Affordable, quality, long-term care and pharmacotherapy of chronic diseases: a framework for low and middle income countries

Report

Commissioned by
The Alliance for Health Policy and System Research, World Health Organization, Geneva

Submission 31 August 2011

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Executive summary

**Background:** Even though global efforts to improve access to healthcare, particularly pharmacotherapy have focused mainly on HIV, tuberculosis and malaria, in many Low and Middle Income Countries (LMIC) chronic diseases are already the most prevalent causes of morbidity and mortality. Health systems in many LMIC are not designed to provide long-term care for chronic diseases as, among other things, they lack a comprehensive approach to provide accessible, affordable long-term pharmacotherapy as part of a care package.

**Objectives:** To propose a framework of accessible and affordable pharmacotherapy for chronic diseases that may be applied in resource poor settings.

**Design:** Systematic literature review of the following databases: PubMed, EMBASE, ISI Web of Science and the International Network for Rational Use of Drugs (INRUD). Review of descriptive and interventional studies on accessibility, affordability of pharmacotherapy for diabetes, asthma and depression and publications proposing chronic care management models with particular focus on LMIC.

**Results:** 1. The barriers to access to pharmacotherapy and related routine care for diabetes, asthma and depression in LMIC are similar to those for acute diseases: affordability of medicines, accessibility in the public and private sector, scarcity of diagnostic and monitoring equipment, lack of trained human resources to provide treatment, paucity of patient and community empowerment strategies among others. However, these barriers have different implications for chronically ill patients, health services and society in general. 2. Most chronic care models in general have limited applicability to resource-poor settings: a) they do not describe in detail how the model is intended to improve pharmacotherapy and b) as most such models are designed for health systems in high income countries, they primarily focus on improvement of quality of care rather accessibility or affordability. 3. A comprehensive framework includes for chronic disease management for LMIC includes the following interrelated domains: policy, community, healthcare system and patient. A framework of chronic care and disease management for LMIC with particular focus on medicines and continuity of care would do well to improving organization, training and incentives for health professional teams, strengthening self-care and community support as well as creating chronic disease partnerships between patients, providers and local communities.

**Conclusions:** Improving access and affordability of medicines and quality of routine care for patients with chronic diseases goes beyond provision of supply of medicines, diagnostics and monitoring equipment and requires the rigorous evaluation of new care models designed for long-term treatment and provision of prepaid medicines. The proposed framework would be a first step to create a road map for improving chronic care with focus on medicines in LMIC.
Acknowledgements

We would like to thank Maryam Bigdeli for her very valuable comments on previous versions of the report as well as all participants of the Overview of ATM Projects funded by the Alliance for Health Policy and Systems Research Meeting in Geneva April 19th 2011 for the useful feedback on the presentation of this report. We are very grateful for the detailed and critical comments of external reviewers of the report: David Beran, Sauwakon Ratanawijitrasin, Annemiek van Bolhuis, Wim Van Damme, Anita Wagner.
ATMCC in LMIC

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<th>Description</th>
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<tbody>
<tr>
<td>AHSPR</td>
<td>Alliance for Health Policy and Systems Research</td>
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<tr>
<td>APN</td>
<td>Advanced Practice Nurse</td>
</tr>
<tr>
<td>ATM</td>
<td>Access to medicines</td>
</tr>
<tr>
<td>ATMCC</td>
<td>Access to medicines for chronic conditions</td>
</tr>
<tr>
<td>CCM</td>
<td>Chronic Care Model</td>
</tr>
<tr>
<td>CDC</td>
<td>Center for Disease Control of the United States of America</td>
</tr>
<tr>
<td>CDP</td>
<td>Chronic disease partnerships</td>
</tr>
<tr>
<td>DALY</td>
<td>Disability-adjusted life years</td>
</tr>
<tr>
<td>DCPP</td>
<td>Disease Control Priority Project</td>
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<tr>
<td>FSDP</td>
<td>Functional service delivery point</td>
</tr>
<tr>
<td>GINA</td>
<td>Global Initiative for Asthma</td>
</tr>
<tr>
<td>GNI</td>
<td>Gross National Income</td>
</tr>
<tr>
<td>GP</td>
<td>General Practitioner</td>
</tr>
<tr>
<td>HAI</td>
<td>Health Action International</td>
</tr>
<tr>
<td>HbA1c</td>
<td>Glycosylated hemoglobin</td>
</tr>
<tr>
<td>HIV</td>
<td>Human Immunodeficiency Virus</td>
</tr>
<tr>
<td>ICCC</td>
<td>Innovative Care for Chronic Conditions</td>
</tr>
<tr>
<td>INRUD</td>
<td>International Network for the Rational Use of Drugs</td>
</tr>
<tr>
<td>LEM</td>
<td>List of Essential Medicines</td>
</tr>
<tr>
<td>LMIC</td>
<td>Low and middle income countries</td>
</tr>
<tr>
<td>MeSH</td>
<td>Medical Subject Headings</td>
</tr>
<tr>
<td>MSH</td>
<td>Management Sciences for Health</td>
</tr>
<tr>
<td>NCD</td>
<td>Non-communicable diseases</td>
</tr>
<tr>
<td>NIH</td>
<td>National Institute of Health</td>
</tr>
<tr>
<td>NGO</td>
<td>Non-governmental organization</td>
</tr>
<tr>
<td>PEPAR</td>
<td>President’s Emergency Program for AIDS Relief</td>
</tr>
<tr>
<td>RCGP</td>
<td>Royal College of General Practitioners, United Kingdom</td>
</tr>
<tr>
<td>SOP</td>
<td>Standard Operating Procedure</td>
</tr>
<tr>
<td>SPS</td>
<td>Strengthening Pharmaceutical Systems</td>
</tr>
<tr>
<td>UK</td>
<td>United Kingdom</td>
</tr>
<tr>
<td>USAID</td>
<td>United States Agency for International Development</td>
</tr>
<tr>
<td>US</td>
<td>United States</td>
</tr>
<tr>
<td>WHA</td>
<td>World Health Assembly</td>
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<tr>
<td>WHO</td>
<td>World Health Organization</td>
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</table>
1. Introduction

Death rates from non-communicable disease (NCD) are higher in Low and Middle Income Countries (LMIC) than in high income countries (Beaglehole et al, 2011). While chronic communicable diseases such as HIV/AIDs are still prevalent and mobilize substantial resources, NCD such as diabetes, hypertension or mental health disorders are becoming a high burden for health systems, patients and communities (Mosynski, 2011).

This increased awareness of the global toll of morbidity and mortality has resulted in the United Nations high level summit on NCD that will take place in New York on 19-20 September. Stakeholders such as the Lancet NCD Action Group have proposed a five overarching actions—i.e, leadership, prevention, treatment, international cooperation, and monitoring and accountability in addition to the implementation of five priority interventions—i.e, tobacco control, salt reduction, improved diets and physical activity, reduction of hazardous alcohol intake, and access to essential drugs and technologies (Beaglehole et al, 2011).

However, achieving the implementation of those actions is difficult for multiple reasons among them the fact, that most health service delivery models were created at a time when acute diseases represented the highest disease burden and often not designed to deliver routine quality care for patients suffering from chronic diseases and are not responsive to these patients' specific needs (Nolte and McKee, 2008). Many verticalized programmes and drug supply systems for patients with chronic communicable diseases such as HIV or TB exist, but these often neither integrated with existing community and primary health care services nor with the higher levels of care (WHO, 2005).

To enable care for patients with chronic diseases, health care systems need to have certain characteristics that are presently different from existing acute care systems: These systems will require new clinical management strategies (routine appointments, patient rosters, adherence monitoring), different modes of staff functioning (interdisciplinary coordination, patient-centered care, performance monitoring), innovative drug supply systems and strengthened community linkages (family and community supports, novel types of outreach) (Nolte and McKee, 2008). A novel model of chronic care needs to emerge in LMIC, that is unique to the economic, geographical, social and health systems environments of these resource poor settings and that may build on the lessons learned from HIV or TB treatment programs.

1.1 What do we mean by chronic disease?

The World Health Organization has defined a chronic disease as diseases of long duration and generally slow progression (WHO, 2011). Sometimes “long-term conditions” are used interchangeably with “chronic diseases” (Royal College of General Practitioners, 2004). The common characteristics of chronic diseases are complex etiology, long period of incubation as well
long-term progression. Most chronic diseases are not curable. There are many aspects which are still unknown about their origin although many factors have been identified as relevant: genetic and environmental factors, individual life-style, etc. Similarly, therapy is complex and outcome depends on multiple factors. A multidisciplinary approach to optimize therapy is desirable. It needs to be stressed that pharmacotherapy is only one part of the disease management which needs to include life-style measures. However, this report as it will be explained in the objectives will focus on pharmacotherapy and interrelated services which are embedded in more general model of caring for patients with chronic conditions.

It seems relevant to briefly lay out the key differences between care for acute and chronic diseases in order to understand why it makes sense at this point to focus on chronic diseases as a separate entity.

Acute diseases require a brief interaction with health systems providers and usually only a one point in time response of the system. This is the case for instance for most infectious diseases (there are exceptions among them such as HIV, tuberculosis and leprosy). In contrast, chronic diseases demand a complex health system response and a continuum of care (Samb et al, 2010). Table 1 summarizes the relevant differences between acute and chronic care.

Table 1: Comparison between acute and chronic care

<table>
<thead>
<tr>
<th>Dimensions</th>
<th>Acute care</th>
<th>Chronic care</th>
</tr>
</thead>
<tbody>
<tr>
<td>Interaction</td>
<td>Short</td>
<td>Long-term (including life-long)</td>
</tr>
<tr>
<td>Treatment goal</td>
<td>Return to normal life</td>
<td>Maintaining an independent life</td>
</tr>
<tr>
<td>Patient role</td>
<td>Short-term engagement</td>
<td>Long-term engagement</td>
</tr>
<tr>
<td>Health provider role</td>
<td>Diagnosis and instructions on how to treat</td>
<td>On-going monitoring of treatment management and outcomes</td>
</tr>
<tr>
<td>Communication between health provider and patient</td>
<td>Often one-way (instructions) and at one point in time</td>
<td>Requirement for two-way and continuous communication</td>
</tr>
<tr>
<td>Provider</td>
<td>Single</td>
<td>Multiple, often includes referral between different levels of care</td>
</tr>
<tr>
<td>Community</td>
<td>Limited role</td>
<td>Continuous support and active role</td>
</tr>
<tr>
<td>Medication</td>
<td>Less costly as expenses are one point in time</td>
<td>High cost burden as continuous expenditure, administration of medication should facilitate adherence</td>
</tr>
</tbody>
</table>

Information adapted from (Holman and Lorig, 2000)

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1 We note the classification of disease criteria by Setel et al. (Am J Public Health. 2004; 94:384–388) using the 2 parameters of chronicity and mortality. All major disease conditions were rated as either acute or chronic along 1 axis, and as having a low or high mortality along the other. The combination of these categories yields a 4-way effect-oriented broad care needs classification scheme: (1) acute care needs, with low- and high mortality subgroups, and (2) long term care and management needs, with low- and high-mortality subgroups. However, for the purpose of this report we will still you a one dimensional separation in acute and chronic.
Medication in acute care are administered at limited times until the patient is cured. Adherence of the patient is required for a certain period of time; expenditures on pharmacotherapy are commonly made only a few times. In contrast, pharmacotherapy for chronic diseases means continuous expenditure, retention of the patient to life-long care by the providers and patient adherence for very long periods of time. 

It is vital to notice the shift in the concept of pharmacotherapy and medicines within health systems: in previous decades medicines have been viewed as the only input that is needed to provide therapy and achieve a cure (Bigdeli, 2011). However, life-long pharmacotherapy for chronic diseases requires much more than the product (medicine); it requires initial diagnosis, monitoring of metabolites (i.e., blood sugar), monitoring of adverse effects, changes of medications, and increasing dosage demands. The pharmacotherapy for chronic diseases requires a set of vital services apart from a product. These services -among others- include the skills of health care workers to monitor treatment continuously, make decisions for treatment changes and empower the patient in its self-care. It also required the retention of the patient in a system that enables continuous patient support long-term. These services should be integrated with an organizational structure ensuring coordination, comprehensiveness and continuity.

The present document focuses particularly, but not exclusively, on three chronic diseases, namely diabetes, asthma, and depression. One reason for choosing these three diseases was due to their contribution to the global burden of disease: chronic respiratory diseases and diabetes together with cardiovascular diseases and cancer are among the four chronic diseases that make the largest contribution to mortality in the majority of low- and middle-income countries. Depression has been reported as the fourth leading cause of disease burden globally and represents the single largest contributor to nonfatal disease burden (Ustun et al, 2004). The other -and perhaps most important- reason for selecting these three diseases is to illustrate the different types of barriers to access of medicines for chronic diseases. Diabetes requires life-long treatment and a high commitment from the patient to be adherent. In this sense it is similar to hypertension and hyperlipidemia, two other chronic diseases with high prevalence which also require patient adherence over a long period of time to prevent complications. Asthma therapy has the principal goal to avoid acute asthma crisis which can result in hospitalization more than prevent long-term complications such as in diabetes. In comparison to diabetes and depression, asthma effects largely children and young people which require potentially different services related to access to medicines as adults. Depression was chosen as it seems that barriers related to the social perception of the disease such as stigma, exist apart from geographical, financial and health systems barriers. Therapy of depression may also require more specialized care than diabetes and asthma so that management has to take place outside primary care.
1.2 Relevance of chronic diseases worldwide and LMIC in particular

Improving care for chronic diseases globally has come into focus only very recently. Most deaths in LMIC are estimated to be due to chronic diseases—primarily from cardiovascular disease, cancer, chronic respiratory diseases, and diabetes (Abegunde et al, 2007; WHO, 2010).

It has been estimated that 63% of 57 million deaths worldwide in 2008 were from chronic diseases and 80% of those occurred in LMIC (WHO, 2010). Deaths from chronic disease in people younger than 70 years accounted for 48% of all chronic disease deaths in these 23 countries.

In terms of burden of disease, measured in DALYs, chronic diseases were responsible for an estimated nearly one half of the total worldwide burden of disease in 2005 and nearly one half of the disease burden in low-income and middle-income countries. In the 23 selected low-income and middle-income countries, chronic diseases were responsible for 50% of their total disease burden in 2005. Total deaths from chronic disease for the 23 selected countries are projected to rise in 2030. In these countries, the overall share of burden of disease in DALYs due to chronic diseases is projected to rise from 50% to 60% in 2030.

Age-specific death rates for chronic disease are higher in many low-income and middle-income countries than in high-income countries. For 15 selected countries with death registration data for causes of death, the overall age-standardized male and female death rates for chronic diseases were 54% and 86% higher, respectively, than those for men and women in high-income countries in 2005. Thus, and perhaps not surprisingly, the aggregate “wealth” of a country is related to the overall burden of chronic diseases. A more detailed analysis of the DALY burden can be found in Appendix 1.

1.3 Role of medicines in the treatment of chronic diseases

We view the existing frameworks of chronic case and disease management through a pharmaceutical “lens” but not only focused on the product (medicines) but also the services and the context of care delivery since adequate pharmacotherapy needs to be embedded into a series of services which include, among others, the active retention of the patient for continuous treatment monitoring and patient empowerment as mentioned above. Most significantly, we appreciate that these services should be integrated with a patient-centered organizational structure, financially affordable to all patients, ensuring coordination, comprehensiveness and particularly continuity of care.

2 The burden of disease is quantified in terms of disability-adjusted life-years (DALYs), which is a summary measure that combines years of life lost due to premature death and years of life lived with disability—i.e., in states of less than full health. One DALY can be thought of as 1 lost year of healthy life, and the burden of disease as a measurement of the gap between the present health of a population and an ideal situation in which everyone in the population lives into old age in full health (Abegunde et al. 2007).

3 There has been criticism of the WHO’s quoted estimates of the number of people dying from NCDs as they do not differentiate between premature and timely deaths. This differentiation is not explicit in the aggregate DALY estimates shown here. Indeed, when population health is good and people are enabled to live into old age, most people will in fact die from non-communicable diseases. Thus, it has been argued that it is essential to concentrate on premature avoidable mortality—deaths that should not occur in the presence of effective and timely healthcare. (Heath, 2011)
Without doubt, life-style changes, mainly tobacco control, regular physical exercise, reduction of salt and saturated fat, refined sugar, are currently the most relevant public health interventions to prevent the occurrence of chronic diseases. However, this report will focus primarily on secondary and tertiary prevention\(^4\) through medication.

Cost-effective pharmacotherapy can contribute to substantial individual and public health benefits. For example, pharmacotherapy for hypertension reduces the incidence of stroke by 35 to 40 percent, heart attack by 20 to 25 percent, and heart failure by more than 50 percent (Neal et al, 2000).

The Disease Control Priorities Project (DCPP) summarizing evidence on the cost-effectiveness of interventions in developing countries found that current treatments available for many chronic diseases are cost-effective and in some cases even cost-saving (World Bank, 2006). A brief summary of the cost-effective or cost-saving medication for diabetes, asthma and depression will be presented in Section 3.

The World Health Assembly (WHA) has endorsed in 2008 its “Prevention and control of noncommunicable diseases: implementation of the global strategy” (WHA, 2008). This includes the reorientation and strengthening of health systems. The first of the six actions proposed, however, includes essential medicines:

“(a) Ensure that provision of health care for chronic diseases is dealt with in the context of overall health system strengthening and that the infrastructure of the system, in both the public and private sectors, has the elements necessary for the effective management of and care for chronic conditions. Such elements include appropriate policies, trained human resources, **adequate access to essential medicines and basic technologies**, standards for primary health care, and well-functioning referral mechanisms.

(b) Adopt, implement and monitor the use of evidence-based guidelines and establish standards of health care for common conditions like cardiovascular diseases, cancers, diabetes and chronic respiratory diseases, integrating whenever feasible, their management into primary health care.

(c) Implement and monitor cost-effective approaches for the early detection of breast and cervical cancers, diabetes, hypertension and other cardiovascular risk factors.

(d) Strengthen human resources capacity, improve training of physicians, nurses and other health personnel and establish a continuing education program at all levels of the health-care system, with a special focus on primary health care.

(e) Take action to help people with non-communicable diseases to manage their own conditions better, and provide education, incentives and tools for self-management and care.

\(^4\) For the purpose of this report the following definitions of primary, secondary and tertiary preventions are used: “Primary prevention aims to prevent disease from developing in the first place. Secondary prevention aims to detect and treat disease that has not yet become symptomatic. Tertiary prevention is directed at those who already have symptomatic disease, in an attempt to prevent further deterioration, recurrent symptoms and subsequent events.” Hall, 2011, http://www.sciencebasedmedicine.org/index.php/the-meaning-of-secondary-prevention
Develop mechanisms for sustainable health financing in order to reduce inequities in accessing health care.” (WHA, 2008)

Two of the recommended indicators to monitor and evaluate progress on the action plan refer explicitly to medicines (WHA, 2008):

- Number of countries in which patients have **access to affordable essential medicines for pain relief and palliative care**, including oral morphine.
- Number of countries in which **essential medicines** for management of **chronic respiratory diseases, hypertension, and diabetes** are affordable and accessible in primary health care.

These indicators are very limited in measuring key aspects related to medicines and related services to ensure availability, affordability and quality care for chronic conditions.

**1.4 Objective of this report**

The objective of this report is to propose a framework of chronic care and disease management with particular focus on medicines that integrates routine care of chronic conditions with aspects of accessibility, affordability and adequate pharmacotherapy.

Thus, while pharmaceutical management and therapy are only a subset of the health system factors in chronic disease models, we emphasize it in this report for precisely the reason that pharmacotherapy is given short shrift in the existing models for chronic care (See Section 4).

Although this report focuses primarily on pharmacotherapy of chronic diseases and not on life-style changes to prevent chronic diseases, we have included some references to primary prevention of chronic diseases through the use of medicines taking as an example the polypill (for more detailed information Appendix 2).

The report has four parts: (i) description of the literature search and analysis, (ii) a summary of the findings of barriers to accessibility, affordability and adequate pharmacotherapy for chronic diseases and interventions to overcome the barriers, (iii) a review of models of comprehensive interventions to improve chronic care, (iv) a proposed framework for chronic disease care with focus on pharmacotherapy.

(i) Literature reviews: This section described two systematic reviews of the literature on which this report is based. First, a review was carried out to identify general barriers for access to medicines for three selected chronic diseases –diabetes, asthma and depression in LMIC. A second review was conducted to describe comprehensive interventions that have been proposed to improve healthcare delivery for chronic diseases.

(ii) General and disease-specific barriers of access to medicines in LMIC: This is the result of the first review and summarizes the findings on the general barriers to access and routine care for diabetes, asthma and depression in LMIC.
(iii) **Comprehensive interventions to improve chronic diseases management:** This is the result of the second part of the literature review and presents models and interventions which have been designed to re-structure or deliver innovative care for chronic diseases. Each type of model identified from the literature will be briefly described with particular focus on pharmacotherapy. Is this the ‘second’ review?

(iv) **Proposal of a framework to improve access to medicines and routine care for people with chronic diseases:** The discussion presents the key elements that a chronic disease framework for access to medicines and routine care should contain and the need for evaluation of the proposed framework. The recommendations identify a number of priority actions which would support the development of the road map.
2. Methods: Literature review

2.1 Literature search of studies on access to medicines and routine care for patients with diabetes, asthma and depression in LMIC

To identify the barriers affecting access to medicines and routine care for diabetes, asthma and depression, the following databases were searched: PubMed, EMBASE, Web of Science, Google Scholar, International Network for Rational Use of Drugs (INRUD) to look for publications of barriers to access and routine care for chronic diseases in LMIC published in English, Spanish and French, between January 1995 to November 2010. Those articles which were identified as highly relevant were checked for references of relevant other publications. Key word searches were restricted to title and abstract. Each title was reviewed. If it was found relevant the abstract was read. Full-text reviews were only read in case the abstract presented issues related to barriers to improve access to medicines and/or routine care related to pharmacotherapy. A part from language, time period and data base, other inclusion criteria were related to the type of publications. Initially, only reviews and original studies were included, however, some discussion papers or editorials summarizing published literature were also included in case the original studies cited in those publications were found to be relevant. Personal opinions, letter to the editor and publications without abstract or full text access were not reviewed.

Each barrier described in the literature was classified according the Access to Medicines (ATM) Framework developed by the Alliance for Health Policy and Systems Research (AHPSR). This framework considers four main domains of access to medicines: (i) affordability, (ii) financing, (iii) reliable health infrastructure, (iv) rational use and selection.

These domains are ordered in a matrix to be matched with four different domains: a) individual/household/community; b) health system; c) policy; d) beyond policy. For the purpose of this report the second of these four domains – health system- was further divided into five categories which are equivalent to the health systems building blocks proposed by the WHO to measure health system performance (service provision, human resources, health related information, medical products, leadership and governance). This was done with the objective to allow more detailed classification at health system level. The different matrices for diabetes, asthma and depression are found in Appendices 3 to 5.

We summarized all the different barriers to access to medicines and routine care for chronic diseases for the three conditions in a single matrix where the vertical columns are arranged according to the ATM framework developed by the World Health Organization (WHO) Alliance for Health Policy and Systems Research (HPSR).

We further complemented this matrix by adapting work done by US Agency for International Development in collaboration with Management Sciences for Health and the program of...
Strengthening Pharmaceutical Systems (USAID/SPS, 2009) on barriers to pharmaceutical management for HIV which is now a chronic condition. The resulting summary matrix is Table 2 and is discussed in Section 3.5

2.2 Literature search of integrated interventions to improve care for chronic diseases in LMIC

A search of the following databases was conducted to identify publications about comprehensive interventions of care for chronic diseases in LMIC published in English, Spanish and French, between January 1995 to November 2010: PubMed, EMBASE, Web of Science, Google Scholar, International Network for Rational Use of Drugs (INRUD).

The search strategy was based on Medical Subject Heading (MeSH) and text terms. The term “Chronic diseases” was searched in combination with “Models, organizational” or “Patient Care Management” or “Disease Management”. For some of the searches “developing countries”, “low income countries”, “resource poor settings” were added as well as geographical regions. Case studies were excluded. All the searches were limited to human subjects. The search function of “related articles” and “cited articles” were used to identify other relevant publications.

A search of grey literature was conducted using a number of selected websites: World Health Organization (WHO), Center for Disease Control (CDC), the National Institute of Health (NIH) as well as general search engines such as Google using the following key words: “chronic disease” and in combination with “medicines”, “drug therapy” and “drugs”. With the support of the Alliance experts in Asia, Latin America and Africa were contacted to share “grey literature” about access and delivery of pharmacotherapy in their country or region (so far only for Asia and Latin America, pending to explore literature from Africa, particularly Sub-Saharan Africa).
3. Barriers to access to medicines and routine care for patients with chronic diseases in low and middle-income countries

At the outset, we note that the barriers we have identified in LMIC are not a comprehensive and exhaustive list. There are country- and healthcare settings for which little information is available and it is likely that each healthcare “ecosystem” has a different combination of barriers with varying impact. For example, for diabetes many publications describe access barriers focusing on pharmacotherapy at the individual/household, health sector and policy levels, but there was far less information published for asthma and particularly depression. Publications dealing with depression were more centered on barriers to health care access generally. Indirect costs were mentioned as a barrier to access (travel time to clinic for instance) but there was very little information in the literature that quantified these indirect costs. In the following we will summarize several key points that emerge from the literature review.

3.1 Affordability of medicines for diabetes, asthma and depression is sub-optimal

Although most of the essential medicines used to treat diabetes, asthma and depression are relatively inexpensive medicines in high income countries, affordability is the other important barrier to pharmacotherapy for LMIC. At individual/household or community level it was found that insulin is the least affordable medicine in LMIC. A snapshot of prices of insulin in 60 countries in 2010 found that prices in the private sector varied widely and implied that purchase was not affordable for a large majority of the population: meanwhile in Egypt 10ml soluble insulin Eli Lily had a reported price of US$2.61, in Indonesia the same product from the same manufacturer had a price of US$45.62 (HAI/WHO, 2010). Affordability is not as easy to calculate as dose requirements vary widely between patients.

Affordability for oral glucose controlling agents in the private sector is also monitored by WHO/HAI. For glibenclamide a government worker with the lowest monthly pay needs to invest between 0.4 and 1.8 days of his salary for a one-month treatment course purchasing the lowest priced generic product and 0.5 to 8.2 days of salary for buying the originator product (Cameron et al, 2009). For the purchase of metformin the lowest paid government worker needs to invest on average 2.1 day salaries on a monthly course of the lowest price generic in the private sector (data from 16 LMIC) (HAI, 2011).

5 Authors’ own calculation on the basis of the information provided by the publically available database of HAI, http://www.haiweb.org/GlobalDatabase/Main.htm
For asthma, affordability issues were highlighted as a barrier to access particularly for inhaled steroids. As a median value over the 30 countries the treatment of asthma with one inhaler beclomethasone and one salbutamol inhaler per month would cost 1.8 working days for the lowest priced generic and 5.5 days for the originator versions for the lowest paid unskilled government worker (World Health Organization-EMR/HAI, 2005). A study conducted in nine countries found that the cost minimum annual costs of treatment with essential asthma drugs for a case of moderate persistent asthma range from US$52 to more than US$200, depending on the country (Ait-Khaled et al, 2000).

For the lowest prices generic of amitryptiline the lowest paid government worker needs to spend on average 1.95 (02. to 6.8) days of the salary on the purchase. The affordability of the lowest priced fluoxetine varied widely between countries: the median number of days of salaries necessary for the purchase was 1.65 days for a 30 day treatment course (variation between a minimum of 0.8 days of salary and 53 days).

Also at individual level the affordability of indirect costs is relevant. For mental health including depression it was found that travel costs to treatment facilities were relevant barriers to receiving medication and services (McDaid et al, 2008).

Another area of barriers to treatment was at health service delivery level. Selection of diabetes medicines were found not reflecting recommendations on low-cost options, rather more expensive types of insulin were preferred (Gill et al, 2010). At the same time this is a barrier which is also related to the policy level as policies could promote strategies for efficient selection and review of lists of essential medicines (LEM). Inefficiency in selection of medicines uses precious resources which could be used for other services. An interesting example for in the literature comes from Zambia and Mozambique where it was found that both countries benefited from a scheme of the producer of insulin (Novo Nordisk) of reduced procurement prices (Beran et al, 2005). Nevertheless, in both countries insulin was not always available freely. Patient fees were not transparent for patients and varied between US$0 and US$15 (Beran et al, 2005).

### 3.2 Sustainable financing is lacking

Two publications were identified that studied the impact of making pharmacotherapy for diabetes more affordable through insurance as a financing mechanism of medicines (Sosa-Rubi et al, 2009; Ehrlich et al, 2009). They concluded that affiliation with health insurance increased the likelihood
of receiving treatment for asthma (Ehrlich et al, 2009) and diabetes Sosa-Rubi et al, 2009). However, in general and not specific to diabetes asthma and depression results other large studies found that insurance did little to improve access to medicines in general including out-of-pocket expenditure (Wagner et al, 2011; King et al, 2009). Given the fact that many health insurance systems do not reimburse the patient for outpatient medicines nor do they guarantee continued availability, health insurance systems which include reimbursement of ambulatory pharmacotherapy and ensure availability might have an effect on promoting access.

For mental health some studies reported that conditions were not included in the reimbursement packages (Karam et al, 2006) or that specific services for young people were not offered by insurances (Borges et al, 2008).

### 3.3 The health infrastructure is often unreliable

On an individual level, the lack of reliable infrastructure was a barrier to obtain medicines for chronic conditions. Geographical distance and the lack of community outreach program were two frequently reported barriers.

Even though cost-effective pharmacotherapeutic options exist for the three conditions studied in this report, the published literature shows that availability of these therapeutic options continues to be a challenge for all in many LMIC. The largest comparable surveys carried out on the topic were conducted by WHO on collaboration with Health Action International (HAI). The average availability of the medicines which are included in the LEM for the treatment of the three diseases studied does not exceed 50% in the public sector as the data published by WHO/HAI shows (HAI, 2011). (An availability of 50% means that out of 100 public health center visited only 50 had the medicine on stock at the time of the visit). Even though the availability of medicines was higher in the private sector the availability for the lowest priced generic medicines exceeded not more than 70% for the majority of medicines studied in this report.

A part from the availability of medicines the literature describes the lack of appropriate equipment and supply of diagnostic and monitoring tools for patients and for health providers. This was very relevant in the case of diabetes which requires continuous monitoring of serum glucose and urine as well as eye examination and sterile equipment for its administration (Beran and Yudkin, 2010). The lack of adequate equipment was also a key barrier documented for asthma treatment which requires monitoring via peak-flow and spirometer and administration of oxygen during acute exacerbation (Desalu et al, 2011). For instance, a recent audit of 68 tertiary care hospitals from Nigeria illustrates the fact reporting that medications such as inhaled short acting bronchodilators and corticosteriods were available in 79.4% of the hospitals. However, compared to medicines there was greater shortage in peak-flow meters (only in 38% hospitals available), spirometers (29.4%), and pulse oximeter (38.2%) which are vital parts of monitoring and acute exacerbation of asthma (Desalu et al, 2011).
3.4 Rational selection and use needs improvement

Barriers at individual, household or community level were a dominant theme in the literature around depression as it is related to stigma in many settings. At the individual level, various studies on diabetes reported the lack of knowledge about condition and the misconception of some treatment options (Haque et al, 2005). Particularly in the case of insulin as an option for those patients whose glucose is uncontrolled with life-style changes and oral glucose lowering agent therapy, such patients were found reluctant to accept insulin as it requires administration via injections (Haque et al, 2005). Adherence was also found to be a problem; as people were feeling better, treatment was discontinued (Beran et al, 2010b).

Gender differences in access to medication seem relevant in various cultural settings (Ehrlich et al, 2005; Mamo et al, 2009) and measurement of access should be reported according for men and women separately. Most studies speculated about the reasons for the gender disparities without providing analysis.

The literature documents that despite the fact that standard treatment guidelines are widely available for depression, asthma and diabetes, there is a wide gap between an adequate level of care and actual care received continues to exist. For instance, cross-sectional surveys in Tanzania and Cameroon found that the prescription of inhaled medication was rare; in rural Cameroon the use of traditional remedies among self-reported asthmatic patients recalling any treatment was more common than standard treatment (62%) (Mugusi et al, 2004). The global Mental Health Survey found that a very low percentage of patients with mental disorders receive adequate treatment: From a minimum of 10.4% in Nigeria to a maximum of (24.5%, 7.1) in Lebanon (Wang et al, 2007).

Possible reasons for implementation are related to all four levels considered (individual, health system, policy and beyond policy level). One reason might be the lack of integration of diagnostic, organizational and educational aspects of care (Tan and Ait-Khaled, 2006) among many other factors. One reasons for the continuation of deviation between of what is known standard treatment guidelines is parents’ as well as care givers’ knowledge about asthma care was reported to be low in Maputo in Mozambique (Mavale-Manuel et al, 2004). For instance a survey of 193 physicians in Iran found that only 29% of the respondents indicated that they would prescribe inhaled corticosteroids for a 6-year-old child with moderate persistent asthma for when it is indicated (Gharagozlou et al, 2008). This is in line with findings from Togo (Hounkpati et al, 2009) where physicians’ prescriptions were deviating from standard treatment guidelines (only 14.5% were using regularly peak-flow meters) and a survey in asthma patients in Morocco where only 26.1% (n=163) were prescribed a recommended prophylactic treatment (inhaled corticosteroids alone or in association with long-acting β-agonists) (Benkheder et al, 2009).

Other obstacles reported for asthma care were the prohibition for nurses to start prescribing them, although they were commonly the main care giver for many patients and the preference of health professionals for use of oral corticosteriods (English et al, 2007). One of the reasons for
deviation from recommended mental care was the argument that mental health is still underprioritized in many countries where very few health care professionals are recruited specialized in mental health (Kigozi et al, 2009).

3.5 Summary matrix: barriers to pharmacotherapy and routine care for chronic conditions in low- and middle-income countries

In Table 2, below, we summarize the various barriers. The colors signify the chronic condition that is most associated with this particular barrier (RED: diabetes; GREEN: depression; BLUE: asthma), with the understanding that these barriers overlap among the three conditions. The barriers in BLACK are those that MSH (USAID/SPS, 2009) has identified as being particularly important for pharmacotherapy and routine care for HIV/AIDS.

Table 2: Summary matrix of barriers to access and routine care for chronic diseases in LMIC

<table>
<thead>
<tr>
<th>Individual/household/community level</th>
<th>Affordability</th>
<th>Sustainable Financing</th>
<th>Reliable Health infrastructure</th>
<th>Rational selection and use</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>1. High indirect costs to household (e.g., transport).</td>
<td>1. Lack of insurance coverage resulting in being unable to purchase care and/or medicines or only some care/medicine.</td>
<td>1. Geographical distances. 2. Lack/few community outreach services.</td>
<td>1. Lack of knowledge about adequate therapy. 2. Lack of continuous education. 3. Lack of independent information. 4. Stigma or cultural barriers.</td>
</tr>
<tr>
<td></td>
<td>2. High direct costs to purchase medicines and other devices to monitor and administer medicines</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Health service delivery level (both public and private)</td>
<td>1. Specific chronic condition (e.g., depression/mental health generally) not included in the package of some health insurance. 2. Lack of financing, in particular for services targeting adolescents and young people.</td>
<td>1. Low standards for pharmacy services. 2. Lack/few community outreach services. 3. Weak self-management support for patients. 4. Failure to deliver integrated health services together with complementary programmes. 5. Inconvenient location of services. 6. No/inappropriate means of transport available. 7. Weak staff interpersonal skills. 8. Late or no referral.</td>
<td>1. Poor dispensing practices. 2. Under prescribing or other deviations from guidelines. 3. Weak laboratory services. 4. Lack of patient-based, inexpensive self-monitoring equipment.</td>
<td></td>
</tr>
<tr>
<td>Human resources</td>
<td>1. High out of pocket expenditure to pay for consultation and payment of health care providers in the private sector.</td>
<td>1. Lack of expertise in implementing a risk pool and/or insurance system.</td>
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<tr>
<td></td>
<td>2. Inconvenient opening hours.</td>
<td>3. Weak or no patient-centered and/or social mobilization efforts with regards to disease management.</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>11. Weak or no patient-centered and/or social mobilization efforts with regards to disease management.</td>
<td>1. Shortages of expertise. 2. Lack of institutional training capacity. 3. Lack of specialists in particular disorder (endocrinologists, mental health). 4. Weak or no patient-centered and/or social mobilization efforts with regards to disease management.</td>
<td></td>
<td></td>
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<tr>
<td></td>
<td>5. Weak self-management support for patients.</td>
<td>1. Shortage of prescribers and dispensers. 2. Lack of autonomy to seek care (e.g. woman). 3. Poor patient adherence, patient's resistance to a particular diagnosis. 4. Weak or no social mobilization efforts with regard to disease management.</td>
<td></td>
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<tr>
<td></td>
<td>6. Weak or no patient-centered and/or social mobilization efforts with regards to disease management.</td>
<td>7. Lack of knowledge about disorder and therapy. 8. Poor laboratory services.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Creation/storage/Delivery of health-related information</td>
<td>1. Inefficient systems to track medicine availability and use. 2. Inability of patients to know prices beforehand. 3. Most cost-effective medicines not included in benefits package.</td>
<td>4. Lack of development and implementation of quantification tools to accurately quantify medicine use. 5. Weak supply chain management leading to medicine stock-outs and losses. 6. Inefficient</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Medicines and all other biomedical products to support pharmacotherapy (self-monitoring, diagnosis and monitoring by health professionals, etc)</td>
<td>1. No indicators to allow for benchmarking and tracking performance, 2. No or weak decision-tracking tools, technical guidelines and procedures to improve evidence based product selection, 3. Weak or no procurement.</td>
<td>1. Weak systems to allow for benchmarking and tracking performance of medical products. 2. No or weak decision-tracking tools, technical guidelines, and procedures to improve evidence based product selection.</td>
<td></td>
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</tr>
<tr>
<td></td>
<td>1. Many inefficient systems to track medicine availability and use. 2. Poor continuity/retention of care. 3. Weak or no patient-centered and/or social mobilization efforts with regards to disease management.</td>
<td>3. Weak or no procurement efficiency as inefficient procurement. 4. Weak procedures to improve evidence based product selection.</td>
<td></td>
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</tr>
<tr>
<td></td>
<td>4. Complexity of billing systems.</td>
<td>5. Weak development and implementation of quantification tools to accurately quantify medicine use. 6. Weak supply chain management leading to medicine stock-outs and losses. 7. Poor laboratory services.</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>5. Complexity of billing systems.</td>
<td>8. Poor laboratory services. 9. Poor laboratory services. 10. Complex billing systems. 11. Inefficient billing systems.</td>
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<td></td>
</tr>
</tbody>
</table>
### 3.6 Barriers: Concluding comments

On the one hand, we have developed a long list of different barriers. Indeed, a multi-method qualitative approach to determine barriers to diabetes care in Tunisia found over 400 (four hundred) potential barriers to care (Alberti et al, 2007), the most frequently mentioned organizational barrier being absence of medication. The literature uncovered here represents some unknown (possibly small) portion of existing knowledge, so this is clearly an inevitable constraint to any truly comprehensive review. Other low and middle income countries where no published studies are available are likely to encounter different combinations of barriers, with different types and varying extents of problems. Therefore, knowledge gaps exist in identifying barriers in those countries.

Further, it is difficult to prioritize why one access barrier should have precedence over another. Why should lack of affordability be more important than lack of appropriate care for instance? Is the training of health care providers more or less important than strategies to improve adherence and patient empowerment?

On the other hand, what becomes clear from the review of documented access barriers is that only overcoming one or two access barriers will not improve access to medicines and routine care for chronic conditions in LMIC.

| Leadership, governance (including health sector policy) | 1. Uncoordinated donor procurement mechanisms for medicines as poor donor resource utilization leads to system inefficiencies. 2. No standard operating procedures (SOPs), and monitoring systems for oversight to increase transparency of procurement and supply systems. | 1. Weak or ineffective planning, implementation and evaluation of financial sustainability of health services. | 1. Many inefficient systems to track medicine availability and use. 2. Weak or no patient-centered and/or social mobilization efforts with regard to disease management. 3. Weak or ineffective planning, implementation and evaluation of health services that efficiently use resources to achieve most appropriate local solutions. | 1. No standard operating procedures (SOPs), and monitoring systems for oversight to increase transparency of procurement and supply systems. |

- Efficiency as inefficient procurement systems cause high medicine prices
- Weak link between product selection, clinical guidelines and decision-support systems
- Procurement systems leading to overages and shortages
- Use of herbal remedies
- Lack of patient-based, inexpensive self-monitoring equipment
A workable framework for access to medicines for chronic diseases needs to overcome a series of barriers to access which exist simultaneously and are interrelated.
4. Results: A Review of comprehensive interventions to improve care for patients with chronic diseases

There is abundant literature on improving care for patients with chronic diseases. It can be divided into two broad groups: (1) empirical studies measuring the impact of interventions to improve prevention and care; and (2) discussion papers, essays and proposals to improve management of chronic diseases in general. The following section focuses on the second type of publications (discussion papers, essays and proposals of frameworks).

The selection of publications presented in the following section was done with the objective to describe each type of proposed model or comprehensive intervention with particular emphasis on aspects related to pharmacotherapy. All of these models have in common that they emphasize the need of to integrate different elements, each of which on its own are insufficient to achieve a high level of quality of care.

4.1 The Chronic Care Model

Patients with chronic diseases face multiple and complex needs in care and treatment. Wagner et al (2001), based on a Cochrane review of successful interventions to improve care for chronically ill patients, constructed the “chronic care model” (CCM) which is probably the best known framework for how to improve care for chronic diseases. The model has two main components that continually interact: the community and the healthcare system. Integrated among these are four domains: self-management support; decision support; delivery system design; and clinical information systems (Figure 1). Since it is the most widely applied model and many publications have cited it, in the following section each of its elements will be described in more detail.

The **health systems organization** includes the following elements:

*a) Health systems*

This is the environment in which the efforts to improve health care for chronic ill patients are supported and encouraged by creating incentives for providers and patients to improve care and adhere to evidence-based guidelines.

*b) Clinical information systems*

The information about individual patients and patient population with chronic conditions is essential to improve effectively programs. The most basic requirement in terms of information is to establish a disease registry that not only identifies the population to be served but also includes information on the performance of various aspects of guideline-informed care. Health care teams with access to a registry can retrieve information on patients with specific needs and deliver proactive care, receive feedback on performance, implement reminder systems, generate tailored treatment planning or produce tailored provider or patient messages to facilitate care or self-care.
c) **Decision Support**  
Effective chronic-illness management programs require that providers have the knowledge and incentives required for optimal patient care. Among the decision-supports that the model identifies as crucial are guidelines and treatment protocols which should be part of daily practice and enforced by reminders.

*d) Delivery system design*  
Involving professionals with specific behavioral and clinical expertise, such as nurse case managers, pharmacists, or health educators is relevant to enhance performance. Knowledge of providers and patient data are insufficient to improve performance unless the composition and functioning of the practice team and appointment systems are appropriate.

The community organization includes the following elements:

**e) Community**  
Peer or community support is intended to address barriers that prevent achieving health goals, and social-environmental factors that determine long-term success. Community support is especially important for vulnerable populations such as the elderly, child/youth, and low income populations.

**f) Self-management support** helps patients and families to deal with the challenges of living with and managing chronic diseases in order to minimize emotional impact and disability. This can be achieved with educational resources and psychosocial support. Successful self-management programs rely on a collaborative process between patients and providers to define problems, set priorities, establish goals, identify barriers, create treatment plans, and solve problems.

*Figure 1: Chronic Care Model according to Wagner et al, 2001*

All the elements in the model have interactions at different levels. The efficient use of community resources and correct application of health system policies can help to assure a better self-management support in patients with chronic diseases. This can only be accomplished with a good organization of health care that includes decision support and systems of clinical information and delivery of care. In this model, patients have an active role and are at the center of care for chronic diseases; they receive information about their disease provided by a proactive and prepared health care team and are empowered in their decision-making and self-care.

- It is significant that, with regards to pharmacotherapy, the description of the CCM does not provide any details in relation to access to medicines and routine care. The only place where access to medicines is explicitly included is the domain of “decision support” where the implementation of clinical guidelines is a key feature.

**Critique of the chronic care model**

Some authors have criticized that the full model (all components) has not been evaluated in trials (Martin and Sturmberg, 2009) although some individual elements—particularly the management of specific diseases—have been evaluated. Others have argued that although multi-staged interventions including elements of the CCM have resulted into improved health outcomes, it is very difficult to attribute the improved outcome to a specific aspect of the multi-staged intervention (Nolte and McKee, 2008).

Some authors have concluded that the CCM is not necessarily superior to other management strategies of chronic diseases but that the key for success is a local consensus on solutions which are appropriate for a specific local context, systematic application, and continuous monitoring and evaluation (RCGP, 2004).

### 4.2 Modified chronic care models

Apart from the CCM, several alternative models have been developed. In the following we would like to describe one other out of a variety of models because it is particular relevant to low and middle income countries: the innovative care for chronic conditions framework (ICCC).

#### 4.2.1. Innovative Care for Chronic Conditions Framework (ICCC)

The World Health Organization contracted a group of health leaders from various developing countries to modify the existing CCM for its application to a global perspective (Epping-Jordan, 2002). The resulting model is the Innovative Care for Chronic Conditions (ICCC) Framework (Figure 2).

It emphasizes the importance of continuity and coordination and the role of community leaders and caregivers. Each member should be informed, motivated and prepared to manage chronic
diseases. The authors argue that information and motivation is not sufficient for a LMIC context, the actors need to be “prepared”. Being prepared means having sufficient resources, an adequate legal framework and sufficient leadership. The authors emphasize the particular need for interaction between the elements in the framework. The ICCC Framework mentions medicines as an essential input for care. In the ICCC framework, the health care organization should be "organized and well equipped". The community element has more weight in the ICCC framework than in the CCM as the authors argue that the community as a far greater role in society in general and hence, needs to have a key position in the management of chronic care in developing countries. In contrast to the CCM, the ICCC framework includes an additional element which is a “positive policy environment” that includes strengthening partnerships, support of legislative frameworks, integrating policies, promoting consistent financing, providing leadership and advocacy, and developing and allocating human resources.

- As with the CCM, this framework offers very little details of the role of pharmacotherapy in the management of chronic diseases management in LMIC, only mentioning that medicines are one essential input for care.

Figure 2: The Innovative Care for Chronic Conditions Framework

4.2.2. Other models which are relevant

A part from the ICCC there are some other relevant models. In the following some of some will be mentioned briefly:

_Prevention as the focus_: One modified model for delivery chronic care emphasizes the need to include more preventive services (Glasgow et al, 2001). The objective of the framework is to
prevent the development of chronic diseases as well as complications and exacerbation of the disease. The modifications are inserted in each of the CCM components without creating new elements of the model.

- In contrast to the CCM, this Glasgow et al. model with a focus on prevention explicitly addresses pharmacotherapy: it says that one of the aims of the model is in preventing side effects. However, there is little specific guidance on how this would occur.

Non-physician led chronic care: Another type of model to deliver care for chronic diseases envisions a health care professional acting as a guide to the patient since the patient has to face a complicated path of care consulting multiple physicians and taking multiple medications. This type of model partly resulted from discussion of how optimize the roles and responsibilities for physicians, nurses, specialists and other health care providers in a way that they act in a more coordinate and efficient manner, particularly in resource limited settings (Katon et al, 2001). Despite many organizational reforms, primary care physicians have remained as the main provider integrating the overall medical care of the patient (Katon et al, 2001).

The Guided Care Model (Boult et al, 2008) and the Model for Promoting Process Engagement (Cumbie et al, 2004) are examples for non-physician led chronic care models. In its center is the nurse or social worker who assists the physicians in being the care coordinator for patients, serving as a link between health institutions and patients. The patient does not have to attend multiple levels of care to improve their health condition, instead the guide (nurse or community care worker) help in optimizing the visits to the care units. The model is supposed to be particularly relevant for patients with several high-risk conditions and complex health care needs.

In the Model for Promoting Process Engagement (Cumbie et al, 2004) an Advanced Practice Nurses (APNs) provide flexible, individualized care for chronic illness. Their training curriculum are designed to enable the APN to meet the role-related core competencies of ethical decision making, consultation, expert guidance, research, clinical and professional leadership, and collaboration. It is proposed that the APNs engage with clients in an individualized plan of care. The “MoPoTsyo” from Cambodia is an adaption of the guided model of care in which diabetes patients are trained to become patient educators to support other patients in the assigned health care district (van Pelt, 2011).

Coleman et al (1998) provides a relevant description of an experience of re-organization of primary care for non-communicable diseases in rural South Africa by letting nurses being the ones who manage the patient.

Patient focused models: another variant of the CCM emphasizes the role of the patients as collaborators with the health care provider (Von Korff et al, 2002). The core aspects of a collaborative model include the collaborative definition of problems, joint goal setting and planning, provision of support services and sustained follow-up (Bauer 2001). This model
ATMCC in LMIC

originates from several behavioral principles as well as from social learning and self-regulation theories developed by Von Korff et al (1997). What is interesting in this model is the emphasis on the psychological skills that the health care providers require so that patients can achieve self care. These skills include anxiety management, recognition and treatment of depression, cognitive behavioural analysis, cognitive behavioural principles of step by step change and the ability to monitor patients’ progress (Von Korff et al, 2002). This implies that the providers need the support of specialists in psychological and psychiatric management to provide supervision and consultation in selected cases.

Functional service delivery point framework (FSDP): A model specifically development for framework for HIV-related services that aims to define the roles of different stakeholders and support to identify gaps in service delivery and to evaluate the progress (MSH, 2002). Even though the framework has been developed for HIV services, it provides valuable proposals that can be applied to other chronic conditions. What seems to distinguish the framework from the ICCC is the detailed development of the demand side and each of its aspects. The authors argue that awareness is the first step for successful client-service interaction and the second that the client is able to identify their own health needs which largely depend on information and social openness. To have the client being aware of their condition and their needs requires effective communication. That the client follows the advice of the providers depends on the social environment, the providers’ attitudes and the information that the client has about their condition. The FSDP emphasizes the critical importance of the communities in facilitating the access to health services where politicians, advocates and grassroots organizations all mobilize local groups to support health services and access to them. Behavior changes are achieved via communities and their efforts to increase public awareness for certain conditions, mobilize local resources and give feedback to providers as well as holding them accountable.

Chronic Disease Partnerships: A very different approach to models of care has been proposed by Goroff and Reich, (2010). Their proposal is intended to resolve particularly the issue of financing of treatment for chronic conditions in LMIC. They propose the formation of chronic disease–specific cross-sector partnerships, or “chronic disease partnerships.” These would involve major research and development–based multinational pharmaceutical manufacturers and local private, public, or nongovernmental organization (NGO) health care providers.

They propose that a pharmaceutical manufacturer help establish and support enterprises in emerging markets to provide comprehensive, integrated, high-quality care, including medicines, for specific chronic diseases. A pharmaceutical manufacturer would not provide comprehensive care and medicines on its own. Rather, it would partner with local health services providers and resources; advocacy or support groups; and other actors, including governmental entities, NGOs, or private businesses. Global NGOs or institutions with relevant expertise could provide support and technical guidance. Several pharmaceutical manufacturers, with complementary rather than competing medicines and roles, could participate in a single enterprise.
A chronic disease partnership could earn revenues from third parties that have obligations to provide care for the relevant chronic disease. Most emerging markets have many such third parties: public health systems, social insurance schemes, private health insurers, and even private for-profit hospitals and clinics. These third parties would contract with the chronic disease partnership to provide its care and medicines to their patients. A chronic disease partnership could also receive direct payments from patients. With few exceptions, health care spending in emerging markets is dominated by out-of-pocket payments at the point of service for care, or at the pharmacy for medicines. Because a chronic disease partnership would treat conditions that are often asymptomatic for extended periods, with high variability as to the timing and extent of complications and costs, the partnership could charge flat periodic payments, rather than fees for specific services or medicines (Goroff and Reich, 2010).

A pharmaceutical manufacturer’s principal role in a chronic disease partnership would be to supply its medicines to the partnership at prices and on terms negotiated between the company and the partnership. The manufacturer would supply medicines directly to the partnership, rather than through normal distribution channels. This would avoid a sizable cost, since markups over manufacturers’ prices in emerging markets are usually high in both the public and private sectors (Goroff and Reich, 2010).

### 4.3 Summary of the models and interventions for chronic diseases

Aside from Goroff and Reich (2010) it is striking how little the described models mention pharmacotherapy. If pharmacotherapy is explicitly mentioned, it is mostly discussed in relation with clinical guidelines including treatment protocols. The majority of the models are designed for health systems in high income countries as they primarily focus on improvement of quality of care rather access or affordability. Exceptions are the ICCC as well as the FSDP framework -which were particularly designed for LMIC. However, there is little evaluation in LMIC. In this context it is interesting to mention a Cochrane review on integration of primary care (the ICCC framework could be viewed as a strategy of primary care integration) which concluded that there are very few studies analyzing the impact of integration of primary care on health outcomes and outputs and that they do not provide conclusive evidence that the integration of care provides improved health outcomes; all of the studies identified through the review describe supply side services, and none describe the demand side of care (Briggs and Garner, 2006).

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6 Supply side refers to the offer of health services by institutions or agencies.

7 Although he authors do not define explicitly what they are referring to with ‘demand side’ they mention the lack of including the views of the patients, users, clients and the community as an outcome measure of the integration of health services.
4.4 Why is it relevant to propose a framework for access to medicines and routine care for chronic diseases rather than relying on the already developed frameworks?

i. Most models and interventions developed over the last two decades to reorganize chronic disease management have not explicitly address pharmacotherapy and the challenges of access and affordability. Access to essential medicines and routine care for chronic diseases include some aspects which are unique to the pharmaceutical sector and do require interventions which are not included in already developed generic strategies to strengthen health systems. One example is the required coordination between registration, production, procurement, prescribing and dispensing to guarantee that guideline-stipulated medicines are available and hence, guidelines can be adhered to.

ii. Very few of the models address concerns and challenges of LMIC since most have been developed in high income countries. As mentioned above health systems in LMIC face some common challenges with high income countries, however, there are also unique challenges which need to be addressed and taken into account, such as trained personnel and lack of system financing.

iii. A framework could help to first, identify the essential building blocks and second, to prioritize certain strategies to achieve availability, affordability, and quality care for chronic conditions.

Many of the key elements of a framework related to medicines and their role in chronic diseases should be complementary to other already developed frameworks such as the framework to strengthen health systems which has been proposed by the WHO (2007). We think that, rather than developing a completely new framework for chronic diseases, it is more feasible to propose an adapted framework linking elements of existing frameworks to improve care for chronic conditions with building blocks of existing models of access to care.
5. A proposal for a framework incorporating access to medicines and routine care for chronic diseases

5.1 Development of the access to medicines for chronic conditions (ATMCC) framework

5.1.1 Why a patient/provider/community centered approach for chronic conditions?

The concept of “access” should reflect a patient/provider/community perspective which is better captured in thinking about “barriers”, which patients/healthcare providers and community face when seeking care, or needing to purchase medicines. As we have identified, patients may not have the cash available at the moment they need it, because payments are mainly out-of-pocket, medicines are often much more expensive than they should be (affordability), for a variety of reasons; patients are prescribed or encouraged to purchase expensive medicines, inadequate medicines, wrong medicines; sub-standard medicines; which are poor value for money for their specific condition. “Access” thus necessarily implicates provision of care, attitudes of providers; incentives for providers; supply and distribution of medicines, and incentives for pharmacists, drug vendors. In addition, it needs to engage the community particularly in low resource settings (Walley et al, 2008), an aspect which has been neglected very often.

We have identified crucial aspects of self-management and peer support and the lifelong aspect of continuity of care is also critical. This is linked to adherence. The fact that treatment for diabetes, asthma or depression is often interrupted (for a wide variety of reasons), and likelihood of an acute episode of the disease then much enhanced is an important aspect of chronic conditions which must be captured in a patient-centered approach.

As opposed to adherence/compliance, retention in care stresses the role of the provider in maintaining a link with a patient, and setting up systems to support that, such as defaulter tracing, reminders. The role of information technology systems (even relatively simple ones using mobile telephony) is going to be critical in this regard.

**Self-monitoring of treatment** for some chronic conditions in LMIC where “laboratory services” may be minimal at best, will default to the patient herself. For diabetes, this entails mainly glycaemia monitoring and blood pressure monitoring, both of which can be self-managed, and do not need “laboratory services” (or providers).

5.2 Key Aspects of the ATMCC Framework

We converted the barriers to access to medicines and routine care for chronic conditions into “interventions” designed to overcome them. The resulting “intervention matrix” (Appendix 6) was used as the basis of the adapted framework (Figure 3) focusing on pharmacotherapy and related
routic care for chronic diseases in LMIC. The “patient” domain in the center is surrounded by the policy environment domain, input from one or more health care organizations and input from the community.

**Figure 3: Access to medicines for chronic conditions (ATMCC) Framework**

We leave a detailed discussion of specific interventions to others but will discuss this framework in a general way. The policy, community, and health system building blocks of the framework contain what we believe are important interventions designed to overcome one or more barriers to care/therapy for chronic conditions in LMICs. The directionality of the arrows is primarily ‘one way’ from the policy domain, but bi-directional communication between the patient and the community and healthcare organizations is vital as part of a continuously evolving relationship between the patient and these entities. The bidirectionality between healthcare organizations, patient and community represents the core of the framework. The linking of social mobilization and ICT domains is a potentially powerful synergy (See Section Community below).

The building blocks will be described in more detail below:

**5.2.1 Policy environment (including financing of medicines)**

The policy environment should promote governance and leadership related to access to medicines and routine care for chronic condition. Overcoming barriers such as the availability of cost-effective medicines can not be solved by the health care organization or the community. There is a need to create a policy environment to promote the research and development of cost-effective...
medicines for chronic diseases. Similarly, making medicines geographically accessible, but also affordable is not a task that health care organizations and the community can resolve on their own. Hence, these elements should be located in a building block of the framework that is outside the health care organizations and the community. With respect to the “innovation” component, it is true that most medicines for chronic diseases already exist and are on the Essential Medicines List, available in generic form and are cost effective. However, there are chronic diseases for which cost-effective treatment options are not available (WHO 2004) so that, continuously ensuring treatment options for those conditions for which such options are currently not available is important.

There are a series of policies which have been proposed to improve the affordability of medicines, one is the development of pro-generic medicines regulatory and health policies, including use of TRIPS flexibilities (Musungu and Oh, 2005) as a means of obtaining low cost, quality assured pharmacotherapy.

The inclusion of medicines in insurance packages and expansion of health insurance coverage at a national level is another important policy. However, the role of developing systems to finance medicines goes far beyond the aim of making them affordable and includes providing incentives for their efficient usage. Organizations such as insurance companies can, in principle, provide an important vehicle to implement these incentives and to evaluate their effects. There is ample evidence from high-income countries on the role of insurance systems in various aspects of access to medicines (WHO/HAI, 2011).

Briefly, Product Selection strategies such as formularies, consumer cost-sharing and generic substitution are used by a number of insurance schemes in LMIC. However, there is a little evidence regarding the effectiveness of these strategies in LMIC. Product Purchasing strategies in LMIC suggest that insurers can use formularies to decrease medicines expenditures and reduce utilization of medicines that are less cost-effective. Formularies are likely more effective when coupled with other strategies, such as consumer cost-sharing schemes. Studies also show that, if designed correctly, consumer cost-sharing schemes in LMIC can provide incentives for appropriate, cost-effective use of medicines and potentially reduce total medicine expenditures (WHO/HAI, 2011). Very few insurance schemes in LMIC use active purchasing strategies, such as generic reference pricing or negotiations with the pharmaceutical industry, to obtain lower medicines prices. Reimbursement Design and Contracting strategies include financial incentives that influence medical utilization or provider prescribing and dispensing. In LMIC, there is a general lack of evidence on the extent of use and the impacts of negotiation on price (WHO/HAI, 2011). The use of economic incentives to influence provider (e.g. hospital, doctor, pharmacist, etc.) behaviour is the most common strategy reported in the literature. Evidence suggests that fee-for-service insurance payment systems increase medicines utilization and expenditures in comparison to having no insurance, but most evidence does not assess whether these increases are cost-effective. Utilization Management strategies are: policies that separate prescribing and dispensing or include educational or care management programs directed at both providers and
members. There is a lack of evidence in LMIC on the impacts of utilization management strategies, such as patient and provider education and disease management programs.

5.2.2 Health care organization

For access to medicines and access to care for chronic conditions the areas of service delivery, human resources, medical products management and information systems are of particular relevance (USAID/SPS, 2009).

Service delivery which fosters patient adherence

As adherence is a key to sustainable access to medicines for chronic conditions the service delivery for patient with chronic conditions needs to include organizational strategies to monitor adherence on a routine basis. There is some evidence that monitoring of adherence on a routine base is not only feasible in low-resource settings but also can be an important tool to identify those patients with low adherence and those health care centers and clinics that would benefit from improving their facility performance (Chalker et al, 2010). Monitoring adherence also provides strong self-management support for patients, and peer educators.

Human resources

Providers are a key part of care for chronic conditions. One of the key reasons for barriers to access medicines and related services for chronic care are related to human resources for service delivery. This includes their number, training, tools, incentives, continued education and supervision. The purpose of education, incentive programs, training and the like in this domain is to improve dispensing practices, coordinate clinical guidelines, monitor prescribing practices and improve laboratory services (USAID/SPS, 2009). Most critically, providers of services are crucial to motivate patients and retain them to ensure continuous care.

To change current health care organizations to provide more and better care for chronic diseases human resources are critically as they need to ensure the successful implementation of interventions. However, human resources have been often been overlooked as a critical input to improve quality and efficiency of care for chronic conditions (Nolte and McKee, 2008). Also often seems that the need to develop organizational competencies in addition to developing clinical skills and capacity to engage in new forms of relationships with the patients (Nolte and McKee, 2008). A series of challenges have been identified that need to be addresses in order to increase adequately trained and motivated health care resources: (i) the need to strengthen that role of professional bodies regulating certification of professionals and being involved of accreditation of educational programs, (ii) ensuring synchronization of health systems requirements of professionals with educational institutions, (iii) improve teaching facilities and number and qualification of teachers (Omaswa, 2011). The Pharmaceutical Management Interventions proposed by Management Sciences for Health proposes the incorporation of the private sector in health care delivery for chronic conditions; examples from Ethiopia and Kenya show that training
of private dispensing facilities of antiretroviral medicines can improve the quality of services provided (USAID/SPS, 2009).

**Medical products management**

Good pharmaceutical management is key to achieve sustainable availability of medicines in public health facilities. Although there have been improvements in the last decades in strengthening supply management—many triggered and supported by international funds for HIV—the availability of many essential medicines in public sector facilities is still low (Cameron et al, 2009) in large part because of the barriers listed above in Table 2 (e.g. poor forecasting, no indicators to allow for benchmarking and tracking performance, no or weak decision-tracking tools, technical guidelines and procedures to improve evidence based product selection, weak or no procurement efficiency).

**Information systems which support monitoring of adherence and medicines supply management**

In the ATMCC the “information system” building block has the objective of collecting, reporting and using pharmaceutical data, to support health system decision making at all levels (USAID/SPS, 2009). This includes information that allows monitoring the pharmacotherapy of the patient and other care. In addition, it should include information on prescription filling which would allow evaluating of adherence and contact the patient in case required filling does not occur. A system that allows routine monitoring of adherence seems extremely relevant for chronic conditions; therefore, it should be indispensable for an access framework to medicines and chronic conditions to emphasize the need for such system. Finally, the information system should be linked to supply management and financing as consumption is one of the important elements to estimate needs and plan procurement.

**Laboratory services and/or self management diagnostics which support adequate pharmacotherapy**

For instance, the existence of laboratory services for diagnosis and monitoring of treatment response to many chronic conditions is a prerequisite for comprehensive pharmaceutical management. The President’s Emergency Program For AIDS Relief (PEPRAR) as well as other organizations advocate for the strengthening of laboratory services hand-in-hand with strengthening the pharmaceutical management system (PEPAFAR, 2010; USAID/SPS, 2009). This is certainly one of the lessons of the scale up of HIV/AIDS care that access to treatment can be made more effective if there are functioning laboratories available which provide quality services (Abimiku et al, 2009). Improving laboratory services and promoting accurate diagnostics to manage some chronic conditions (like HIV/AIDS) at community level will save lives and prevent wastage of valuable resources. Increasing levels of resistance to inexpensive, first-line ARVs means that many poor countries must promote new, more expensive treatment. Although, it may seem important to include laboratory services as one of the elements of an adapted framework for access to medicines for chronic conditions, laboratory services are often not available or, if available, only really needed intermittently for other chronic conditions once the condition can be self-managed adequately (e.g., the intermittent need for A1C testing in diabetes).
For instance, screening for undiagnosed diabetes is a low-priority intervention in the general population mainly because of its relatively high cost per life-year gained (Narayan et al., 2006). However, screening for undiagnosed diabetes can be a worthwhile intervention for subpopulation groups, such as those that have a high- or a suspected high prevalence of undiagnosed diabetes (possibly children in the Western Pacific) or for patients with risk factors for other chronic diseases, such as hypertension, high lipid profiles, and prediabetes.

**Primary mental health which treats and prevents mental conditions and fosters patient adherence to medication**

Current evidence is clear that chronic diseases and mental health are linked (Chapman et al., 2005). In addition some authors found that the burden of self-management could itself be a cause of distress since depression could act as a barrier to effective self-management or result from failures of self-management (Bower et al., 2011). Hence it seems increasingly important that mental health care is one of the building blocks in any health care organization that offers care for other chronic conditions (cardio-vascular conditions, diabetes, respiratory diseases, etc). On one side the prevention and treatment of mental conditions could also have a spill-over effect on the health outcomes of other chronic conditions. On the other side, the timely treatment of mental health condition would like result in a reduced burden of chronic disease (Chapman et al., 2005).

**Behavioral and education programs which promotes patient medication adherence**

A series of reviews on interventions to improve health outcomes for patients with chronic conditions found that interventions based on learning theory and models of behavior change can be very effective in achieve desired results for patients and clinicians (see for example Renders et al., 2001; Clarke et al., 2009; Coster and Norman, 2009). Renders et al. (2001) in a systematic review of interventions to improve diabetes care concluded that interventions to target patient can improve care, those intervention that combined education of patient with interventions that facilitated patient adherence. However, which individual elements of a multi-faced intervention are exactly causing the effects is often unknown (Coster and Norman, 2009).

### 5.2.3 Community

**Peer support or care partners to improve self management**

A large number of publications on interventions to improve chronic care and health outcomes have focused on the use of peers (other patients affected by the condition or a similar condition) or of carers to improve self-management. One out of several arguments in favor is that peer or carer support does not mean additional direct costs to the health care organization which is an important aspect, particularly in resource poor settings. However, the evidence of peer support on outcomes (psychosocial well being or symptom control) is limited (Rogers et al., 2008). For instance, a review of lay leader support for patients with chronic conditions found that can improve patient self-efficacy, self-rated health, cognitive symptom management, and frequency of
aerobic exercise but there was no evidence to conclude that it improves psychological health, symptoms or health-related quality of life, or that they significantly alter healthcare use (Foster et al, 2007). The authors concluded that there is a need for studies measuring the long-term effects including the impact on health outcomes.

**Social Mobilization**

How can community support and participation in chronic disease management and care be achieved? Social Mobilization, as defined by UNICEF, is a broad scale movement to engage people's participation in achieving a specific development goal through self-reliant efforts (UNICEF, 2011). It involves all relevant segments of society: decision and policy makers, opinion leaders, bureaucrats and technocrats, professional groups, religious associations, commerce and industry, communities and individuals. Mobilizing the necessary resources, disseminating information tailored to targeted audiences, generating intersectoral support and fostering cross-professional alliances are also part of the process.

Social mobilization has been identified as a key strategy to achieve not only community participation but also leadership. Gupta et al (2008) among other authors described social mobilization as an important element for structural changes. Five elements of social mobilization have been proposed: analysis, engagement, alignment, implementation and evaluation. The first phase aims at analyzing key social drives, the second at the engagement of different groups of the community and the third phase the alignment of different community activities (USAID/SPS, 2009). A prerequisite for the successful execution require the support of national communication campaigns. Social media can be highly instrumental in achieve certain coordination and distribution of information across the society (Cugelman et al, 2011).

The increase in the use of Information and Communication Technology (ICT) services such as mobile phones and the Internet continues unabated as there has been a steady growth of the number of mobile cellular subscriptions, reaching an estimated 4.6 billion by the end of 2009 and a penetration level of 68 per 100 inhabitants globally (United Nations Development Program, 2010). Growth in mobile telephony continues to be strongest in the developing world, where there are now more than twice as many mobile subscriptions as in the developed world (3.2 billion and 1.4 billion, respectively). China and India account for most of the users in the developing countries, with over 1.2 billion subscriptions (about 750 million and 525 million, respectively). Linking the “social mobilization” and ‘information systems’ building blocks is a potentially extremely powerful way of improving access to medicines and routine care for chronic diseases. Through the convergence of wireless technology, the Internet, and mobile devices, mobile health offers a range of technology-enabled innovations that can support patient engagement in their personal health; it can also support chronic disease management through facilitating self management capabilities, including medication adherence, health education, and health information access (Kahn et al, 2010; Quinn et al, 2010). Examples include diabetes software, such as VREE T2DM (http://www.vree-health.com/vhealth/vree-health/faqs.jsp), or integrating self-monitoring by linking measurements of blood pressure with glycaemia devices (Sultan and Mohan, 2009).
Networking and peer support could be facilitated by ICT e.g. for patient support groups, patient associations, patient purchaser groups, and the like. For retention in care, for defaulter tracing, for reminders, appointment systems; patient information systems, all linked to peer support groups. One example from Burkina Faso shows the use of social mobilization to promote vaccination and family planning and demonstrate some positive effects (Cohen, 2007).

However, new and improved ways of communication alone are insufficient to achieve social mobilization, as it is necessary to build a well-defined management structure and to achieve close coordinative planning and implementation.

As formal organizations run by the states often lack skilled staff this implies that the community-based organizations need to be staffed adequately so as to fill the gaps in services that are not provided elsewhere. At the same time there is evidence that most care for people suffering from chronic conditions is delivered by informal care givers including family, friends, neighbors and volunteers from religious or other non-profit organizations (Nolte and McKee, 2008). Adequate staffing would support communities to play a more active role in the prevention and management of chronic conditions.

### 5.2.4 Patient

The patient domain or building block is the end-result of a functioning framework listing a series of ideal patient behaviors, e.g., the patient is encouraged to develop appropriate health seeking behaviours, motivated to self-manage their condition, if that is possible, and as a result, will receive adequate and acceptable care and therapy.

### 5.3 Monitoring and evaluation of progress of access to medicines and quality routine care for chronic diseases

The development of strategies to implement a low-cost monitoring and evaluation mechanism for progress on access to medicines and routine care for chronic diseases is all important. Current surveillance systems –if they exist- are tailored towards disease prevalence and not health care process, output or outcome data (Adeyi, 2007). Several authors have pointed out the relevance of monitoring changes in how countries respond to the growing burden of chronic diseases (Adeyi, 2007). At the same time these authors emphasize the lack of robust data for evaluation of progress in many countries, particularly in health outcomes (Alwan et al, 2010). For instance, a comparison of chronic disease burden between 2000 and 2010 used survey data from Ministries of Health obtaining information about the health systems response to chronic diseases; although most countries’ Ministries of Health responded that they had policies for prevention and treatment of chronic diseases in place and an independent unit dedicated to chronic diseases, an assessment of function and efficiency of implementation was not possible and the results were of limited reliability (Alwan et al, 2010). Regular surveys at national level would be highly relevant to
allow analyzing the effect of policies as well as information systems which allow surveillance (Adeyi, 2007).

Hence, for monitoring and evaluation, the definitions of indicators and their measurement are urgently needed. The WHO has developed indicators to assess the pharmaceutical situation of countries. A set of indicators to evaluate access to medicines and routine care for chronic diseases should be complementary to the already existing indicators. What are indicators unique to measure progress in promoting access to medicines for chronic diseases and their routine care? Currently there is no agreement on a set of common indicators which would allow not only intra-country measurement to evaluate progress but also inter-country/cross country comparison.

Currently the WHO is working on an extended rapid assessment survey based on the original RAPIA survey tool which would be applicable to a wider range of chronic diseases (WHO, 2010). This assessment instrument which was originally developed for diabetes could be a very important generic tool to measure progress on access to pharmacotherapy for chronic diseases in the next years. The survey explores the following topics: health care structure, health financing, health insurance and social security, disease related plans and programs, supply and procurement, resource allocation and availability, price of services and supplies including medicines, treatment and referral. These aspects would be measured in a given country at national, regional and local level. The objective of this new instrument would be to provide relevant information for policy making to promote access to medicines and care for chronic conditions, to allow cross-country comparison and to promote networking among people involved in the provision and collection of data (WHO, 2010). In addition, the measuring affordability of medicines should include both, system as well as household affordability. Finally, we cannot overemphasize the importance of being able to translate the “hard” results of monitoring and evaluation into comprehensible and relevant policy recommendations, a subject well beyond the scope of the present document.

5.4 Concluding remarks

We consider the proposed ATMCC framework as a first attempt to identify key elements which should be in place to guarantee access to medicines and access to care for chronic conditions. We have given particular emphasis to health care organizational and community related aspects in our proposed ATMCC Framework as we think that other aspects such as financing and the existence of cost-effective medicines for treatment is not unique to either chronic or acute conditions.

For many acute diseases the availability of medicines at the point of care and one, or at most a few points in time, seems key to ensure patient recovery. For successful management of chronic diseases, continuous access to medicines should be linked with access to care throughout the course of the disease (Beran et al, 2008). Until the last decade, chronic conditions have not been the priority for many health systems in LMIC and the organizational structures do not support continuity and coordination of medicines and care between different levels of the system.
One of the problems of promoting access to medicines and access to care for chronic conditions in LMIC is the existence of a series of access “barriers” and that these vary in type and importance between different chronic conditions. As these barriers are often interrelated, it is hard to focus on one barrier only as this would not achieve the desired outcome. Hence, an integrated strategy to overcome the series of barriers is required.

For this report we first reviewed existing comprehensive strategies to improve chronic care. Second, we reviewed access barriers to medicines in LMIC for three conditions (diabetes, asthma and depression). Both reviews have contributed valuable elements to the development of the ATMCC Framework.

However, future work on a more advanced framework of ATMCC should include a systematic review of the literature to identify those interventions that have actually improved access to medicines for chronic conditions in LMIC. We think that a defined set of high impact, cost-effective interventions that improve access to medicines should guide the development of version 2.0 of the proposed ATMCC framework.
6. References


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