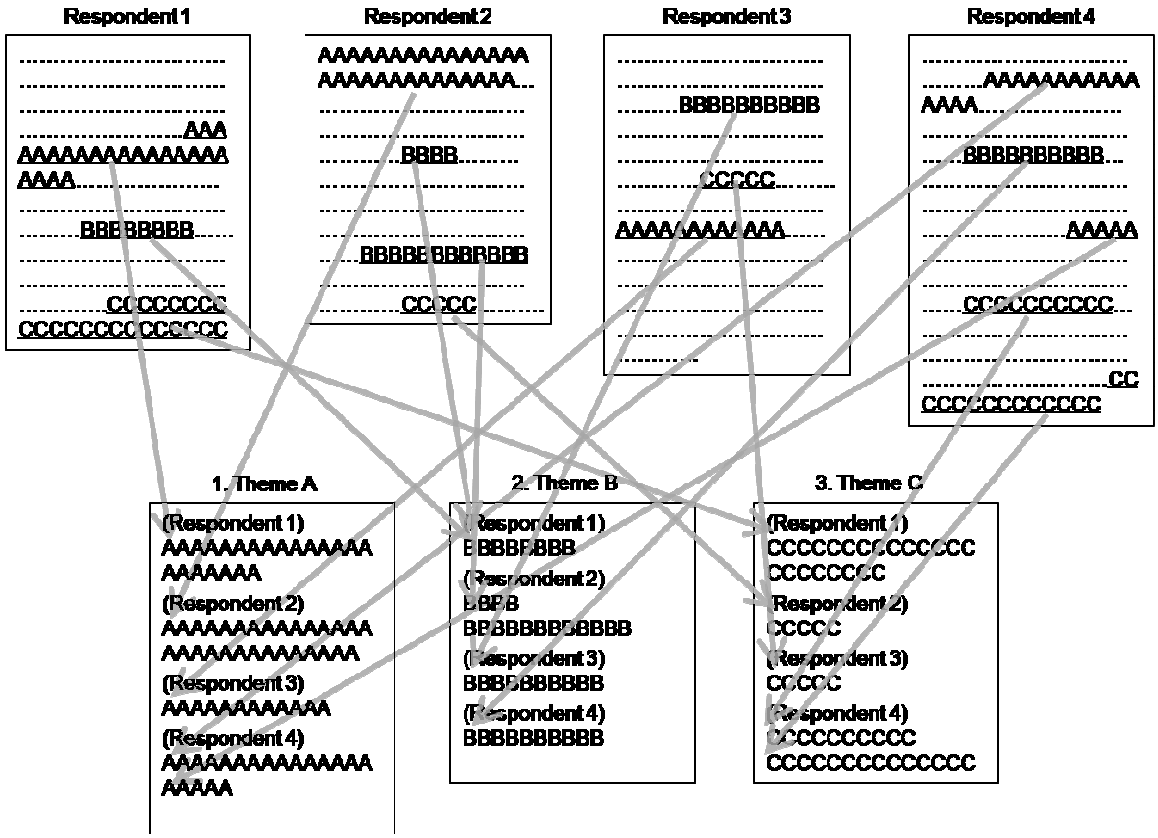
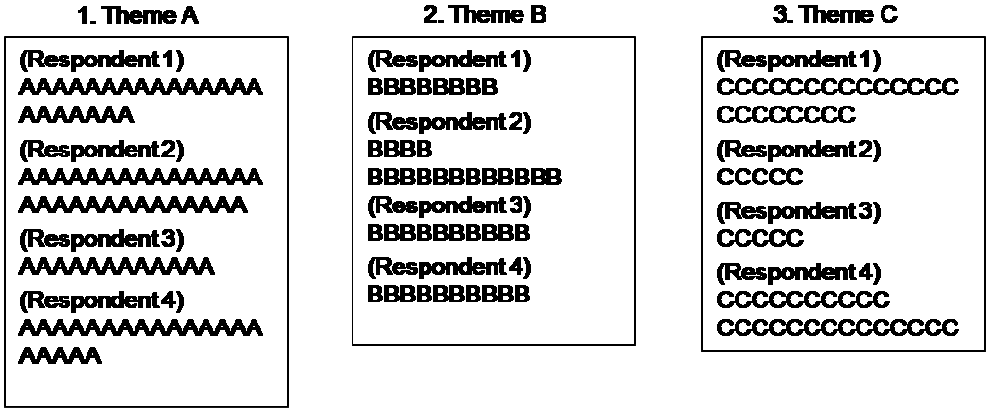


Figure 9.5: Data sorted by theme



Computer assisted qualitative data analysis software (CAQDAS), such as NVivo, can be used. CAQDAS can index data and selectively retrieve indexed data digitally. 'Cut and paste' work is managed in the software, and the data can be sorted easily once a digital database for themes is created in CAQDAS. However, some initial training may be required to manage such software, and it is usually expensive to purchase.

9.3.4 Interpretation

After being sorted by theme (category), data are summarised, synthesized and abstracted in each category. This process distils the essence of the evidence for presentation. The framework used for indexing may be used for the results sections in the report. The simple analysis described above may be enough to answer research questions, or further analysis may be conducted when necessary. For further analysis, refer to textbooks on qualitative research.(86-88)

Analysis of this stage may be conducted by combining other types of data (see 9.4. below).

9.4 Combined analysis

At the initial stage, document reviews, primary quantitative data (from observations and interviews), and primary qualitative data (from interviews) may be analysed separately, as described in 9.1 –9.3. Then all data will be integrated by theme for further analysis.

Findings which are relevant for each theme, for example, important points from the document reviews, summaries computed from quantitative data, and quotes from qualitative interviews, are presented for them. The researcher summarizes and synthesizes the findings, and then interprets what is happening and why these findings are obtained, in particular, when there are differences observed across the data sources, across the target groups.

An example: The national health report indicates that universal insurance coverage has been almost achieved and the current coverage rate is 90%. However, the percentage of insurance coverage among facilities investigated was 70% and among the interviewed patients it was 60%. Qualitative interviews with patients suggest that although enrolment in health insurance was easy, it was difficult to continue due to complex administrative processes if they had an NCD.

Data should be presented in the following order:

1. Results from national level
2. Results from intermediate level
3. Results from local level
4. Results from individual level

Presentation of these data should either show consistency, with all levels giving the same information, or if inconsistencies exist try to explain them.

For further analysis, comparison by subgroup may be possible. Possible comparisons are listed below:

<u>Health facility subgroups</u>
- By site
- By type (e.g. hospital and clinic)
- By public/private

Patient subgroups
- By gender
- By site
- By health facility that the respondent uses (e.g. public health facility and private health facility)
- By age group (e.g. under 50 years old and 50 years old or over, adults and children)
- By disease (e.g. asthma and diabetes)
- By insurance status (e.g. with health insurance and without health insurance)
- By period of diabetes history (e.g. less than 10 years and 10 years or more)

However, careful attention should be paid when quantitative data, in particular quantitative data from facilities, is compared by sub-group. Since the total sample size of facilities is much smaller than the total sample size of patients, the sample size of a group may become too small to summarize.

9.5 Strengths and limitations of the methods

The methodology described above recognizes the survey's pragmatism, speed, balance and cost-effectiveness. Both quantitative findings and qualitative findings will be indicative and sufficiently enough. As a result of this, the survey can be useful and practical for future actions.

However, certain limitations due to methodological characteristics should also be recognized, in particular, with regard to representativeness and generalization. Sampling methods in this survey require careful attention, as described in Chapter 5. In general, in a quantitative study, random samples are taken in a controlled setting so that the samples are representative of the population, and findings from the samples can be generalized to the population. A qualitative study, on the other hand, usually requires fewer respondents based on non-random or non-probability sampling in a natural setting but more in-depth information. Since this manual tries to apply a rapid assessment protocol, which collects both quantitative data and qualitative data from the same respondents who are purposively sampled, there may be a compromise. When interpreting findings, in particular quantitative findings, researchers should be aware that they are based on non-representative, though indicative, data.

When findings suggest obtaining further representative information, refer to other established survey methods explained in Chapter 11. Also refer to Appendix 1 for key web sites and references.

Chapter 10. Reporting and dissemination

The purpose of this survey is to stimulate actions to improve access to NCDs care. This effort requires rapid and accurate reporting, as well as effective dissemination. The survey results should be presented in the most meaningful way to all the necessary stakeholders and should be disseminated to both specific audiences and the general public. Previous experiences of policy actions after the survey had been conducted are shown in Chapter 11. Key results from previous RAPIAs are shown in Appendix 13.

10.1 Debriefing

As soon as possible after completing data collection, the survey team needs to have debriefing sessions with relevant parties. At this stage, findings may be still incomplete. However, the principal investigator needs to ensure that all people to be involved are informed before moving toward further actions. The stakeholders should at least be informed as to what has been done so far and what is planned for the next future.

Debriefing can be conducted in a variety of ways: individually, in specific group sessions or in a workshop style, inviting different groups of people at the same time. Debriefing should include the following:

- Title of the study
- Name(s) of the organization(s) that undertook the survey and the principal investigator's name and contact addresses (email and postal)
- Why this survey was planned
- Aims and objectives
- Outline of methods
  - Number of surveyed sites
  - Target groups surveyed
  - Sampling method and the number of samples in each target group
  - Summary of data collection (tools, methods, fieldworkers and schedule)
  - (Planned) methods of analysis
- Preliminary findings
- Possible discussion points
- Future plans and schedule
  - Schedule for report generation
  - Schedule for a presentation or dissemination workshop if planned

Interaction with people in relevant sectors informs researchers about what needs to be discussed in the final report. A contact list for future dissemination (both email and postal addresses) should be completed at this time.

10.2 Report generation

Different styles of dissemination materials are required for different audiences. A full report can be the basis for other types of formats.

10.2.1 Full report

A complete report should include the following content:

- Executive summary
- Title of the study
- Name(s) of the organization(s) that undertook the survey and principal investigator's name and contact addresses (email and postal)
- Background (statement of the problem)
- Literature review
- Aims and objectives
- Methods
  - Study method (reference can be made to this manual)
  - Survey setting (information on the surveyed country and summary of surveyed sites)
  - Target groups surveyed
  - Sampling method and the number of samples in each target group
  - Summary of data collection (tools, methods, fieldworkers, and schedule)
  - Methods of analysis
- Ethical considerations
- Findings by theme (these may be listed according to the thematic index)
  - Document reviews
  - Quantitative summaries
  - Findings of qualitative thematic analysis
- Discussion by theme
- Policy and practice implications and recommendations
- Conclusion

Data collection tools actually used, such as questionnaires, checklists, sample list forms and fieldworker instructions, should be attached to the report. However, it is crucially important to strictly protect the respondents' personal information in any part of the report. Since anonymity does not always guarantee confidentiality, special attention is required when describing surveyed sites and target groups.

It is often beneficial to ask selected stakeholders to review a draft report before it is finalized. Possible reviewers who are interested in giving comments can be found during debriefing.

10.2.2 Other reporting formats

Other styles of reporting may be appropriate for some audiences. The full report can be submitted together for those who want detailed information and as evidence of the strength of the findings.

Short summary: A short (4–5 page) summary report highlighting the survey's key findings and recommendations in an easy-to-read format is useful for people who do not have time to read the full report and may be more appealing to audiences, such as the media and NGOs.

Policy briefing paper: The survey findings and recommendations can be reported as bullet points on a one-page policy brief for busy people, such as high officials and senior managers, so that they can take in key issues at a glance. Adding a schema which extracts and highlights very important points will help to convey the impact of the findings.

Brochure: A brochure in simple words that lay people can understand is more suitable for patient groups than a complete report written in an academic style.

Journal articles: The survey report will provide the basis for an article for publication in a health-related journal. Satisfying academic audiences is an important dissemination strategy since it could help policy-makers and other stakeholders use research findings to inform their decision-making. Examples of such articles are identified in Appendix 1.

10.3 Presentation/dissemination workshop

Just circulating a written report is not a very effective way of disseminating survey results and recommendations even if it is accompanied by an executive summary and additional reader-friendly material. Making a presentation can appeal to the eye and the interactive nature of the presentation is useful both for researchers and the audience.

Holding a workshop with invited stakeholders is one possible strategy. It can hopefully trigger discussion among them to take the next steps. It is not always necessary for the workshop to be organized by a group. For example, a relevant section in the Ministry of Health can hold it, officially inviting stakeholders. This may make the Ministry of Health more likely to authorize action plans developed during the workshop. Such plans will hopefully be used as the basis for future strategies.

10.4 Possible target audience

A full report and/or (an)other material(s) should be sent to all target audience members. They can be posted or they may be distributed at presentations and/or workshops. Distributing findings to individual patients may be difficult; however, efforts to inform them through health offices, hospitals, clinics and/or patient groups should be made. Besides respondents, the following organizations are possible targets for dissemination. They may be invited to a presentation and/or a dissemination workshop.

- Health professional associations (physicians association, nurses association, etc.)
- National hospital association
- National pharmacy association

- National laboratory association
- Patient organizations (national and international, e.g. National Diabetes Association)
- Health-related NGOs (national and international)
- Bilateral and multilateral donors organizations
- WHO (country offices, regional offices and headquarters)
- Associations of pharmaceutical companies (multinational and national)
- Individual pharmaceutical companies (multinational and national)
- The Ministry of Finance
- The Ministries of Trade and Commerce
- Academic and research institutions, public health institutions
- National medical research council
- Medical journals
- Relevant members of parliament (with a briefing paper)
- Media

Chapter 11. Follow-on activities

When the survey has been completed, analysed and disseminated, follow-on questions may be asked, which may relate to the survey itself. Such questions include:

- "Why are the prices of medicines in our country so high compared to international reference prices?"
- "Why is the availability so poor in rural areas?"
- "Why do patients complain about waiting times so frequently?"

These are questions that can be investigated using methods described in different WHO manuals, such as the WHO/HAI pricing manual or the WHO publication "How to investigate drug use in the community". There may also be questions about how well the national and local health system compares to other systems. The approach to such questions is described in 11.1 below. Another question that may be asked is "Are things getting better since the assessment was completed?" This question can be addressed by the use of monitoring and evaluation tools described in 11.2. In addition to this tool can be used as a means to inform and change policies with regards to NCDs, as described in Section 11.3.

Although the main purpose of the survey is to stimulate actions to improve access to care for NCDs through the development of targeted projects and policies, the methods described in this tool can also be used as a means to compare health systems and as an evaluation tool.

11.1 Health system comparisons

One of the questions that the World Health Report in 2000 posed was, "how do we know if a health system is performing as well as it could?"(89) The Report highlights that the way health systems are designed, managed and financed all impact the health and well-being of people. The health system's role is to produce "health actions whose primary intent is to improve health" and is assessed by the:

1. Overall level of population health.
2. Health inequalities (or disparities) within the population.
3. Overall level of health system responsiveness (a combination of patient satisfaction and how well the system acts).
4. Distribution of responsiveness within the population (how well people of varying economic status find that they are served by the health system).
5. Distribution of the health system's financial burden within the population (who pays the costs).

Country comparisons on the way these functions are actually implemented provide a basis for understanding why performance varies over time and among countries.

Analysing a health system's ability to deliver care for diabetes and other NCDs provides insight into the health system as a whole through the use of 'tracer conditions'. Kessner et al.(90) first put forward the concept of tracers with regards to health systems in 1973. The

concept of tracers for health systems was based on clinical tracers such as radioactive tracers used by healthcare workers to see how different organs work. Six criteria for a tracer condition were established and these are, in order of importance:

1. The condition used as a tracer should have a measurable impact on the patient and treatment of this condition should also influence outcomes
2. A tracer condition should be well defined and easily diagnosed
3. The prevalence of the diseases should be significant enough to allow for adequate data collection
4. The progression of the disease should vary with how the health system is used
5. Medical/Clinical management of the condition should be well defined in at least one of the following areas: prevention, diagnosis, treatment or rehabilitation
6. Non-medical aspects of the condition should be known as well as the epidemiology

The example of how Type 1 diabetes is an appropriate tracer with regards to these six criteria is detailed in the table below.

Table 11.1: The suitability of Type 1 diabetes as a "tracer" condition(91)

Criteria for "tracer" condition based on Kessner et al.(90)	Factor related to Type 1 diabetes
- Condition should have a measurable impact on the patient - Treatment of this condition should also influence outcomes	- Type 1 diabetes has a clear health impact on the individual if poorly managed - Without insulin the person will die
- Well defined and easily diagnosed condition	- Type 1 diabetes is clearly defined clinically with specific diagnostic criteria
- Prevalence of the diseases should be significant enough to allow for adequate data collection	- Each population no matter where should have at least some people with Type 1 diabetes
- Progression of the disease should vary with varying use of the health system	- Progression and development of complications is directly linked to use of health system
- Medical/Clinical management of the condition should be well defined in at least one of the following areas: o Prevention o Diagnosis o Treatment o Rehabilitation	- Type 1 diabetes qualifies in the following areas: o Diagnosis o Treatment
- Non-medical aspects of the condition should be known as well as the epidemiology	- These are known and clearly described in the literature. - Epidemiology in most settings is known. In others where it is unknown, predictions have been developed as Type 1 diabetes is present to varying degrees in all populations

Nolte et al.(92) applied this concept and developed a mortality to incidence ratio for 29 countries using data on diabetes incidence and mortality. Using a mortality/incidence ratio as a crude indicator of "case fatality" they then used this as an overall indicator for quality of healthcare. This measure was used to identify differences in the performance of health systems.

As described previously based on work by the IIF, eleven elements have been identified as being key to providing diabetes care, and possibly care for all NCDs.(48, 68) These components have been used in order to structure results and recommendations in country reports. In addition in the Philippines and Viet Nam these elements were used to compare these health systems.(46)

11.1.1 The examples of the Philippines and Viet Nam

At similar periods in 2008 the authors carried out assessments of the health systems in the Philippines and Viet Nam with regards to diabetes care.(46) The findings were that care was mainly provided in specialized facilities and appropriate referral systems were lacking. In Viet Nam, no problems were reported with regards to diagnostic tools, whereas this was a concern in the public sector in the Philippines. Both countries had high prices for medicines in comparison to international reference standards. Availability of medicines was better in Viet Nam than in the Philippines especially for insulin. This impacted adherence as did a lack of patient education. The Table below presents a comparison of the costs of diabetes care in the Philippines and Viet Nam.

Table 11.2: Costs of different aspects of diabetes care in the Philippines and Viet Nam

Mean cost of aspects of diabetes care to the individual (US$)	Insulin (per month)	Oral medicines (per month)*	Travel (per visit)	Syringe (unit)
	Median	Median	Median	Median
Philippines	19.59	13.36	0.87	0.22
Viet Nam	7.35	30.61	4.90	0.09

* In the Philippine survey, actual monthly expenses for insulin and oral medicines were not asked for. Monthly expenses here were calculated from unit prices and daily doses in patient answers. Calculation is based on an assumption that the patient takes medicines according to the prescription. In Viet Nam, this is the cost per vial, including individuals who received insulin free of charge. For oral medicines this is cost per month, again including those who received all or part of their treatment for free.

This research into diabetes care, however, gave insight into two other policy areas these countries were pursuing: decentralization and universal coverage. Through the results of this work, it was apparent that in trying to achieve universal coverage in parallel to decentralization, national and local governments needed to define guidelines for how diabetes should be treated, but the same could be argued for all conditions. Also it was found that insurance schemes needed to play a more active role in prevention and in devolving care away from tertiary facilities.

11.2 Monitoring and evaluation

Monitoring and evaluation (M&E) is an essential component of any project or intervention. M&E allows those working on the project to see if the programme is doing things in the right way and is also doing the right things. This enables those involved to learn both from the actual work they are doing as well as to provide examples for other settings. Useful tools for M&E combine both quantitative and qualitative assessments of projects. For example, M&E for a training programme would look at numbers trained, increase in test scores, etc., but also at qualitative aspects, such as the trainees' perception of the course.

Monitoring is mainly used during the course of the project and gives an indication of progress towards completing the overall goal. It helps to identify problems in order to take corrective action. Evaluation is done to verify the achievement of the overall goal and the effectiveness of the overall aspects of the project. For both M&E, indicators are essential as they establish the aim of the project and progress towards its achievement.

11.2.1 The example of Mozambique

Mozambique was the first country where the RAPIA was implemented in 2003.(49) Following the assessment, the results were presented to local stakeholders and recommendations were prioritized. These were then developed into projects by both the Ministry of Health and National Diabetes Association with the technical assistance of the IIF and external financial support from WHO, the World Diabetes Foundation and Diabetes UK. Projects included:

- A training of trainers programme
- Specialized training
- Development of patient education materials
- Organization of World Diabetes Day events
- Advocacy and policy support to Ministry of Health
- Development of diabetes association

The initial assessment using the RAPIA therefore gave baseline data and indicators against which these projects could be monitored. In addition, the Ministry of Health developed a National NCD Plan which included data from the initial RAPIA and had as one of its activities to carry out another RAPIA assessment in order to monitor and assess progress.

In 2009, a second assessment of the RAPIA was carried out in Mozambique.(93) Results showed that the diabetes association had increased its membership 8-fold, 265 health workers had been trained in diabetes care in all provinces, the development of patient education materials and the expansion of public awareness, particularly from events associated with World Diabetes Day had been achieved.

As well as these programmatic successes, a variety of health system factors had also improved over the period 2003-2009. These are described in the table below.

Table 11.3: Comparison of key indicators from the Mozambique RAPIA 2003 and 2009, in 2009 standardized prices (adapted from Beran et al.(93))

Indicator	2003	2009	Implication(s)
Insulin			
Ministry of Health expenditure on insulin for 18 months	$706,550	$271,800	- Better tender price - Less wastage
Average tender price per vial of insulin (18 months)	$8.03	$4.50	- Decrease in tender price
Total quantity of insulin purchased (18 months)	115,800	60,400	- Less wastage
Insulin expenditure as %age of total spending on medicines by the Ministry of Health	1.73%	0.54%	- Better use of finite resources
Proportion of total amount of insulin in Capital City	77%	46%	- More equitable/better distribution
Time for tender (maximum) for insulin	12 months	9 months	- Improved tendering practices
Insulin always present at %age of hospitals	20%	100%	- Improved availability
Average price per vial of insulin to public pharmacies	$6.62	$4.50	- Decrease in facility purchase price - More resources available
Average price per vial of insulin to patient (private)	$10.40	$12.39	- Decreased affordability in the private sector
Average price per vial of insulin to patient (public)	$1.32	$0.20	- Increased affordability in the private sector
Syringes			
Price of syringes private sector	$0.23	$0.34	- Decreased affordability in the private sector
Presence of diagnostic tools			
Blood glucose machine	21%	87%	- Improved availability
Consumables available for the blood glucose machine	6%	27%	- Improved availability, but not in line with improved availability of blood glucose machines
Urine testing strips	18%	73%	- Improved availability
Ketone strips	8%	73%	- Improved availability
Health-care workers			
Number of health-care workers who have received training in diabetes (2003 basic, 2009 specialized)	52%	65%	- Increase in number of trained personnel - Impact on diagnosis and management of people with diabetes

These improvements in the health system and its delivery of a variety of aspects linked to diabetes care (insulin, health-care worker training and diagnostics) meant that estimated life-expectancy for someone with Type 1 diabetes had increased during the period 2003-2009.(93)

11.3 Policy implications

WHO has recognized the need for countries to develop national NCD strategies, including through the different WHO Regional and Moscow Declarations. As a means to develop these strategies, WHO proposes a stepwise approach with the following stages(94):

1. Assess the risk factors and burden of chronic disease in the given country
2. Development of a chronic disease policy that details the steps for prevention and control of the major chronic diseases
3. Planning and implementation of the most effective methods of attaining the proposed policies

By using this manual, countries will be able to assess the capability of their health system to address the challenge of NCDs and what strengths and weaknesses are present within the existing system. In applying the WHO approach and its three steps, this manual helps:

1. Assess the barriers to care at all levels of the health system with regard to NCDs
2. Use this analysis to address these barriers in a way that is adapted to the system and its resources
3. Through an in-depth understanding of the system planning and implementation will be facilitated

Examples from Kyrgyzstan and Mozambique as to how the RAPIA influenced policy-makers are detailed in 11.3.1.

11.3.1 Policy implications

In both Kyrgyzstan and Mozambique the recommendations from the RAPIA were prioritized by local stakeholders. In Kyrgyzstan this led to a "Diabetes Action Plan" that included:

1. Training of doctors and nurses
    a. Addressing the issue of fragmented service delivery
    b. Practical training
2. Equipment and medicines
    c. Development of a tool-kit adapted to each level of the health system
    d. Improve access to metformin
    e. Insulin – address the issues of analogue versus human insulin and penfill versus syringes as a means of delivery
3. Guidelines for health-care workers and people with diabetes
4. Increase the role of Diabetes Association/Community/Village Health Committees
5. Diet/Education/Lifestyle
    f. Upstream measures (primary prevention)
    g. Advice to at-risk people
6. Development of a Diabetes Register

In Mozambique, a similar process of integrating the RAPIA recommendations into a policy document took place. However, rather than being diabetes-specific, the results were incorporated into an overall NCD Strategy, which included CVD (including hypertension), diabetes, asthma and some cancers. Projects and interventions developed, based on the RAPIA, focused on diabetes and hypertension in order to develop models that could be replicated for other conditions. For example, the development of "chronic consultations", "health fairs" and NCD focal points in each province.

11.4 Wider implications

In September 2011, the United Nations held a High-Level Meeting on NCDs. This is only the second time since its 2001 landmark Summit on HIV/AIDS that the United Nations has addressed a global public health problem in this way. This global attention is also reflected in Member States having endorsed a variety of initiatives through several World Health Assembly resolutions to address NCDs. WHO has responded to this by laying the foundations for action and research to be carried out in the area of NCDs with both the "Action Plan for the Global Strategy for the Prevention and Control of Noncommunicable Diseases"(8) and a "Prioritized Research Agenda for Prevention and Control of Noncommunicable Diseases".(9)

With NCDs on the global agenda, viewed by Member States and WHO as a major threat to global public health, local decision-makers need a practical tool to assess their health systems with regard to their ability to deliver care for NCDs to their populations. This manual fills the gap in that it offers decision-makers and individuals responsible for programmes the opportunity to take WHO guidance, such as the ICCC Framework and WHO PEN and assess the given situation in their country in order to develop suitable responses to any of the challenges identified. This not only allows for a situation analysis at a given point in time, but also a chance for cross-country comparisons as well as using the methodology as a tool for M&E.

The importance of health systems and access to medicines for NCDs cannot be negated. Without a shift in focus from acute to chronic care, health systems throughout the world will be unable to address the increasing burden of NCDs. Medicines for NCDs are available in generic form and are extremely low cost and without improving access to NCD medicines MDG 8 cannot be met. Highlighting that "research is fundamental to generate knowledge and information for formulating evidence-informed policies and practices in support of global public health and health equity"(9), the Sixty-third World Health Assembly, in May 2010, in resolution WHA63.21, endorsed the WHO Strategy on Research for Health and laid out the role and responsibilities of WHO in health research. Within this strategy, the 'Prioritized Research Agenda for Prevention and Control of Noncommunicable Diseases' was developed to align this research global agenda with the '2008–2013 Global Strategy Action Plan'. Within this 'NCD research agenda' the focus is on low- and middle-income countries with research targeted at prevention and control of NCDs. This manual delivers an approach that helps achieve an understanding with regards to existing barriers in health systems and access to medicines and contributes to achieving the Global Strategy Action Plan on NCDs as well as the larger goal of the enjoyment of the highest attainable standard of physical and mental health for all.

References

1. *Preventing chronic diseases: a vital investment*. Geneva, World Health Organization, 2005. [cited 2005 13 October]; Available at: www.who.int/chp/chronic_disease_report/en/index.html.
2. Beaglehole R, Yach D. Globalisation and the prevention and control of non-communicable disease: the neglected chronic diseases of adults. *Lancet*, 2003, Sep 13, 362(9387):903-908.
3. Beaglehole R et al. Improving the prevention and management of chronic disease in low-income and middle-income countries: a priority for primary health care. *Lancet,* 2008, Sep 13;372(9642):940-949.
4. Landers J. Historical epidemiology and the structural analysis of mortality. *Health Transition Review*, 1992, 2(Suppl):47-75.
5. Mascie-Taylor CG, Karim E. The burden of chronic disease. *Science*, 2003 Dec 12, 302(5652):1921-1922. Available at: http://www.sciencemag.org/content/302/5652/1921.full
6. Boutayeb A. The double burden of communicable and non-communicable diseases in developing countries. *Transactions of the Royal Society of Tropical Medicine and Hygiene*, 2006, Mar,100(3):191-199.
7. Miranda JJ et al. Non-communicable diseases in low- and middle-income countries: context, determinants and health policy. *Tropical Medicine and International Health*, 2008, Oct, 13(10):1225-1234.
8. *2008-2013 Action plan for the global strategy for the prevention and control of noncommunicable diseases*. Geneva, World Health Organization, 2008. Available at: http://www.who.int/nmh/Actionplan-PC-NCD-2008.pdf
9. *A prioritized research agenda for prevention and control of noncommunicable diseases*. Geneva, World Health Organization, 2011. Available at: http://whqlibdoc.who.int/publications/2011/9789241564205_eng.pdf
10. Cameron A et al. Medicine prices, availability, and affordability in 36 developing and middle-income countries: a secondary analysis. *Lancet*, 2009, 373(9659):240-249.
11. Mendis S et al. The availability and affordability of selected essential medicines for chronic diseases in six low- and middle-income countries. *Bulletin of the World Health Organization*, 2007, Apr;85(4):279-88. Available at: http://www.who.int/bulletin/volumes/85/4/06-033647.pdf
12. Cardiovascular diseases factsheet. Geneva, World Health Organization, 2009. Available at: http://www.who.int/mediacentre/factsheets/fs317/en/index.html.
13. World Health Organization (WHO)/International Society of Hypertension (ISH) statement on management of hypertension. *Journal of Hypertension*, 2003, Nov 21(11):1983-1992.
14. *The global burden of disease: 2004 update*. Geneva, World Health Organization; 2008. Available at: http://www.who.int/healthinfo/global_burden_disease/GBD_report_2004update_full.pdf
15. *Global health risks: mortality and burden of disease attributable to selected major risks*. Geneva, World Health Organization, 2009. Available at: http://www.who.int/healthinfo/global_burden_disease/GlobalHealthRisks_report_full.pdf
16. Gaziano TA et al. for the International Society of Hypertension. The global cost of nonoptimal blood pressure. *Journal of Hypertension*, 2009, Jul;27(7):1472-1477.
17. *The atlas of heart disease and stroke*. Geneva, World Health Organization, 2004.
18. *The African Region Health Report*. Brazzaville, World Health Organization Regional Office for Africa, 2006.

19. *WHO Model List of Essential Medicines, 17th List*. Geneva, World Health Organization, 2011. Available at: http://whqlibdoc.who.int/hq/2011/a95053_eng.pdf

20. *Use of glycated moglobin (HbA1c) in the diagnosis of diabetes mellitus. Abbreviated report of a WHO Consultation*. Geneva, World Health Organization 2011. Available at: http://www.who.int/**diabetes**/publications/**report**-**hba1c**_2011.pdf

21. *Complications of diabetes*. Geneva, World Health Organization, 2010. Available at: http://www.who.int/diabetesactiononline/diabetes/basics/en/index3.html.

22. *Definition, diagnosis and classification of diabetes mellitus and its complications - report of a WHO consultation Part 1: diagnosis and classification of diabetes mellitus*. Geneva, World Health Organization, 1999. Available at: http://www.staff.ncl.ac.uk/philip.home/who_dmg.pdf

23. Unwin N et al. eds. *Diabetes Atlas*, 5th ed. Brussels, International Diabetes Federation, 2011.

24. Chuang LM et al. Diabcare-Asia Study G. The status of diabetes control in Asia--a cross-sectional survey of 24 317 patients with diabetes mellitus in 1998. *Diabetic Medicine*, 2002, Dec, 19(12):978-985.

25. Khatib OMN, ed. *Guidelines for the prevention, management and care of diabetes mellitus*. Cairo, WHO Regional Office for the Eastern Meditarranean, 2006. Available at: http://www.emro.who.int/dsaf/dsa664.pdf

26. Global surveillance, prevention and control of chronic respiratory diseases. A comprehensive appoach. Geneva, World Health Organization, 2007. Available at: http://www.who.int/gard/publications/GARD%20Book%202007.pdf

27. Mathers C, Loncar D. Projections of global mortality and burden of disease from 2002 to 2030. *PLoS Med*. 2006;2006:e442. Available at: http://www.plosmedicine.org/article/info:doi/10.1371/journal.pmed.0030442

28 Ait-Khaled N et al. Access to inhaled corticosteroids is key to improving quality of care for asthma in developing countries. *Allergy*, 2007, 62(3):230-236.

29. Cameron A et al. Differences in the availability of medcines for chronic and acute conditions in the public and private sectors of developing countries. *Bulletin of the World Health Organization*, 2011, 89(6):412-421. Available at: http://www.who.int/bulletin/volumes/89/6/10-084327.pdf

30. Gulliford M et al. What does 'access to health care' mean? *Journal of Health Services Research and Policy*, 2002, Jul;7(3):186-188.

31. *Health services accessibility*. Bethesda, The National Center for Biotechnology Information, National Library of Medicine, National Institues for Health. Available at: http://www.ncbi.nlm.nih.gov/mesh/68006297?ordinalpos=26&itool=EntrezSystem2.PEntrez.Mesh.Mesh_ResultsPanel.Mesh_RVDocSum.

32. Aday LA, Andersen R. A framework for the study of access to medical care. *Health Services Research*, 1974, Fall, 9(3):208-220.

33. Millman ML, ed. *Access to health care in America*. Washington, DC, Institute of Medicine, National Academy Press, 1993.

34. Wiedenmayer KA. Access and availability of pharmaceuticals in international health. In: Anderson SC et al., eds. *Managing pharmaceuticals in international health*. Basel, Birkhauser Verlag, 2004. p.19-31.

35. Andrulis DP. Access to care is the centerpiece in the elimination of socioeconomic disparities in health. *Annals of Internal Medicine*, 1998, September 1, 129(5):412-416.

36. Devoe JE et al. Insurance + access not equal to health care: typology of barriers to health care access for low-income families. *Annals of Family Medicine*, 2007, Nov-Dec, 5, (6):511-518.

37. Hall AG et al. Expanding the definition of access: it isn't just about health insurance. *Journal of Health Care for the Poor and Underserved*, 2008, May, 19(2):625-638.

38. *General principles of good chronic care: Integrated management of adolescent and adult illness.* Geneva, World Health Organization, 2004. Available at: http://www.who.int/hiv/pub/imai/generalprinciples082004.pdf

39. Yach D et al. The global burden of chronic diseases: Overcoming impediments to prevention and control. *Journal of the American Medical Association*, 2004, June 2, 291(21):2616-2622.

40. Nolte E, McKee M. Integration and chronic care: a review. In: Nolte E, McKee M, eds. *Caring for people with chronic conditions: A health system perspective*. Maidenhead, Open University Press; 2008.

41. Nolte E, McKee M. Introduction. In: Nolte E, McKee M, eds. *Caring for people with chronic conditions: A health system perspective*. Maidenhead, Open University Press, 2008.

42. *Innovative care for chronic conditions: building blocks for action.* Geneva, World Health Organization, 2002. Available at: http://www.who.int/diabetes/publications/iccc_exec_summary_eng.pdf

43. *Package of essential noncommunicable (PEN) disease interventions for primary health care in low-resource settings.* Geneva, World Health Organization, 2010. Available at: http://whqlibdoc.who.int/publications/2010/9789241598996_eng.pdf

44. *A gateway to the UN system's work on the MDGs*. United Nations, 2010. Available at: http://www.un.org/millenniumgoals/.

45. *The Millennium Development Goals*. United Nations Development Programme. Available at: http://www.beta.undp.org/undp/en/home/mdgoverview.html.

46. Beran D, Higuchi M. Delivering dabetes cre in the Philippines and Vietnam: Policy and Practice Issues. *Asia-Pacific Journal of Public Health*, 2011, Jul 3.

47. Beran D, McCabe A, Yudkin JS. Access to medicines versus access to treatment: the case of type 1 diabetes. *Bulletin of the World Health Organization*, 2008 Aug, 86(8):648-649. Available at: http://www.who.int/bulletin/volumes/86/8/07-048710.pdf

48. Beran D, Yudkin JS. Diabetes care in sub-Saharan Africa. *Lancet*, 2006, Nov 11, 368(9548):1689-1695.

49. Beran D, Yudkin JS, de Courten M. Access to care for patients with insulin-requiring diabetes in developing countries: case studies of Mozambique and Zambia. *Diabetes Care*, 2005, Sep, 28(9):2136-2140.

50. NCD Alliance. *Access to essential medicines and technologies for NCDs*. Geneva, NCD Alliance, 2011. Available at: http://ncdalliance.org/sites/default/files/resource_files/NCD%20Alliance%20briefing%20paper%20-20Access%20to%20Essential%20Medicines%20and%20Technologies%20for%20NCDs%20%28full%20references%29.pdf

51. *Strengthening the global partnership for development in a time of crisis: MDG Gap Task Force Report 2009*. New York, United Nations, 2009. Available at: http://www.un.org/millenniumgoals/pdf/MDG_Gap_%20Task_Force_%20Report_2009.pdf

52 Gale EA. The rise of childhood type 1 diabetes in the 20th century. *Diabetes*, 2002, 51(12):3353-3361.

53. Owens DR, Zinman B, Bolli GB. Insulins today and beyond. *Lancet*, 2001, 358(9283):739-746.

54. Alberti K. Insulin: availability and cost. *World Health Forum*, 1994, 15:6.

55. Alberti K. Insulin dependent diabetes mellitus: a lethal disease in the developing world. *British Medical Journal*, 1994, 309(6957):754-755.

56. Alemu S et al. Access to diabetes treatment in Northern Ethiopia. *Diabetic Medicine*, 1998, 15(9):791-794.

57. Deeb L, Tan M, Alberti K. Insulin availability among International Diabetes Federation member associations. *Diabetes Care*, 1994;17:220-223.

58. McLarty D, Swai A, Alberti K. Insulin availability in Africa: an insoluble problem? *International Diabetes Digest*, 1994, 5:15-17.

59. Beran D, Yudkin JS, de Courten M. Assessing health systems for type 1 diabetes in sub-Saharan Africa: developing a 'Rapid Assessment Protocol for Insulin Access'. *BMC Health Serices Research*, 2006, 6:17.

60. International Insulin Foundation. Projects. London, International Insulin Foundation. Available at: http://www.access2insulin.org/html/our_project.html.

61. Scrimshaw NS, Gleason GR, eds. *Rapid assessment procedures - Qualitative methodologies for planning and evaluation of health related programmes*. Boston, International Nutrition Foundation for Developing Countries (INFDC), 1992.

62. Manderson L, Aaby, P. An epidemic in the field? Rapid assessment procedures and health research. *Social Science and Medicine*, 1992, 35:839-850.

63. Ong B, Humphris G. Rapid appraisal methods in health. In: Popay Jaw G, ed. *Researching the people's health*. London, Routledge, 1994.

64. Beebe J. Basic concepts and techniques of rapid appraisal. *Human Organization*, 1995, 54(1):42-51.

65. Scrimshaw SCM, Hurtado E. Rapid assessment procedures for nutrition and primary health care. Anthropological approaches to improving programme effectiveness. Tokyo, The United Nations University, 1997.

66. Rhodes T et al. Rapid assessment, injecting drug use, and public health. *Lancet*, 1999, 354:65-68.

67. *SEX-RAR guide: the rapid assessment and response guide on psychoactive substance use and sexual risk behaviour*. Geneva, World Health Organization, 2002. Available at: http://www.unodc.org/documents/hiv-aids/RAR%20sex.%20behavious%20guide.pdf

68. Beran D. *The Diabetes Foundation report on implementing national diabetes programmes in sub-Saharan Africa*. London, International Insulin Foundation, 2006. Available at: http://www.access2insulin.org/uploads/4/9/1/0/4910107/iif_full_final.pdf

69. Higuchi M. *Costs, availability and affordability of diabetes care in the Philippines*. Tokyo, Foundation of Advanced Studies on International Development, 2009. Available at: http://www.fasid.or.jp/chosa/jyosei/list_pdf/19-1-e.pdf

70. Higuchi M. Access to diabetes care and medicines in the Philippines. *Asia-Pacific Journal of Public Health*. [Proceedings Paper]. 2010 Jul;22:96S-102S.

71. *How to investigate drug use in health facilities: selected drug use indicators*. Geneva, World Health Organization, 1993. Available at: http://apps.who.int/medicinedocs/en/d/Js2289e/8.6.html

72. Hogerzeil HV et al. Field tests for rational drug use in twelve developing countries. *Lancet*, 1993, Dec 4, 342(8884):1408-1410.

73. *Medicines use in primary care in developing and transitional countries: fact book summarizing results from studies reported between 1990 and 2006*. Geneva, World Health Organization, 2009.

74. *Medicine prices: A new approach to measurement*. Geneva, World Health Organization, 2003. Available at: http://www.haiweb.org/medicineprices/pdf/PDF%20MP%20Brochure.pdf

75. *Measuring medicine prices, availability, affordability and price components.* 2nd ed. Geneva, World Health Organization, 2008. Available at: http://apps.who.int/medicinedocs/index/assoc/s14868e/s14868e.pdf

76. Gelders S et al. *Price, availability, and affordability: An international comparison of chronic disease medicines*. Cairo, World Health Organization Regional Office for the Eastern Mediterranean, 2006. Available at: http://apps.who.int/medicinedocs/index/assoc/s14135e/s14135e.pdf

77. Golafshani N. Understanding reliability and validity in qualitative research. *The Qualitative Report*, 2003; 8(4):597-607.

78. Holloway I. *A-Z of qualitative research in healthcare*. Chichester, UK, Blackwell Publishing, 2008.

79. Holm L, Smidt S. Uncovering social structures and status differences in health systems. *European Journal of Public Health*, 1997, 7:373-378.

80. Green J. Commentary: grounded theory and the constant comparative method. *British Medical Journal*, 1998 Apr 4, 316(7137):1064-1065.

81. Mays N, Pope C. Qualitative research in health care. Assessing quality in qualitative research. *British Medical Journal*, 2000 Jan 1, 320(7226):50-52.

82. Faltermaier T. Why public health research needs qualitative approaches. *European Journal of Public Health*, 1997, 7(4):357-363.

83. Pope C, Mays N. Reaching the parts other methods cannot reach: an introduction to qualitative methods in health and health services research. *British Medical Journal*, 1995, July 1, 311(6996):42-45.

84. Smith JA. Semi-structured interviewing and qualitative analysis. In: Smith JA, Harre R, Van Langenhove L, eds. *Rethinking methods in psychology*. London, Sage Publications Ltd., 2008.

85. Birbili M. Translating from one language to another. *Social Research Update*, 2000, 31:1-4.

86. Pope C, Ziebland S, Mays N. Qualitative research in health care. Analysing qualitative data. *British Medical Journal*, 2000, Jan 8;320(7227):114-116.

87. Green J. Analysing qualitative data. In: Green J, Browne J, eds. *Principles of social research*. Maidenhead, UK, Open University Press, 2005. p.75-92.

88. Ritchie J, Spencer L, O'Connor W. Carrying out qualitative analysis. In: Ritchie J, Lewis J, eds. *Qualitative research practice: A guide for social science students and researchers.* London, Sage Publications, 2003. p.219-262.

89. *The World Health Report 2000: Health systems: improving performance*. Geneva, World Health Organization, 2000. Available at: http://www.who.int/whr/2000/en/index.html

90. Kessner D, Carolyn E, Singer J. Assessing health quality: the case for tracers. *New England Journal of Medicine*, 1973, 288:189-194.

91. Beran D. *Developing a hierarchy of needs for type 1 diabetes*. London, University College London, 2011.

92. Nolte E, Bain C, McKee M. Diabetes as a tracer condition in international benchmarking of health systems. *Diabetes Care*, 2006, 29(5):1007-1011.

93. Beran D, Silva Matos C, Yudkin JS. The Diabetes UK Mozambique Twinning Programme. Results of improvements in diabetes care in Mozambique: a reassessment 6 years later using the Rapid Assessment Protocol for Insulin Access. *Diabetic Medicine*, 2010 Aug;27(8):855-861.

94. Epping-Jordan J et al. Preventing chronic diseases: taking stepwise action. *Lancet*, 2005 online. Available at: http://www.sciencedirect.com/science/article/pii/S0140673605673424

List of Appendices

Instructions for data collection checklists

Appendix 2 provides an example of data collection checklists. The research team does not have to follow this example strictly. Please read Chapter 5 before using them. Instructions on how to use sample checklists include:

1. For the **national level**, the indicated sheet can be used for a survey. One column is for one questionnaire. More than one person can be a key informant for different themes, and also one theme may need to be answered by multiple key informants.

2. For the **intermediate level**, the indicated sheet can be for each area (e.g. urban, peri-urban, rural). One column is for one questionnaire. More than one person can be a key informant for different themes, and also one theme may need to be answered by multiple key informants.

3. For the **local level**, the indicated set (currently 3 pages) is an example for an urban area. For the 'facility checklist' one block is for one facility (hospital/health centre/clinic). For other areas (peri-urban and rural) reduce the number of rows, according to the recommended sample sizes in Table 5-1 as well as to local needs and situations.

4. For the **individual level**, the indicated set (3 pages) is an example for an urban area. For other areas (peri-urban and rural) reduce the number of rows, according to the recommended sample sizes in Table 5-1 as well as to local needs and situations.

Instructions for sample data collection tools

Attached in Appendices 3 – 10 are sample data collection tools. The research team does not have to follow these examples strictly. Please read Chapters 6 and 8 before developing specific data collection tools. Some instructions on how to use sample tools include:

1. It is not necessary to use all the listed questions. Based on the local needs and situations, some of them can be omitted and/or revised. Additional questions may also be included.

2. Samples are given for a survey for diabetes as an example. Specific terms (e.g. 'diabetes' and 'oral hypoglycaemic agents') should be changed according to the target disease(s) of the survey. For example, if the target disease is cardiovascular diseases (CVDs), change 'diabetes' to 'cardiovascular diseases', and other diabetes-related items (e.g. 'oral hypoglycaemic agents', 'insulin' and 'blood glucose level') to CVD-related items. To identify necessary items for each disease, or NCDs as a whole, refer to documents such as:

   - Package of Essential Noncommunicable (PEN) Disease Interventions for Primary Health Care in Low-Resource Settings
   - National Essential Medicines List and/or WHO Model List of Essential Medicines
   - National standard treatment guidelines for the target disease(s)

3. The health facility questionnaire can be used for hospitals, health centres/clinics, pharmacies and laboratories. Choose only relevant questions for each target institution.

4. The health-care worker questionnaire is a master questionnaire for all types of health-care workers (e.g. specialist doctors, general doctors, nurses, pharmacists, laboratory technicians, dieticians/nutritionists) identified in each facility. Choose only relevant questions for each occupational group.

5. Questions that have pre-defined options (for quantitative data) should be changed according to the local situations.

6. Blank columns in the left can be used for question numbers.

7. Blank columns in the right can be used for 'skip' instructions.

8. Questions that have pre-defined options (for quantitative data) and open-ended questions (for qualitative data) might be asked separately if this is more convenient for field workers to collect and enter data.

These data collection tools are still in the process of development. Feedback and comments from field testing will be integrated to improve these tools.

Instructions for sample informed consent sheets

Attached in Appendices 11 and 12 are sample informed consent sheets. They are developed when written information and a written consent is necessary. Types for informed consent are:

- Written information is provided to a participant and the participant gives written consent to the research team
- Oral information is provided to a participant and the participant gives written consent to the research team
- Oral information is provided to a participant and the participant gives oral consent to the research team

Check with the ethical review committee that the research team contacts which informed consent type is advisable. When the research team submit informed consent sheet(s), which might be attached to the research proposal, to the ethical review committee, it might be necessary to use a given format. If this is not the case, the attached format will be useful. Instructions on how to use sample checklists include:

1. Shadowed part ('diabetes') should be changed according to the target disease(s) of the specific survey.
2. Blank lines can be used for specific names (e.g. the name of the survey country and principal investigator's name), specific time/date, and others.
3. In case the principal investigator is an external consultant, it might be better to put the national collaborator's name instead of the principal investigator's name on the sheet(s). Respondents might prefer a national researcher's name to a foreign researcher's one.
4. Change terms based on local situations. For patient information, in particular, use lay terms and avoid technical terms.