The Power of WHO in Resource-Limited Settings

- Accessibility of Drugs for Multidrug-Resistant Tuberculosis (MDR-TB) Patients in the Republic of Cameroon -

Master’s Thesis

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<th>Description</th>
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<tbody>
<tr>
<td>ACSM</td>
<td>Advocacy-Communication-Social Mobilization</td>
</tr>
<tr>
<td>AFD</td>
<td>Agence Française de Développement</td>
</tr>
<tr>
<td>ALES</td>
<td>Aide aux Lépreux-Emmaus Suisse</td>
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<tr>
<td>Am</td>
<td>Amikacin</td>
</tr>
<tr>
<td>Amx/Clv</td>
<td>Amoxicillin/Clavulanate</td>
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<tr>
<td>BCG</td>
<td>Bacille Calmette-Guérin</td>
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<tr>
<td>BMRC</td>
<td>British Medical Research Council</td>
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<tr>
<td>CAPP</td>
<td>Center of Pharmaceutical Products Supply</td>
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<tr>
<td>CDC</td>
<td>U.S. Centers for Disease Control and Prevention</td>
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<tr>
<td>CENAME</td>
<td>National Center for Supply of Consumables and Essential Drugs</td>
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<tr>
<td>Cfz</td>
<td>Clofazimine</td>
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<tr>
<td>CIDA</td>
<td>Canadian International Development Agency</td>
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<tr>
<td>CIM</td>
<td>Centre for International Migration and Development</td>
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<tr>
<td>Clr</td>
<td>Clarithromycin</td>
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<td>Cm</td>
<td>Capreomycin</td>
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<td>Cs</td>
<td>Cycloserine</td>
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<tr>
<td>CXR</td>
<td>Chest X-ray</td>
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<tr>
<td>DED</td>
<td>German Development Service</td>
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<tr>
<td>DFID</td>
<td>UK Department for International Development</td>
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<tr>
<td>DOT</td>
<td>Directly Observed Treatment</td>
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<tr>
<td>DOTS Strategy</td>
<td>Directly Observed Treatment, Short-course Strategy</td>
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<td>DOTS-Plus</td>
<td>Directly Observed Treatment for MDR-TB Cases Strategy</td>
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<tr>
<td>DST</td>
<td>Drug-susceptibility Testing</td>
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<td>DTCs</td>
<td>Diagnosis and Treatment Centers</td>
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<td>E</td>
<td>Ethambutol</td>
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<tr>
<td>EBM</td>
<td>Evidence-based Medicine</td>
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<td>E.LILLY</td>
<td>Eli Lilly</td>
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<tr>
<td>Eto</td>
<td>Ethionamide</td>
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<tr>
<td>FAQ</td>
<td>Frequently Asked Questions</td>
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<tr>
<td>F.CFA</td>
<td>Central African Franc</td>
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<td>FLDs</td>
<td>First-line Drugs</td>
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<tr>
<td>GATES</td>
<td>Bill &amp; Melinda Gates Foundation</td>
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<tr>
<td>Acronym</td>
<td>Full Form</td>
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<td>---------------------------------------------------------------------------</td>
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<tr>
<td>GAVI</td>
<td>Global Alliance for Vaccines and Immunization</td>
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<td>GDF</td>
<td>Global Drug Facility</td>
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<tr>
<td>GDP</td>
<td>Gross Domestic Product</td>
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<tr>
<td>GFATM</td>
<td>Global Fund to Fight AIDS, Tuberculosis and Malaria</td>
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<tr>
<td>Gfx</td>
<td>Gatifloxacin</td>
</tr>
<tr>
<td>GLC</td>
<td>Green Light Committee</td>
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<td>GLI</td>
<td>Global Laboratory Initiative</td>
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<td>GTZ</td>
<td>German Technical Cooperation</td>
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<tr>
<td>H</td>
<td>Isoniazid</td>
</tr>
<tr>
<td>HDI UNDP</td>
<td>Human Development Index of the United Nations Development Programme</td>
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<tr>
<td>HIPC</td>
<td>Heavily Indebted Poor Countries</td>
</tr>
<tr>
<td>HSS</td>
<td>Health Sector Strategy</td>
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<tr>
<td>IDA</td>
<td>International Dispensary Association</td>
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<tr>
<td>IDP</td>
<td>Internally Displaced Person</td>
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<tr>
<td>IGRA</td>
<td>Interferon Gamma Release Assay</td>
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<tr>
<td>IMF</td>
<td>International Monetary Fund</td>
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<tr>
<td>Ipm/Cln</td>
<td>Imipenem/cilastatin</td>
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<tr>
<td>KfW</td>
<td>Reconstruction Loan Corporation</td>
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<tr>
<td>Km</td>
<td>Kanamycin</td>
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<tr>
<td>Lfx</td>
<td>Levofoxacin</td>
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<tr>
<td>LRRD</td>
<td>Linking Relief, Rehabilitation and Development</td>
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<td>Lzd</td>
<td>Linezolid</td>
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<tr>
<td>MDGs</td>
<td>Millennium Development Goals</td>
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<tr>
<td>MDR-TB</td>
<td>Multidrug-Resistant Tuberculosis</td>
</tr>
<tr>
<td>Mfx</td>
<td>Moxifloxacin</td>
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<tr>
<td>MoPH</td>
<td>Ministry of Public Health</td>
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<tr>
<td>MOU</td>
<td>Memorandum of Understanding</td>
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<tr>
<td>MSF</td>
<td>Médecins sans Frontières</td>
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<tr>
<td>NGO</td>
<td>Non-Governmental Organization</td>
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<tr>
<td>NTCC</td>
<td>National Tuberculosis Control Committee</td>
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<tr>
<td>NTCP</td>
<td>National Tuberculosis Control Program</td>
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<tr>
<td>ODA</td>
<td>Official Development Assistance</td>
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<tr>
<td>Ofx</td>
<td>Ofloxacin</td>
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<tr>
<td>Acronym</td>
<td>Full Form</td>
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<tr>
<td>OGAC</td>
<td>Office of the U.S. Global AIDS Coordinator</td>
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<tr>
<td>PAS</td>
<td>Para-aminosalicylic Acid</td>
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<tr>
<td>PIH</td>
<td>Partners In Health</td>
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<tr>
<td>PRS</td>
<td>Poverty Reduction Strategy</td>
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<tr>
<td>PRSP</td>
<td>Poverty Reduction Strategy Paper</td>
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<tr>
<td>Pto</td>
<td>Protionamide</td>
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<td>R</td>
<td>Rifampicin</td>
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<tr>
<td>RDPC</td>
<td>Rassemblement Démocratique du Peuple Camerounais</td>
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<tr>
<td>Rfb</td>
<td>Rifabutin</td>
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<td>S</td>
<td>Streptomycin</td>
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<td>SAPs</td>
<td>Structural Adjustment Programs</td>
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<td>SDF</td>
<td>Social Democratic Front</td>
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<td>SLDs</td>
<td>Second-line Drugs</td>
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<td>SWAp</td>
<td>Sector Wide Approach</td>
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<tr>
<td>TB</td>
<td>Tuberculosis</td>
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<tr>
<td>TB-CTG</td>
<td>Tuberculosis Central Technical Group</td>
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<tr>
<td>TB-HIV</td>
<td>Co-infection of Tuberculosis and HIV/AIDS</td>
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<tr>
<td>The UNION</td>
<td>International Union Against Tuberculosis and Lung Disease</td>
</tr>
<tr>
<td>Thz</td>
<td>Thioacetazone</td>
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<tr>
<td>Trd</td>
<td>Terizidone</td>
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<tr>
<td>UN</td>
<td>United Nations</td>
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<tr>
<td>UNFPA</td>
<td>United Nations Populations Fund</td>
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<tr>
<td>UNICEF</td>
<td>United Nations Children’s Fund</td>
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<tr>
<td>USAID</td>
<td>United States Agency for International Development</td>
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<tr>
<td>WCC</td>
<td>World Care Council</td>
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<tr>
<td>WHO</td>
<td>World Health Organization</td>
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<tr>
<td>XDR-TB</td>
<td>Extensively Drug-resistant Tuberculosis</td>
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<td>Z</td>
<td>Pyrazinamide</td>
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1. Introduction

Within the introduction, the problem statement and the research question, the state of the art and goal of the study as well as the link between multidrug-resistant tuberculosis (MDR-TB) and humanitarian assistance are described and a reader’s guide is given.

1.1 Problem Statement and Research Question

“Tuberculosis (TB) is the number one single infectious disease killer (highlighted in the original), taking nearly [1.3] million lives per year. So great is concern about TB that in 1993, the World Health Organization (WHO) declared TB a ‘global emergency’ (qtd. in the original)” (NFID, “Factsheets: Tuberculosis: A Global Emergency”). Every second, a person is newly infected with TB around the world and an estimated one-third of the global population carries the TB pathogen. Hereof, five to ten percent will, at some point in their lives, develop an active TB disease (WHO, “What is TB?”).

For the year 2008, the WHO estimated that about 9.4 million individuals developed TB, augmenting to a total of 11.1 million existing active cases (WHO, “Factsheets: Tuberculosis”). Between 95 and 98 percent TB deaths occur in developing nations - to 75 percent among the performing age group (15 to 50 years) – while these encompass 25 percent of all preventable adult fatalities in developing nations (WHO, “Tuberculosis Care and Control in Refugee and Displaced Populations”). The incidence rate of newly infected cases per capita peaked with about 350 cases per 100,000 population in Sub-Saharan Africa (compared to about 180 cases per 100,000 population in South-East Asia), where additionally the largest mortality rate per capita caused by TB was observed (WHO, “Factsheets:
Tuberculosis”). Moreover, in the last two decades, MDR-TB\(^1\) emerged, more recently followed by extensively drug-resistant tuberculosis (XDR-TB)\(^2\) and lately by totally drug-resistant tuberculosis. This challenges the management of TB due to an increasing probability of obtaining a stage, where no treatment is effectively functioning. Accordingly, of these 11.1 million existing active cases, about 440,000 individuals were infected with MDR-TB strains. Hereof, solely 7 percent were detected and subsequently reported to WHO. Further, of these 30,800 cases only one-fifth (6,160 cases) were medically cared for, in accordance with the central principles of WHO outlined in its *Guidelines for the Programmatic Management of Drug-resistant Tuberculosis*. This translates into proportion of 1.4 percent treated by international standards cases of the MDR-TB infected worldwide, while its lethality was about 150,000 deaths in 2008. If this trend cannot be curbed, MDR-TB raises the risk of becoming the prevailing TB type (Gandhi et al. 1830/1831).

In 2000, WHO set-up a global health-based partnership institution, named the Green Light Committee (GLC), for which WHO also serves as a permanent affiliate and Secretariat. The GLC fosters access to high-quality second-line drugs (SLDs) against MDR-TB through subsidization and concessional loans. For receiving these quality-guaranteed and concessional priced SLDs, a National Tuberculosis Control Program (NTCP) has to apply to the GLC, which in-turn approves these applications solely on condition of the conformity of their treatment schemes for MDR-TB with the principles outlined in the *Guidelines for the Programmatic Management of Drug-resistant Tuberculosis* of WHO (Gupta et al., “Increasing Transparency in Partnerships for Health” 970, 972). In addition, in early 2002, the Global Fund to Fight AIDS, Tuberculosis and Malaria (GFATM), demanded that any funding application of a NTCP for SLDs against MDR-TB as well as their procurement ought to be solely processed by the GLC. Notably, most NTCPs in countries with a high MDR-TB burden, particularly transitional and developing countries are primarily funded by the GFATM (Nathanson et al. 1395). As the drugs of complete treatment regimen for one MDR-TB patient cost on average between 16,000 and 19,000 US-dollars in high-income countries and between 5,000 and 7,000 US-dollars in low-income countries, particularly low-income countries are reliant on executing treatment regimens with concessional-priced and quality-guaranteed SLDs from the GLC or GFATM that cost on average for one MDR-TB case

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1 Multidrug-resistant tuberculosis (MDR-TB) is defined as resistance of the *M. tuberculosis* to at least two of the most important anti-TB medications isoniazid (H) and rifampicin (R) (Gandhi et al. 1830).

2 Extensively drug-resistant tuberculosis (XDR-TB) is defined as resistance of *M. tuberculosis* to H and R, “… any fluoroquinolone, and one of the three injectable drugs, capreomycin, kanamycin and amikacin” (Gandhi et al. 1830).
between 1,000 and 2,000 US-dollars (Gupta et al., “Responding to Market Failures” 1049). On the contrary, treatment alternatives presently exist as shown by the remarkable observational study among new MDR-TB patients with an HIV-negative status in the resource-poor setting of Bangladesh from May 1997 to December 2007 of van Deun et al., whereof its first results were published in August 2004 and its final outcomes in May 2010. In general, this study presented a 9-month long treatment regimen for MDR-TB with an overall healing rate of 87.9 percent for the costs of about 225 Euros per MDR-TB patient (2-8, 12, 15-19, 30, 38); compared to the 18- to 24-month long treatment regimen for MDR-TB with an overall success-rate solely between 54 and 69 percent for the costs up to 19,000 US-dollars outlined by the central principles WHO (cf. WHO, “Guidelines for the Programmatic Management”). The Republic of Cameroon bases its alternative standardized treatment regimen “4KmGfxPtoHCfzEZ/ 8GfxPtoCfzEZ” for new MDR-TB patients on this study of van Deun et al. However, when the NTCP of Cameroon applied for quality-guaranteed and concessional-priced SLDs for its standardized treatment regimen for MDR-TB to the GLC (NTCP Cameroon, “Application to the GLC March 2008”), the GLC rejected this application, as this treatment regimen is not in conformity with the central principles of WHO. Thus, it can be assumed that for transitional and developing countries, the

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3 To my knowledge, has proofed the superiority of the WHO recommended standardized treatment scheme for MDR-TB versus alternative ‘experimental’ standardized short-term regimens for the treatment of MDR-TB cases. For a more detailed discussion hereon, see section 4.2 (A/N).

4 In 2004, the first results of this long-term study of van Deun et al. were already published under the title “Results of a Standardised Regimen for Multidrug-resistant Tuberculosis in Bangladesh” in the renowned International Journal of Tuberculosis and Lung Disease. Since this point in time, short, highly effective and inexpensive standardized treatment regimens for MDR-TB patients as an alternative to the central principles outlined in the Guidelines for the Programmatic Management of Drug-resistant Tuberculosis of WHO have been recognized and discussed (A/N).

5 The Republic of Cameroon is located in the Central African region and has a land area of approximately 475,000 km² with an estimated 19 million inhabitants in early 2010 (Auswaertiges Amt, “Kamerun”). On the topic of its diverse geography, it is frequently characterized as “Africa in Miniature” and its climate is defined as tropical (The CIA Worldfact Book: “Cameroon”). Since 1st January 1960, Eastern Cameroon is independent from the French colonial rule, whereas the British dominated area of Western Cameroon followed on 1st October 1961. On 20th May 1972, both parts were united under the Republic of Cameroon. The current form of state is described as a presidential regime with the “Rassemblement Démocratique du Peuple Camerounais (RDPC)” being the governing party and its administrative structure is illustrated as a centralized state with 10 regions (Auswaertiges Amt, “Kamerun”). Cameroon has a capitalist economic system with a Gross Domestic Product (GDP) per capita of 1,116 US-dollars in 2007. Moreover, it is in the lowest fifth of countries with a medium human development. This implies that presently about one-third of Cameroonians live below the international poverty line of 1.25 US-dollars per day being reliant on annual Official Development Assistance (ODA) (UNDP, “Human Development Report 2009”). With regards to the demographic profile of the Republic of Cameroon in 2008, the life expectancy at birth was 51 years being reflected in the annual crude death rate of 14 per 1,000 individuals, the under-five mortality ratio of 131 and the total fertility rate of 4.6 births per woman (UNICEF, “Info by Country: Cameroon: Statistics”).

6 The habitually used abbreviation for standardized TB treatment regimens reads as follows: the Arabic numbers in front of the abbreviated anti-TB drugs indicate the duration in months of the two - intensive and continuation - phases of treatment separated by the punctuation mark of a slash (A/N).
establishment of an NTCP including alternative MDR-TB treatment regimen is virtually impossible, if these do not respect the central principles of WHO and do not have an alternative donor organization for support. Out of this context arises the overall research question of this study: “Is Access to Drugs for Multidrug-Resistant Tuberculosis (MDR-TB) Patients in the Republic of Cameroon Restricted as a Result of International Health Policy Guidelines?”

1.2 State of the Art and Goal of the Study

Within this study, the theoretical concept of the policy analysis triangle of Walt and Gilson is applied to the overall hypothesis “Access to Drugs for Multidrug-Resistant Tuberculosis (MDR-TB) Patients in the Republic of Cameroon Is Restricted as a Result of International Health Policy Guidelines” of this thesis. This general theoretical concept arises from the scientific article of Walt and Gilson 1994 as well as a chapter of monograph of Buse, Mays and Walt 2007. The central elements of this policy analysis triangle, the context, the process and the actors are underlined accordingly by the works of Leichter 1979, Sabatier and Jenkins Smith 1993, as well as Varvasovszky and Brugha 2000. The study of Trostle et al. 1999, which describes the connection between health researchers and health policymakers via the four health programs of HIV, cholera, family planning and immunization in the Mexican Republic, utilizes the health policy triangle of Walt and Gilson as a holistic analytical framework. It becomes apparent that for coping with some main contemporary health challenges, for instance the increasing resistance to anti-TB drugs, the identification of the link between health policies and its implementation is essential (Buse, Mays, and Walt 5). To date, most of the research has been undertaken in industrialized countries. In developing countries, as illustrated, the analysis of policies and their implementation according to the theoretical concept of Walt and Gilson has been extremely limited with this one recognized study (cf. Walt and Gilson 353); thus, there is a demand for further research in this field. Accordingly, with the application of the policy analysis triangle of Walt and Gilson as a holistic analytical framework to the central principles for the treatment of MDR-TB of the specialized United Nations (UN) agency for health, WHO, affecting the case study of a developing country, the Republic of Cameroon, this study intends to compensate this research shortfall.

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7 A policy is defined as “[a broad] statement of goals, objectives and means that create the framework of activity” (Buse, Mays, and Walt 4).
8 “[Health] policy is assumed to embrace courses of action (and inaction) that affect the set of institutions, organizations, services and funding arrangements of the health system” (Buse, Mays, and Walt 6).
The description from agenda-setting to the conceptualization of the policy process mainly builds on the journal articles of Atun et al. 2010, Ghandi et al. 2010, Gupta et al. 2002, Nathanson et al. 2006, Ogden, Walt and Lush 2003, as well as Raviglione and Uplekar 2006; to ultimately reach at the Guidelines for the Programmatic Management of Drug-resistant Tuberculosis of WHO updated in 2008, which form the contemporary central principles of the treatment scheme for MDR-TB patients and hence, the content dimension of the policy. The illustration of the NTCP of the Republic of Cameroon is based on its program’s publication by the Ministry of Public Health (MoPH) of the Republic of Cameroon of 2004, and the journal contribution of Kuaban and Noeske. For the first time in this study, an analysis of the impact of the application of the central principles for the treatment of MDR-TB of WHO via the GLC and GFATM on an NTCP of resource-limited country, hereby exemplary with the help of the case study of Cameroon, is conducted.

In the year 2001, a journal contribution by Cullinan briefly criticized the contemporary power allocation resulting from international health policies for MDR-TB that are predominantly implemented in transitional and developing countries. This unfolding discussion, however, was not publicly continued for the following years. This present state of the art highlights the necessity of an intensive study of this subject. Therefore, this research picks up this critical discourse by inter alia referring to the final outcomes of the study of van Deun et al. published in 2010, to a journal editorial of Andrew Nunn 2010, as well as to the two applications of the NTCP of Cameroon to the GLC in 2008 and its responses by the GLC, and further elaborates and innovates it.

To conclude, the overall goal of this study is to assess the influence of the central principles of the treatment scheme for MDR-TB outlined in the Guidelines for the Programmatic Management of Drug-resistant Tuberculosis of WHO within the field of International Health Policy on the access to drugs for MDR-TB patients in resource-limited settings with the help of the policy analysis triangle and the case example of the Republic of Cameroon.

1.3 MDR-TB in Humanitarian Assistance

Within the third implementation approach “[to address] prisoners, refugees and other high-risk groups and situations” (WHO, “Stop TB Strategy” 6) one of the main activities to meet the second component is “[to address] TB/HIV, MDR-TB and other challenges” (WHO, “Stop TB Strategy” 6) of the present Stop TB Strategy of 2006, the link between MDR-TB and humanitarian assistance becomes apparent (WHO, “Stop TB Strategy” 6). These special
populations groups are particularly at risk to develop MDR-TB due to the following factors: their socio-economic situation, for instance overcrowding and limited access to health institutions, their health situation including a mal- or deficient nutritional status and poor medical conditions, such as measles or HIV/AIDS as well as their migration (WHO, “Stop TB Strategy” 13). In more detail, living in overcrowded sites, e.g. camps, informal settlements or prisons, facilitates the communication of TB and MDR-TB, the so called primary resistance. As these groups are frequently mal- or undernourished resulting into a deficient immune system, they are at higher risk of developing TB. This risk is further increased when holding a positive HIV-status. Notably, in developing and transitional countries, TB is the principal underlying cause of the morbidity and mortality rate connected to HIV; in particular, in a number of nation-states in Sub-Saharan Africa, the co-infection rate of TB patients with HIV is as high as 70 percent and in this region, the expanding TB illness is predominantly attributed to the rising HIV-incidence. Ultimately, TB has been observed to be a central cause of illness and death among refugee and IDP populations, for instance in Sudan in 1985, Kenya in 1994 and Ingushetia in 2000.

In addition, special populations, such as refugees and IDPs as well as prisoners, are more prone to TB treatment failures than stable populations because of their mobility. In turn, cases of TB treatment failure are known to have a higher chance of developing MDR-TB. Even though, in view of this fact and furthermore drug-resistance to anti-TB medications is increasing worldwide and thus affecting effective TB management programs in humanitarian emergency situations, the challenge of MDR-TB is not prioritized due to its multifaceted and costly treatment. Herein, an MDR-TB outbreak is prevented by assuring a well-functioning program against drug-susceptible TB (WHO, “Tuberculosis Care and Control in Refugee and Displaced Populations” 2, 4, 6-7).

Since the issuance of the Communication from the Commission to the Council and the European Parliament on Linking Relief, Rehabilitation and Development (LRRD), COM(96) 153 final of the European Commission (EC) on 30th April 1996, the concept of “Linking Relief, Rehabilitation and Development (LRRD)” was initiated in the field of humanitarian assistance. With this communiqué, the EC emphasized the status quo at the time and highlighted gaps and overlaps between the humanitarian and development sphere. The LRRD concept recognizes the interface, the so-called transitional phase or “grey zone”, between

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9 For further information on this subject, see the journal article of Schaible and Kaufmann (A/N).
10 For a more detailed explanation of the correlation between HIV- and TB-infection, see page 4-6 of this field manual Tuberculosis Care and Control in Refugee and Displaced Populations of WHO (A/N).
short-term humanitarian assistance solely aiming at saving lives immediately after the occurrence of an emergency, and long-term development cooperation as a support to the economic, political and social rebuilding of a state. Thus, it encourages development cooperation already pre-, in and post-disaster to hence support relief operations (EC, Commission of the European Communities, “LRRD – An Assessment” 3). For refugee and IDP populations, TB cure and control programs commence once the primary health system is set up and/or accessible. With the aim of being sustainable, these programs address the NTCP of the respective host nation already during the humanitarian emergency, and thus adhere to the LRRD-approach. Hereby, if possible, the NTCP of the host country is gradually expanded to these risk groups to guarantee timely commencement or completion of an effective TB treatment, while considering information and measures about the NTCP of the country of origin. Finally, this element is additionally crucial as a hand-over of the TB cure and control program for refugee and IDP populations to the NTCP of the host-country is envisaged in a post-disaster context (WHO, “Tuberculosis Care and Control in Refugee and Displaced Populations” 52-53, 59, 63).

In the case example of the Republic of Cameroon in January 2010, there were approximately 100,000 refugees of which about 85 percent are from the Central African Republic, 10 percent from Chad and 5 percent of various origins. These refugees reside mainly in settlements along the Eastern and Northern border of Cameroon, where the malnutrition rate for children under five years of age is as high as 7.2 percent and access to primary health care facilities is limited (UNHCR, “Cameroon”). Moreover, there are presently about 23,000 inmates in 73 prisons of the Republic of Cameroon, whereof an estimated five to ten percent are so-called “political detainees” (Noeske, “Health Behind Bars” 1), who are considered as enemies by the dictatorial Cameroonian government (cf. ICRC, “Why Does the ICRC Visit Prisoners?”). In general, these prisoners live in overcrowded cells with poor hygienic conditions, having limited access to health services, and among them the rates of malnutrition and HIV are high (Noeske, “Health Behind Bars” 1). As a result of their status and these poor living conditions, they are in need of humanitarian assistance (cf. ICRC, “Why Does the ICRC Visit Prisoners?”). In collaboration with the NTCP of Cameroon, currently about 40 percent of the inmates are covered by the so-called “TB and HIV Prison Initiative” including prevention, treatment and care of these two communicable diseases (Noeske, “Health Behind Bars” 2).

To conclude, this study is considering the link between humanitarian assistance and MDR-TB by discussing the access to drugs for the treatment of MDR-TB within the NTCP
of the Republic of Cameroon and the frame of international health policy guidelines of all population groups, including refugees and IDPs as well as prisoners.

1.4 Reader’s Guide

In the following section of this study, the methodology approach of this study, including the collection of data, its analysis by utilizing the theoretical concept of the policy analysis triangle of Walt and Gilson, and its limitations are described. Subsequently, the dimensions of this policy analysis triangle serve as an analytical framework. Thus, it is applied onto the case study of the Republic of Cameroon within the consecutive sub-sections of context, process, actors and content. Thereafter, the discussion is outlined with the help of three critical arguments. In the concluding section of this study, the overall research question is answered by summarizing the policy analysis of the international health policy guidelines and their impact on the case study of the Republic of Cameroon, and by offering recommendations for prospectively ameliorating the current situation of the access to drugs for MDR-TB patients in particular in the Republic of Cameroon and in general in transitional and developing countries worldwide.

2. Methodology

Within the methodology chapter, the general methodological approach, the methods of collection and analysis of data as well as the limitations of the applied methodology are included.

2.1 Methodological Approach

The methodological approach applied to test the overall hypothesis of this thesis “Access to Drugs for Multidrug-Resistant Tuberculosis (MDR-TB) Patients in the Republic of Cameroon Is Restricted as a Result of International Health Policy Guidelines” can be characterized as a qualitative observational case study applying the theoretical concept of the policy analysis triangle of Walt and Gilson.

In more detail, the methodological approach of a qualitative analysis including non-metric data accumulated via a quasi-experimental design (observation) is utilized in this thesis (cf. Mayring 190, 192), due to the situation that this social science research area - of treatment for MDR-TB patients directed by international health policy guidelines - has previously hardly been explored and information hereon is extremely limited. Therefore, a
single case study on the access to medications for MDR-TB patients directed by the international health policy guidelines in the Republic of Cameroon is conducted. This choice is based on the fact that the explanatory range of each theoretical concept or theory can be assessed via the two methods of experimentation and observation (van Evera 27). Taking into account that “[in the field of] political science experiments are seldom feasible … observation as [the] prime method of testing” (van Evera 29) results. Hereby, an observational research design is based on either large-n analysis or case studies depending on the quantity of available information hereon. The selection of an observational research design based on a few (or a single) case studies is further underlined by its two advantages: first, case studies offer unique empirical data to assess the explanatory power of a theory and second, these provide detailed empirical data on the causal process portrayed by a theory. As a result, in political science, an observational research approach based on case studies is the principal method for assessing and deducing from theoretical explanations when sufficient information is recorded hereon (van Evera 29, 54/55).

Pursuant to van Evera, about six of eleven criteria may guide the decision to select a case in order to test the explanatory range of a theory. Hence, conferring to van Evera, the case study of the Republic of Cameroon was chosen for the following reasons:

1. The overall data on this case study is sufficiently recorded and international experts are willing to provide further information on specific sub-themes hereon.

2. In general, “[it] is often argued that one should select cases that are representative or typical of the universe of cases” (van Evera 79). On the contrary, according to van Evera, a case example should be selected that is a-typical as the explanatory range of the theory is assessed strongly by a unique case. Likewise, the expected results encompass extreme values, which are improbable to derive from other intervening factors than included in the case study. Hence, in this thesis, the Republic of Cameroon was chosen due to its promising exceptional 12-month standardized treatment regimen against MDR-TB.

As per van Evera, “[the] following case attributes are possible reasons for case selection: (1) data richness, (2) extreme values on the independent variable, dependent variable, or condition variable; (3) large within-case variance in values on the independent, dependent, or condition variable; (4) divergence of predictions made of the case by competing theories; (5) the resemblance of case background conditions to the conditions of current policy problems; (6) prototypicality of case background conditions; (7) appropriateness for controlled comparison with other cases …; (8) outlier character; (9) intrinsic importance; (10) appropriateness for replication of previous tests; and (11) appropriateness for performing a previously omitted type of test” (77/78). Hereof, solely criteria number 1, 2, 3, 5, 10, and 11 are applied when testing a theory (van Evera 88).
3. The case study of Cameroon represents contemporary unfolding discussions about the critics on international policies for MDR-TB implemented in transitional and developing countries within the area of global health governance.

4. In prospect, with the help of this case example, the explanatory power of the theoretical concept may be tested. Subsequently, it can be discussed in how far the observations of this study together with either further case studies of other resource-limited countries, or with other related topics within the social science field of health, e.g. HIV/AIDS, can be generalized to similar situations (cf. van Evera 77-88).

In summary, the rationale for selecting the case of access to drugs for MDR-TB patients directed by the international health policy guidelines of the Republic of Cameroon to test the theoretical concept of the policy analysis triangle of Walt and Gilson is that it highly serves the objective of this thesis while fulfilling four of six criteria that may guide the decision of a case-selection outlined by van Evera.

2.2 Collection of Data

To enhance the reliability of the data collected in this thesis and the validity\(^{12}\) of its research results, herein triangulation\(^{13}\) as multiple methods of a literature-review, qualitative unstructured interviews with international experts and the approach of applying the policy analysis triangle of Walt and Gilson are performed (cf. Silverman 132/133). Moreover, triangulation was selected to further increase the quantity of data on this innovative research topic of restricted access to drugs for MDR-TB patients in the Republic of Cameroon as a result of international health policy guidelines.

For this thesis, principally the method of a literature-review is applied by mainly utilizing scientific journal articles, reports, official documents, and acknowledged websites for the description of the case example, as well as chapters of books for the theoretical concept. Furthermore, with regards to the critical analysis section that was developed from the case study, unstructured interviews with five international experts in the field of international health policy guidelines and MDR-TB were conducted, and application documents of the Cameroonian NTCP and the response to these applications from the GLC were reviewed.

\(^{12}\) Validity is defined as “[the] extent to which an indicator measures what it intends to measure” (Green and Browne 167).

\(^{13}\) Triangulation is defined as “[using] different data sets, methods or approaches to improve the validity of findings” (Green and Browne 167).
For acquiring this literature, the following search strategy was applied. Initially, the theory was acquired via the fundamental textbook *Making Health Policy* of Buse, Mays and Walt out of the series “Understanding Public Health” edited by staff of the London School of Hygiene and Tropical Medicine. With regards to the pathology of TB, the websites of the WHO and the Centers for Disease Control and Prevention (CDC) were searched, and literature recommendations by two physicians knowledgeable about TB were considered. Respecting the pyramid search scheme, the bibliographies of these reference works were looked at to determine lacking information. Thereafter, for information about international health policy guidelines for the treatment of MDR-TB, the PubMed database of the U.S. National Library of Medicine and the National Institutes of Health, which contains literature from MEDLINE, life science journals and web-based books, was searched with the following terms in different combinations: multidrug-resistant tuberculosis (MDR-TB), World Health Organization (WHO) and Green Light Committee (GLC) (for a list of search words see annex 1). Moreover, the search-engine googlescholar via the proxy of the University of Groningen and the search functions of the scientific journals, The Lancet and The International Journal of Tuberculosis and Lung Disease, were additionally explored for these words. Also, all the volumes of the last two years of the latter journal were screened for obtaining a detailed knowledge on the status quo in this field. Furthermore, referring to the pyramid search scheme, each institution’s website, e.g. of the WHO, the GLC, the Stop TB Partnership, or the Global Drug Facility (GDF), was regarded. Third, for the case study of the Republic of Cameroon, the information of certain well-known websites was used to form the geopolitical country background. Consecutively, via the search engine googlescholar, the present literature found with the key words Health Sector and Cameroon was obtained from the year 2005 onwards. Additionally, the bibliographies of the scientific journal articles were searched for further citations, and the website of WHO provided statistical data. Besides, the information on national health policy guidelines for the treatment of MDR-TB was gained via a search of the website of the MoPH of Cameroon and references suggested by the “German-Cameroonian Health-/HIV-Programme” of the German Technical Cooperation (GTZ). For the section on the TB treatment regimen in Cameroon additionally to these reference works, the international expert number 111\textsuperscript{14}, knowledgeable in the field of treatment for MDR-TB patients, commented hereon. The critical analysis was generated from the knowledge attained

\textsuperscript{14} To preserve the anonymity of the international experts, their names are not mentioned in this thesis. However, to provide sufficient information for further assessment of these sources, their backgrounds are mentioned within this chapter 2.2, and their unstructured nameless interviews can be found in annex 2 (A/N).
in the previous chapters of this thesis. Moreover, the first 100 references resulting from the search on google scholar with the following key words: pharmaceutical industry, influence, World Health Organization (WHO), and Green Light Committee (GLC) were assessed. Also, unstructured qualitative interviews including particular questions on the power allocation in the international governance system for MDR-TB, on the restrictions that international health policy guidelines pose on the NTCP of Cameroon, as well as on the reasons for this situation were conducted with four international experts from the following backgrounds: number 111 and 444 are professional in the field of treatment for MDR-TB patients, number 222 is in charge of supply of anti-TB drugs and number 333 ensures the implementation and follow-up of TB programs; for their unstructured nameless interviews see annex 2. Hence, their selection accounted for different perspectives on the same sub-topics covered by the unstructured interviews. Finally, the application documents of the Cameroonian NTCP and the response to these applications from the GLC were utilized (cf. Mukherjee et al. 474).

2.3 Analysis of Data

The conceptual theoretical framework that serves the discussion of the overall hypothesis of this thesis, based on an analysis of the gathered data, is the policy analysis triangle of Walt and Gilson. This framework encompasses the four factors: context, content, process and actors to illustrate policy change, particularly of health policy, over time (see fig. 1) (Buse, Mays, and Walt 4).

![Figure 1. The Analytical Framework of the Policy Analysis Triangle from Walt and Gilson 354](image)

Herein, the interplay between these four factors is displayed (Buse, Mays, and Walt 9), as actors – the who – are engaged in policy change, while the process – the how – focuses on the conceptualization and application of this policy and the context provides the background to
this policy change that is characterized via its content – the what – (Walt and Gilson 353/354). Thus, the four factors are defined as follows:

- The context is defined via “[systemic] factors – political, economic, social or cultural, both national and international – which may have an effect on health policy” (Buse, Mays, and Walt 4).

- An actor is a “[short-hand] term used to denote individuals, organizations or even the state and their actions that affect policy” (Buse, Mays, and Walt 4).

- The policy process is defined as “[the] way in which policies are initiated, developed or formulated, negotiated, communicated, implemented and evaluated” (Buse, Mays, and Walt 4).

- The content is defined as the “[substance] of a particular policy which details its constituent parts” (Buse, Mays, and Walt 4).

Consequently, international, national or local actors are affected by their surrounding context. The context is influenced by numerous external and internal political, economic, cultural or environmental aspects. The process is additionally affected by the activities of the actors, who frame and apply policies, operating within the context. Finally, the content of the health policy change results from these the complex interplay of these factors (Walt and Gilson 355, 359).

The analysis of policy via this theoretical concept can be conducted retrospectively or prospectively. An assessment of the policy is retrospective, whereas planning of a policy is prospective. Consecutively, an assessment of policy facilitates proposing a policy (Buse, Mays, and Walt 16/17). Accordingly, this theoretical concept is retrospectively applied onto the case study of the Republic of Cameroon via the arrangement of the collected data on the case into the four factors of the policy analysis triangle: Context, Content, Process, and Actors.

2.4 Limitations of the Applied Methodology

With regards to the applied methodology of this study, observational research designs utilizing case studies to test the explanatory power of theories are generally criticized for their limited ability to regulate the effects of intervening third variables. Experimental and large-n designs are therefore the most suitable methods due to their possibility of randomizing and correlating the data. However, this criticism can be eliminated when deciding for a case holding an extreme value on the variable that is to be assessed by the research. Secondly, small-n case studies, particularly single case studies, are frequently disapproved as their
outcomes cannot be applied to further cases because of omitting theoretical preconditions for initiating the causal relationship. This limitation can only be corrected by prospectively conducting additional case studies (van Evera 51-54).

In this study, the measure of triangulation by the multiple methods of a literature-review, qualitative unstructured interviews, and a policy analysis is performed. However, triangulation is limited as simply gathering more qualitative data does not automatically reveal the “truth”. Therefore, each dataset collected via a literature-review or via unstructured interviews is thoroughly analyzed; interviews are moreover solely conducted considering a deficit of information on the overall research theme (cf. Silverman 134).

Finally, any qualitative study is exposed to the subjectivity of the researcher. In this case, my biography is the following: I am a student of the Joint European Master’s in International Humanitarian Action (NOHA) specialized in public health in emergency operations at the University of Groningen, Netherlands and Louvain-la-Neuve, Belgium, holding a background in political science. My current interests are TB and health policy issues, being employed as a consultant in the “German-Cameroonian Health- and HIV-Programme” at GTZ in Yaoundé in Cameroon. Conversely, pursuant to Silverman, this reflexivity itself does not guarantee a “true” research result, which rather relies on the validity and reliability of the chosen research design within this study (cf. 123).

3. Application of the Theoretical Concept of the Policy Analysis Triangle of Walt and Gilson onto the Case Study of the Republic of Cameroon

Within this chapter, the four theoretical dimensions – context, process, actors and content – of the policy analysis triangle of Walt and Gilson are described and thereafter applied onto the case study of the Republic of Cameroon. In a third step, these applications are analyzed.

3.1 The Dimension of Context

3.1.1 The Dimension of Context Derived from the Theoretical Concept of the Policy Analysis Triangle

The context as a dimension of the theoretical concept of the policy analysis triangle of Walt and Gilson is composed of the four categories: “… situational, structural, cultural and
environmental …” (Walt and Gilson 365) factors as outlined in the public policy analyzing scheme of Leichter (Walt and Gilson 365). These four categories are defined as follows:

- “A situational factor is more or less transient, impermanent, or idiosyncratic condition or event that has an impact on policy making. … Seemingly transient event can even be relatively long in duration. … In addition, it is recognized that at some point an enduring situational factor, such as a change in political regime, becomes a structural factor” (Leichter 39). Furthermore, a situational factor may be a particular occurrence striking once (Buse, Mays, and Walt 11).

- “Structural factors are the ‘relatively unchanging elements of the society and polity’ (qtd. in the original). Structural factors include the more permanent and persistent features of a system, such as its economic base, political institutions, or demographic structure. … [These hold] generally [a] more predictable impact on policy than situational factors” (Leichter 39).

- “Cultural factors are the ‘value commitments of groups within the community or the community as a whole’ (qtd. in the original). … [This] definition of cultural factors includes both political and general culture values” (Leichter 39/40).

- “Environmental factors are events, structures, and values that exist outside the boundaries of a political system but that influence decisions within the system” (Leichter 40).

It follows, that in order to comprehend the change or stagnation of health policy, an analysis of the impact of the policy context composed of these four categories (Buse, Mays, and Walt 12), therein linking different variables with an individual degree of influence ought to be conducted. Accordingly, a proposed and non-exhaustive list of variables forming the four categories of the health policy context is provided, in view of a subsequent analysis thereof (see fig. 2) (Leichter 40/41).

I. Situational factors
   A. Violent events: international and civil wars, communal conflict, terrorism, assassination
   B. Economic cycles: depression, recession, inflation
   C. Natural disasters: epidemics, droughts, floods, oil spills, earthquakes
   D. Political events and conditions
      1. Political status change: achieving independence, joining or leaving an international association, integration with another political unit
      2. Political regime change: revolution, coup d’état, election of a radical political party
      3. Change of government: electoral shift in power from conservative to liberal party
      4. Political reform: extending suffrage
      5. Political corruption or scandal
      6. Change in political leadership
   E. Technological change: inventions
   F. The policy agenda: competition among policy issues and their proponents for the time, attention and resources available to decision makers
II. Structural factors
A. Political structure
   1. Type of political regime: military or civilian, socialist or nonsocialist, competitive or noncompetitive party system
   2. Type of political organization: federal or unitary system
   3. Form of government: parliamentary, presidential, nondemocratic
   4. Group activity: number, strength, and legitimacy of interest groups
   5. Political process: legislative-executive relations, budgetary process, nature of bureaucracy
   6. Policy constraints: incrementalism, prior policy commitments
B. Economic structure
   1. Type of economic system: socialist vs. capitalist free market, planned, or mixed economy
   2. Economic base: primarily agrarian or industrial, diversified or one-product dependency
   3. National wealth and income: size and growth rate of GNP, distribution of wealth
   4. Complexity of economic organization: modern or traditional economy
C. Social, demographic, and ecological structure
   2. Degree of urbanization: proportion of population living in urban and rural areas
   3. Natural resources: land, water, minerals
   4. Geographic location: island or landlocked, tropical or temperate climate, proximity to militarily strong or weak neighbors

III. Cultural factors
A. Political culture
   1. National heritage
   2. Political norms and values: concerning the role of the individual and the state (Leichter 41)
B. Cultural pluralism
   1. Nation’s linguistic
   2. Racial, religious and cultural structure (Leichter 48)

IV. Environmental Factors
A. Policy and issue diffusion
B. International agreements, organizations and obligations (Leichter 65)

Finally, the rationale for dividing the policy context into situational, structural, cultural and environmental factors with corresponding sub-variables is the demonstration of their various

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15 In addition, via the differentiation of a federal or unitary system, the administration of policy including the source of its budget is determined (Leichter 55).
16 The economic system influences the raising of financial means for a particular policy by governments, e.g. via taxation, national loans or deployment of charges for consumers of public goods and services, and thus the agenda-setting process (Leichter 53/54).
17 When the economic base of a state consists of a monopolistic product structure, it is more prone to its conjuncture on the world market resulting from demand and supply (Leichter 51).
18 The national wealth of a state influences the decisions on expenditures for public goods, e.g. health services. Thus, in general, in poorer countries, the public health sector is more limited than in better situated nations (Leichter 51).
19 “Political culture may be defined as the set of values, beliefs, expectations, and attitudes concerning what government should do, how government should operate, and what the proper relationship is between the citizen and the state. … It involves beliefs and attitudes concerning both the input side of politics (i.e., the nature of political participation and the processes by which decisions are made) and the output side (i.e. what governments can and should do)” (Leichter 60).
20 The national decision-makers on public policies are increasingly affected by the decisions of international institutions, for instance of the United Nations specialized agencies as well as public and private financial organizations. Hereby, public policies results have to be analyzed in view of the impact of donor countries vis-à-vis developing countries by placing conditions upon their grants and loans (Leichter 67/68). Furthermore, environmental factors are resulting in an increased inter-dependence between nation-states that in-turn impacts national sovereignty over the health sector (Buse, Mays, and Walt 11).
impacts on public policy change or stagnation, particularly in the field of public health (Leichter 47).

3.1.2 The Dimension of Context of the Case Study of the Republic of Cameroon

3.1.2.1 Situational Factors of the Context of the Case Study of the Republic of Cameroon

Following the pathology of TB (extracted from annex 3), the infectious agent of TB is typically the *Mycobacterium tuberculosis*, an acid-alcohol resistant rod-bacterium. It is directly transmitted by coughing, sneezing or speaking from a human carrier of these TB pathogens to another individual via an airborne droplet infection (Harries et al. 23). Thereafter, about 30 percent of these exposed persons are infected with TB and about 10 percent develop the illness, mainly within an incubation period from one to three months (Renz-Polster, Krautzig, and Braun 471). The TB illness that follows is divided into two stages: primary TB and post-primary TB also called isolated organ-tuberculosis (Harries et al. 25/26). These conditions that both reflect active disease should be differentiated from latent TB infection that does not reflect an active TB illness. While primary TB may be self-limiting and transient, and latent TB cases by definition do not display any symptoms, post-primary TB patients possess unspecific symptoms, for instance broncho-pulmonary symptoms, as continuous severe cough with blood or sputum, shortness of breath (dyspnoea) and chest-pains, as well as signs of general malaise, e.g. fever, night sweats, chills and general fatigue (CDC, “Basic TB Facts”). Besides, extra-pulmonary TB generates symptoms indistinct to respective other illnesses (Renz-Polster, Krautzig, and Braun 470). The latter differentiation is important for assessing the risk of transmission and of individual disease eruption. A sufficient immune system reaction, leads to a latent TB infection, whereby the pathogens are dormant in the human organism. Hence, the individual does not show any illness symptoms and this individual latently TB infected cannot transmit TB. On the other hand, a person with an active TB disease feels ill and shows TB symptoms. Due to an insufficient immune system reaction, this case has a high bacillary burden and may transmit the pathogens to others (CDC, “Basic TB Facts”). The diagnosis of TB is often attained - only after suspicion is raised - by a thorough anamnesis, and by subsequently correctly interpreting clinical signs and symptoms by the physician. To raise suspicion, the risk of obtaining TB should be considered. Moreover, a tuberculin skin test (‘Mantoux’) or a laboratory blood test (interferon gamma release assay (IGRA)), which displays an immune system response of antigens expressed by tubercle bacilli not shared with most other
mycobacteria, may be used to detect sensitization of the host’s immune system, but cannot differentiate between active TB or a latent TB infection (cf. CDC, “TB Elimination: Diagnosis of Tuberculosis Disease”). However, these tests have been shown to be inexact and insensitive as individuals with overwhelming infection of severe immune compromise may test falsely negative (Renz-Polster, Krautzig, and Braun 472). A chest x-ray (CXR) may help to discover a TB infection (CDC, “TB Elimination: Diagnosis of Tuberculosis Disease”); this diagnostic tool is also not entirely specific (Renz-Polster, Krautzig, and Braun 472). Therefore, to confirm TB a bacteriological examination of the sputum, termed sputum-smear test, has to be conducted, preferably followed by a culture. Finally, the sensitivity of the \textit{M. tuberculosis} to anti-TB medications needs to be assessed, termed drug-susceptibility testing (DST), to predict the response to TB treatment, and to timely detect drug-resistant organisms (CDC, “TB Elimination: Diagnosis of Tuberculosis Disease”).

MDR-TB occurs either via selective antimicrobial pressure with single drug treatment allowing naturally occurring drug-resistant mutants to repopulate the TB lesions (acquired resistance) (Gandhi et al. 1830, 1832), or once a patient is infected with drug-resistant organisms, transmission to other persons never treated with anti-TB medications, is possible (primary resistance). While the clinical symptoms of MDR-TB are indistinguishable from drug-susceptible TB (Weyer 75), its medical treatment is significantly more expensive - at times surpassing an annual family income\textsuperscript{21}, more care-intensive, and carries higher risks for adverse drug effects than for new or retreatment TB cases susceptible to standard TB medications. This results into increased default as well as higher morbidity and mortality rates\textsuperscript{22} and is thus less effective (Gandhi et al. 1830, 1834, 1836).

With regards to prophylaxis, particularly exposure prevention is essential, which includes an assessment of the patient’s environment (Renz-Polster, Krautzig, and Braun 473). Subsequently, solely for persons at risk, an immunization with the Bacille-Calmette-Guerin (BCG) live attenuated vaccine can be carried out (Harries et al. 212/213). Finally, a regular chemo-prophylaxis with the anti-TB drug H over the time-period of half to a year is recommended for immune deficient patients, e.g. with HIV/AIDS and infants below one year

\textsuperscript{21} The medical treatment of an MDR-TB-patient is about 100 times more expensive than a drug-susceptible TB-case (Weyer 75).

\textsuperscript{22} Mainly the elevated mortality rate is observed during the initial two months prior to case-identification and commencement of treatment (Gandhi et al. 1836).
of age (Renz-Polster, Krautzig, and Braun 473); however considering contacts to proven MDR-TB patients, whereby H chemo-prophylaxis is obviously ineffective.\footnote{Chemo-prophylaxis with the anti-TB drug H is ineffective for contacts to proven MDR-TB patients, because MDR-TB is \textit{qua definitione} a form of TB resistant to H (and R) (primary resistance) (A/N).}

In Sub-Saharan Africa, TB is the communicable disease with the highest mortality rate after HIV/AIDS (Cambanis et al., “Chapter 6” 42). In the Republic of Cameroon in 2008, the estimated incidence rate of TB was 190 cases per 100,000 inhabitants; mainly caused by poverty, a significantly positive correlation between the HIV-prevalence and TB as well as an extensive resistance to anti-TB medications (Awah Ndukum et al. 2). During the same year, the estimated TB prevalence rate was with 150 per 100,000 populations slightly lower (WHO, “Global Tuberculosis Control: A Short Update”). Further, the number of notified new pulmonary TB cases with a positive sputum-smear microscopy increased from 10,661 in 2003 to 14,232 in 2008. Correspondingly, the notified TB prevalence also rose from 16,478 in 2003 to 25,125 in 2008 (Kuaban and Noeske 157). Moreover, the TB mortality rate increased from 19 deaths per 100,000 cases in 1990 (WHO, “Country Health System Fact Sheet 2006: Cameroon”) to 39 deaths per 100,000 cases in 2008. In the same year, the rate of MDR-TB among the new TB incidences was 1.7 percent and among previously treated TB patients, it was 8.3 percent (WHO, “TB Country Profile: Cameroon”). In total, 173 MDR-TB cases were notified between 2005 and the third quarter of 2010 (NTCP Cameroon, “Notification TB MDR”).\footnote{Since the end of 2005, the NTCP of Cameroon sends quarterly and/or annually the data for the number of notified MDR-TB cases in the frame of the therefore pre-designed forms to the national office of WHO in Yaoundé, Cameroon. This data is based upon consequent and reliable data collection and long-term observations of experts. However, until today, the national WHO office did not succeed in forwarding these data to the international WHO office in Geneva, Switzerland as required (cf. NTCP Cameroon, “Formulaire Stat OMS”).} Further statistical information on the case study Cameroon, and in particular on its tuberculosis profile can be found in annex 4.\footnote{In general in Sub-Saharan Africa, the specialized diagnosis and treatment centers are supposed to provide the data for MDR-TB patients through a recording and reporting system to the NTCP of a country and thereafter, to the respective national office of WHO. The national WHO offices further transmit these data to the international WHO office. As a consequence, WHO serves as the central collector and estimator of data on MDR-TB patients. Therefore, it is the most complete and reliable source of data on TB, in particular MDR-TB (A/N).}

Consequently, pursuant to the above outlined “Scheme for Analyzing Public Policy” of Leichter, the situational factor classified as “Natural disasters”, the essentially man-made epidemic of TB in particular the occurrence of MDR-TB, is identified in the case study of the Republic of Cameroon in view of the analysis of the overall hypothesis of this thesis.
3.1.2.2 Structural Factors of the Context of the Case Study of the Republic of Cameroon

The Republic of Cameroon is located in the region of Central Africa, surrounded by Nigeria, Chad, the Central African Republic, the Republic of Congo, Gabon and Equatorial Guinea as well as the Atlantic Ocean, with its capital Yaoundé. Its land area amounts to approximately 475,000 km$^2$, comparable to the size of Germany, while encompassing an estimated 19 million inhabitants in early 2010 (Auswärtiges Amt, “Kamerun”).

On the topic of geography, Cameroon is regarded as a diverse country ranging from volcanic and tropical coastal lines in the Southwest, via mountains in the West and high plateaus in the center, to plains in the north. Therefore, the lowest point is the Atlantic Ocean, and the highest elevation is marked by the active volcano Mount Cameroon with 4,095 meters above sea-level. Likewise, approximately 13 percent of the land in Cameroon is utilized for cultivation (The CIA Worldfact Book: “Cameroon”). In view of the climate, Cameroon is generally described by a tropical weather, however varying from the desert north with an arid, via the savanna in the center with a semi-arid, to the southern tropical rain forests with a humid weather (Auswärtiges Amt, “Kamerun”). Annually, there are roughly the following four seasons: first, the arid season lasting from about November to March with day temperatures in the high 29°C, night temperatures under 20°C and a mean humidity of 63 percent; second, the small rainy season persisting from April to June with slowly decreasing day temperatures to 27°C and constant night temperatures under 20°C as well as with 179 millimeters of rainfall per month; third, a temporal semi-dry season in July and August with continuous cooler day temperatures of 27°C and night temperatures of 18/19°C but an average humidity of 75 percent; and finally, the rainy season with rainfalls varying from 144 millimeters to 297 millimeters monthly and constant mean temperatures of 27°C at day-time and 18°C at night-time from late August to November (Climate and Temperature Website, “Cameroon”).

On 1$^\text{st}$ January 1960, Eastern Cameroon became independent from the French colonialists, while the independence of the British dominated Western area of Cameroon followed on 1$^\text{st}$ October 1961. On 20$^\text{th}$ May 1972, a referendum united both parts to the Republic of Cameroon. The current form of state is a presidential regime, in which the president, Paul Biya, (governing since November 1982) appoints and dismisses the prime minister and the members of the cabinet and thus influences greatly the state’s policies. The government is furthermore established by the national assembly with 180 seats headed by the prime minister, Philémon Yang, whereof the governing party, the former single political party, the RDPC holds 153 seats, whereas the opposition, the “Social Democratic Front
“derived from the Anglophone Western regions of Cameroon, maintains 16 seats (Auswaertiges Amt, “Kamerun”). The remaining seats are kept by further opposition parties. The administrative structure of Cameroon is illustrated as a centralized state with 10 regions, 58 departments, 306 municipalities, 54 districts and 339 communes, although the revised constitution entails a decentralization concept (République du Cameroun, “Stratégie Sectorielle de Santé” 7).

The Republic of Cameroon has a capitalist economic system. In 2009, the national GDP was gained to about 50 percent out of the service sector and to approximately 20 percent out of the agricultural sector, wherein the majority of the Cameroonian population (70 percent) is working as small-scale farmers. The remaining 30 percent are acquired through industrial sector. In addition, the main export products are oil and petroleum, coffee and cacao, timber, aluminum, as well as cotton sold to the Netherlands, Spain, Italy, China, the USA and France as well as further African countries (The CIA Worldfact Book: “Cameroon”). However, in the classification of the Human Development Index of the United Nations Development Programme (HDI UNDP), Cameroon was placed 118th of 160 countries in 1990 (UNDP, “Human Development Report 1992”) and in 2009, 153rd of 182 countries. Hence, Cameroon is portrayed in the lowest fifth of the countries with a medium human development (UNDP, “Human Development Report 2009”). The GDP per person ranged from 1,000 US-dollars in 1990 (UNDP, “Human Development Report 1992”) to 1,116 US-dollars in 2007, in contrast to Norway (HDI UNDP rank number 1 in 2009) of 82,480 US-dollars in 2007 (UNDP, “Human Development Report 2009”). This implies that contemporarily about one-third of the Cameroonian population lives below the international poverty line of 1.25 US-dollars per day, being additionally supported by an approximate annual ODA of 1.9 billion US-dollars.

The basic health indicators for the Republic of Cameroon worsened due to the severe economic crisis of the end of the 1980s/early 1990s and the in-turn implemented Structural Adjustment Programs (SAPs) by the World Bank and the International Monetary Fund (IMF). In 1990, the life expectancy at birth averaged 55 years, whereas it decreased to approximately 51 years in 2008 (UNICEF, “Info by Country: Cameroon: Statistics”). Hence, this indicator is considerably below the present global mean life expectancy at birth of 68 years (WHO, “Cameroon Health Profile 2007”), and this trend is additionally reflected in the annual crude death rate that rose from 13 to 14 per 1,000 individuals, despite the fact that the under-five mortality ratio fell from 149 in 1990 to 131 in 2008 and the total fertility rate measured via births per woman dropped from 5.9 to 4.6 during the same time (UNICEF,

In summary, pursuant to the suggested structural factors of the above outlined “Scheme for Analyzing Public Policy” of Leichter, the “Political structure” of the Republic of Cameroon is classified to be a presidential government within a civilian, non-socialist political regime, underlined by a multiparty system and organized in a centralized system. The economic system of Cameroon within the structural factor of “Economic structure” is classified as capitalistic. Furthermore, the majority of the Cameroonian population works within the agricultural sector, whereas the service sector is the main contributor to the GDP. In addition, Cameroon has a variety of natural resources, in particular oil, timber, and aluminum, and exports multiple products and is hence not classified as a mono-culture fostering economic dependence. On the other hand, Cameroon’s national wealth is insufficient. Thus, it is categorized as a developing country being reliant on ODA. Finally, the “Social, demographic, and ecological structure” of the Republic of Cameroon is displayed in its population holding a low life-expectancy, a rising death rate, and a decreasing under-five-mortality and fertility rate, an increasing literacy rate as well as in its geographical location on the Western coast of the African continent with a tropical climate. For the assessment of the overall hypothesis of this study, primarily the political, the economic as well as the social and demographic structure of Cameroon considered.

3.1.2.3 Cultural Factors of the Context of the Case Study of the Republic of Cameroon

The health sector’s context is formed by a decade of severe economic crisis from the end of the 1980s in Cameroon with a decrease of household incomes and a rise of individual poverty due to unemployment, a general depression as a decrease of the Gross National Product (Kamgnia 4), as well as the respective implementation of SAPs by the World Bank and the IMF (Boyer et al. S13). Therefore, in the beginning of 1992, this healthcare system was restructured with the establishment of a health cost recovery scheme demanding private patients for financial contributions (Kamgnia 1) and the reduction of healthcare institutions.

26 The economic dependence on ODA of the Republic of Cameroon is of central importance, as its policies are highly influenced by the conditions and interests of international donors. In this study, the national policy on the treatment of MDR-TB patients is extremely affected by the central principles for the treatment of MDR-TB patients of WHO, which is outlined in more detail in chapter 3.1.2.4 and chapter 4.1. For further information on the general subject of dependency of the Republic of Cameroon on international donors, see the Africa Report of the International Crisis Group (A/N).
Since then, eight national hospitals in the capital Yaoundé and the economic hub of Douala exist that oversee the regional hospitals with about 200 beds in the ten regional capitals; and moreover, there are district hospitals that constitute referral centers for patients from primary healthcare centers or accredited treatment centers (ACTs)\textsuperscript{27} on a community level that encompass from 100 to 150 beds and a permanent medical doctor (Boyer et al. S6). At the end of 1993, public expenditures and hence salaries were downsized up to two-thirds and in January 1994, the currency of the Central African Franc (F CFA) was devaluated (Kamgnia 3). Hereby, three-quarter of the total health staff was left unpaid or employed on a voluntary contract, resulting into a de-motivation and impoliteness towards patients (Soh 119) as well as into pursuing different strategies of income-generation, for instance vending medications, private treatment of patients and demanding extra fees for healthcare services. In addition, these circumstances negatively affected the individual health status, access to the health system of vulnerable population groups and the quality of medical care provided by the health system (Boyer et al. S13).

In general, healthcare institutions are selected upon quality of medical care, acceptable costs and proximity by the Cameroonian population. Public healthcare services are known for their nearness but also for being underequipped and -staffed and are highest in comparable costs, while private health centers are preferred due to their quality of service, and traditional healers or self-medication because of their minimum charges (Kamgnia 25/26, 28). However, in view of the fact that most of the sick in rural areas ought to utilize public transport to arrive at the nearest hospital - for which approximately one-third has to borrow financial means and one-quarter must sell parts of their personal belongings (Cambanis et al., “Chapter 6” 42) - public institutions remain with approximately 50 percent utilization the leading healthcare structure, followed by the attendance of one-third of the population of private institution and the remaining of the traditional sector. In the late 1990s, this shift to the private and traditional healthcare sector from the public sector was observed, attributable to less financial means and service quality (Kamgnia 1, 24, 29). Besides, the time elapsed before attending a healthcare institution and thus prior to the diagnosis and treatment of TB (‘patient delay’) is strongly dependent on the status of being the major household income earner, on the stigmatization of TB as being significantly associated with or mistaken for an

\textsuperscript{27} To become an Accredited Treatment Center (ACT), the primary healthcare center must conform to standards set by the MoPH, e.g. possess an administrative system, a basic laboratory, a pharmacy procuring its medications via the National Center for Supply of Drugs and Consumables Essential Medicines (CENAME), a primary anti-tuberculosis program as well as educated healthcare staff (Boyer et al. S6).
HIV-infection as well as on the knowledge on TB and hence the general literacy rate (Cambanis et al., “Chapter 6” 45).28

From the mid-1990s onwards, the Government of Cameroon augmented the financial resources of the MoPH, and in the beginning of 1996 it passed a fundamental national health policy law (Soh 120). However, as per current health related statistics, the central Government of Cameroon allocated only 3 percent of its expenditure to the health sector between 1998 and 2007, compared to 10 percent for the military defense within the same period (UNICEF, “Info by Country: Cameroon: Statistics”). Moreover, only about one-third of the total expenditure on health was borne by this government in the year 2003, whereas the private payments augmented to the remaining two-thirds in the same year. Therefore, public institutions currently spend 11 US-dollars on average per capita in health care. Pursuant to contemporary statistics of the Cameroonian health system, there are 2 medical doctors, 16 nurses, less than 1 pharmacist, 1 lab technician and about 4 health administration staff per 10,000 population, which is roughly average in the African region (WHO, “Country Health System Fact Sheet 2006: Cameroon”). Within the Cameroonian health sector, the NTCP is one of the best functioning vertical subsystems, for the following reasons:

- No stock-outs for materials and drugs exist
- A quality-control for laboratory exams is established
- A timely and complete recording and reporting system for all patients is in place
- The NTCP is supervised quarterly by an intermediary level and biannually by the central level
- The NTCP is annually externally evaluated by the International Union Against Tuberculosis and Lung Disease (the UNION)
  (Kuaban, Noeske and Trébucq, “Personal Interview”).

In view of the overall hypothesis of this thesis, the “Cultural factor” derived from the “Scheme for Analyzing Public Policy” of Leichter that principally affects the access to drugs for MDR-TB patients in the Republic of Cameroon within international health policies is found to be the political norms and values respective to the roles of individuals and the Government of Cameroon of the “Political culture”. Due to the economic crisis of the late 1980s, the Cameroonian healthcare system was restructured and financially cut back. Thus,

28 With regards to the reliability of findings, the study of Kamgnia is supported by the field experiment of Litvack and Bodart. The link between patient delay and major household income earner was further demonstrated in the studies of Chiang et al. and Rojibulstit et al. The connection of patient delay and stigmatization of TB was illustrated by Liefooghe et al., Lawn and Gelaw et al. and the link between knowledge on TB measured via the literacy rate by Cambanis et al., “Rural Poverty”, Odusanya and Babafemi and Ouedraogo et al. (A/N).
the health sector currently encompasses inadequately paid health staff within the public sector, a health recovery scheme for private patients, as well as reduced public healthcare institutions. This results into a decreased quality of medical care with de-motivated and impolite health staff pursuing further income-generation strategies, a negatively affected health status of the population considering the individual costs, a challenging access to the health system for vulnerable population groups, and a shift to consulting the private and traditional healthcare sector compared to the public healthcare sector. Moreover, variables of “Cultural pluralism”, such as gender regarding the role of the main household income earner, the stigmatization of TB and the knowledge on TB linked to the general literacy rate within wide parts of the Cameroonian population, will have an impact on the effect of the national TB policy within international health policy guidelines.

3.1.2.4 Environmental Factors of the Context of the Case Study of the Republic of Cameroon

With regards to development cooperation, Germany is the second largest bilateral donor after France with 39 million Euros financial and technical cooperation of the year 2008/2009. This budget is mainly allocated via the following institutions - the GTZ, the German Development Service (DED), the Reconstruction Loan Corporation (KfW) as well as the Centre for International Migration and Development (CIM) - within the three central areas of German Development Cooperation, additionally prioritized by the Government of Cameroon for poverty reduction, including health and HIV/AIDS, sustainable management of natural resources as well as decentralization, political participation and good governance. Furthermore, in December 2007, Germany released Cameroon from the re-payment of 1.4 billion Euros debts within the concept of the Enhanced Heavily Indebted Poor Countries (HIPC) Initiative due to its successful collaboration with the IMF and the World Bank (Auswaertiges Amt, “Kamerun: Beziehungen zu Deutschland: Entwicklungspolitische Beziehungen”).

Besides, international development cooperation via international organizations, e.g., the WHO, the World Bank the United Nations Children’s Fund (UNICEF), the United Nations Populations Fund (UNFPA), bilateral institutions, such as the GTZ or the Agence Française de Développement (AFD), or Non-Governmental Organizations (NGOs), technically and financially supports the health sector’s improvement under supervision and coordination of the Cameroonian MoPH (Soh 119/120).

With regards to the overall hypothesis of this thesis, the two “Environmental factors”, “Policy and issue diffusion” and “International agreements, organizations and obligations”, of
the “Scheme for Analyzing Public Policy” of Leichter are of crucial importance. First, within the *Guidelines for the Programmatic Management of Drug-resistant Tuberculosis*, WHO directs the central principles of the treatment scheme for MDR-TB. As WHO predominantly technically and financially supports the Cameroonian health sector, a transfer of these central principles to the Cameroonian NTCP is conditioned. This, in-turn, influences majorly the access to drugs for Cameroonian MDR-TB patients. Second, Cameroon’s dependence on ODA, also for the health sector, makes an independent decision on the implementation of these central principles virtually impossible owing to the powers of international organizations and the incurred agreements.

### 3.2 The Dimension of Process

#### 3.2.1 The Dimension of Process Derived from the Theoretical Concept of the Policy Analysis Triangle

The process of public-policy making of the theoretical concept of the policy analysis triangle of Walt and Gilson is defined as “… the way in which policies are initiated, developed or formulated, negotiated, communicated, implemented and evaluated” (Buse, Mays, and Walt 13), and became known as the “how” (Walt and Gilson 364). Notably, this policy process is not linear due to the influence of actors and contextual factors. With reference to the analytical approach of Sabatier and Jenkins Smith of 1993, hereby the so-called model of “stages heuristic” is applied:

- Step 1: Detection and acknowledgement of the problem studies the agenda-setting of policies; the why some problems are considered and others not.
- Step 2: Policy conceptualization studies the actors engaged to form, consent to and communicate the policy.
- Step 3: Policy implementation studies the action of application.
- Step 4: Policy evaluation studies in how far the implemented policy conforms to the conceptualized policies and its effects (Buse, Mays, and Walt 13/14).
3.2.2 The Dimension of Process Projecting the Central Principles for the Treatment of MDR-TB Patients of International Health Policy Guidelines onto the Case Study of the Republic of Cameroon

3.2.2.1 Detection and Acknowledgement of the Problem

In industrialized countries, TB decreased rapidly owing to the improvement of the living conditions of the populations and improved medications against TB from the 1940s onwards. Thus, even though being one of the main infectious diseases and hence a principle challenge within the field of public health, it disappeared from the international public health agenda for the following decades, while remaining problematic in developing nations. In the 1970s, further enhanced drugs against TB shortened the, at the time existing, treatment regimen from 1.5 years to six months, whereas WHO continued to disregard the TB problem on an international level until the beginning of the 1990s (Ogden, Walt, and Lush 180). In the 1980s, the rising HIV/AIDS pandemic had an important influence on the industrialized countries and its connection to the occurrence of TB became apparent. Moreover, during this time period growing resistances to anti-TB drugs were observed. On the other hand at the end of the 1980s/ early 1990s attributable to the long-term negligence of TB in international health policies, SAPs recommended by the Bretton-Woods institutions, the World Bank and the IMF, were implemented in developing countries resulting into declines of national budgets exemplary for health (cf. Atun et al. 1). The subject of TB only returned onto the international health agenda, when WHO in 1993 acknowledged the communicable disease TB as a “Global Emergency” (NFID, “Factsheets: Tuberculosis: A Global Emergency”). About one year later, it issued a five-component TB control plan to combine and direct international commitments in the process to eliminate TB, advancing into the initial directly observed treatment, short-course (DOTS) policy (cf. Atun et al. 1) in 1995 (P. Nunn et al. 471). This internationally recognized policy for TB control of WHO is founded on a standardized short-course treatment scheme against drug-susceptible TB to avert the generation of drug resistance. However, this treatment scheme proves insufficient for individuals with MDR-TB. Accordingly, the average percentage of successful treatment of newly infected MDR-TB cases is only 52 (range 11 to 60) percent, and of retreated MDR-TB patients 29 (range 18 to 36) percent, whereas the relapse rate of an MDR-TB infection averages at 28 percent (Nathanson et al. 1389). For an overview of the chronology of the following policies, strategies and plans as well as for a chart of their connections and the actors within the field of TB of the health governance system see annex 5.
3.2.2.2 Policy Conceptualization

In 1998, the first Stop TB Partnership Policy was formulated by WHO (Atun et al. 1) and in the same year, further implementing DOTS, the WHO founded the strategy to control MDR-TB, termed DOTS-Plus. The objective of this strategy is to recommend to WHO, MDR-TB control policies in developing countries (Gupta et al., “Increasing Transparency in Partnerships for Health” 971) and set out minimum criteria for treatment projects of MDR-TB (P. Nunn et al. 474). DOTS-Plus reflects the complexity of the management of MDR-TB with SLDs compared to drug-susceptible TB, as SLDs (a) more frequently encompass toxic adverse reactions, (b) are higher-priced and need more advanced diagnostics (Gupta et al., “Increasing Transparency in Partnerships for Health” 971), (c) ought to be provided under DOT from 18 to 24 month (Nathanson et al. 1392), as well as (d) generally more multifaceted supervision of programs’ results and operation is demanded (Gupta et al., “Increasing Transparency in Partnerships for Health” 971). Subsequently, these policies were followed by the primary Global Plan to Stop TB 2001-2005, which was generated from the first Stop TB Partnership Policy of 1998, entailing the goals of promptly extending the DOTS strategy, of responding to the rising HIV/AIDS and MDR-TB incidence, and of enhancing medical material and diagnostic tools (Atun et al. 1). In the beginning of the year 2000, to achieve the general objective of the DOTS strategy of complete access to well-functioning national systems for acquisition and supply of anti-TB medications supported by international affiliations, the Stop TB Initiative organized a conference of the Ministers of Health, Finance and Development of 20 states greatly affected by TB; that adopted the Amsterdam Declaration to Stop TB. Furthermore, in May of the same year, the 53rd World Health Assembly promoted the commitment to the Amsterdam Declaration by all its members, initiating the creation of national action plans to foster the DOTS implementation (WHO, “Prospectus: Global TB Drug Facility” Preface, 1). In September 2000, the UN published the Millennium Declaration including the MDGs (Atun et al. 1, 3) with its aim 6 to “[combat] HIV/AIDS, Malaria and other Diseases” (UN, “United Nations Millennium Development Goal 6”), more particularly target 6.3 to “[have] halted by 2015 and begun to reverse the incidence of malaria and other major diseases” (UN, “United Nations Millennium Development Goal 6”) under which the TB incidence and prevalence is considered (UN, “United Nations Millennium Development Goal 6”). Since then, TB is acknowledged as a main concern of the international health and development agenda, which in turn encouraged an augmented funding for TB, HIV/AIDS, and malaria. In 2006, the WHO developed via the DOTS policy a revised Stop TB Strategy building the foundation for the second Global Plan
to Stop TB 2006-2015 (Atun et al. 1, 3) that illustrates concrete actions hereof (WHO, “Global Tuberculosis Control 2009” 2) and holds an approximate budget of 56 billion US-dollars for 10 years (Raviglione and Uplekar 954). This contemporary Stop TB Strategy envisages “… a world free of tuberculosis …” (Raviglione and Uplekar 953) and its overall objective is consequently to drastically decrease the TB presence considering the MDGs, the former Stop TB Partnership Policy (Raviglione and Uplekar 953) and the World Health Assembly goals (WHO, “Global Tuberculosis Control 2009” 34). To achieve this, the Stop TB Strategy is composed of six central components: (1) Engage in qualitative DOTS enlargement and improvement, (2) Focus on cases detected with the co-infection of TB and HIV/AIDS (TB-HIV), MDR-TB and vulnerable groups, (3) Support health sector reinforcement built upon primary health care, (4) Incorporate all medical care suppliers as public-private partnerships and standard setting actors, (5) Advocate for TB patients and society via partnerships, and (6) Facilitate and foster research. Thus, in section 1, the new Stop TB Strategy includes the DOTS policy via political and funding efforts, high-quality case identification, standardized treatment regimes, a continuous medication provision and an effective control concept as well as an assessment and evaluation system and accounting for effects (Raviglione and Uplekar 953). Section 2 of the Stop TB Strategy demands the management of MDR-TB via enhanced access to quality-guaranteed SLDs against TB, and the avoidance of resistance development to these medications (WHO, “The Green Light Committee Initiative: FAQ” 2) and hence, integrates the DOTS-Plus strategy herein (Nathanson et al. 1393).

Lastly, WHO published the Guidelines for the Programmatic Management of Drug-resistant Tuberculosis in 2006, updated in 2008, which outline the contemporary central principles of the treatment scheme for MDR-TB and form the content dimension of the policy.

3.2.2.3 Policy Implementation

The NTCPs integrated into national primary health care systems reflect international and national strategies for TB control (Atun et al. 1, 6), by actively engaging the respective actors and government institutions. Currently, about 155 countries worldwide, particularly the developing countries, possess a national strategic policy with regards to TB (WHO, “Global Tuberculosis Control 2009” 3, 37) and in 2002, the majority of nations in cooperation with WHO – “… as the UN agency responsible for the management of
tuberculosis …” (Gupta et al., “Increasing Transparency in Partnerships for Health” 972) – had outlined detailed concepts for enlarging their DOTS programs (Atun et al. 3).

Based on the objectives of the 53rd World Health Assembly, the overall goal of the NTCP of the Republic of Cameroon is to continuously decrease the morbidity and mortality of TB via accurate case management. Therefore, its sub-objectives are:

- to cure at minimum 85 percent of newly identified pulmonary TB cases with a positive sputum-smear laboratory;
- to annually identify at minimum 70 percent of prevalent pulmonary TB cases with a positive sputum-smear laboratory, forming an infection source (République du Cameroun, “Programme National” 15, 17, 23-28);
- and to annually vaccinate at minimum 80 percent of newborns against TB with the BCG-vaccine (Kuaban und Noeske 156).

Consequently, to reach this overall objective and its sub-goals, the NTCP implements the following strategies:

- Accurate case-management including case-identification through sputum-smear laboratories and treatment via a standardized therapeutic regime;
- Prevention of TB via early passive case-identification, treatment of active contagious TB patients with positive sputum-smear microscopy, continuous BCG-vaccination of newborns, as well as chemoprophylaxis of specific exposed population groups, for instance newborns and children under five years of age;
- Education of health staff on all vertical levels of the Cameroonian health system (République du Cameroun, “Programme National” 19/20);
- “… Advocacy-Communication-Social Mobilization (ACSM) activities …” (Kuaban and Noeske 156) through awareness-raising campaigns of the public on TB symptoms, treatment options, the nearest Tuberculosis Diagnosis and Treatment Centers (DTCs) and re-integration of cured TB patients;
- Epidemiological monitoring through quarterly reports on case-finding and treatment results.

Finally, to realize these strategies, the NTCP includes the following central activities:

- Assure the distribution of medical material to health entities;
- Assure the rehabilitation of hospitals and laboratories;
- Assure the provision of medications against TB via the central system for obtaining and providing essential medicines;
• Needs-based education of health staff on the three levels;
• Manage, monitor and evaluate the activities of the NTCP on the three levels;
• Perform research activities.

The NTCP of the Republic of Cameroon has adopted an alternative standardized treatment regimen for new MDR-TB patients based on a long term study of van Deun et al. in Bangladesh (see annex 12) and applied since May 2008 (see section 3.4.2), which takes the following additional arguments into account:

• The Cameroonian NTCP has limited financial resources utilized for drug purchase, biological (sputum-smear tests and cultures (DST)) and medical exams and facilities, as well as for the salary of few human resources.
• In Cameroon currently SLDs are seldom prescribed and if so, only for short periods of time due to their cost-intensiveness.
• To date, the National Tuberculosis Reference Laboratory has proven the drug-susceptibility of *M. tuberculosis* to Ofloxacin (Ofx) or Kanamycin (Km) in Cameroon (Abena et al., “Preliminary Draft” 14/15).
• The exemplary standardized scheme of Bangladesh was prolonged for three months and Protionamide (Pto) was included in Cameroon due to the increasing TB-HIV prevalence.

3.2.2.4 Policy Evaluation

Overall, this global commitment resulted in a decreased TB incidence rate, treatment of 43 million TB cases via the DOTS programs (whereof 36 million individuals were healed), and the prevention of 6 million deaths within the period from 1995 to 2008. On the other hand, many TB cases are still undetected, and MDR-TB as well as TB-HIV figures are constantly rising (Atun et al. 2). Therefore, the present key objectives for the international fight against TB are a decreasing incidence rate of TB by 2015, a reduction of the TB prevalence and mortality rate by 50 percent as compared to 1990 by 2015, an identification of and medical care for at minimum 70 percent of newly smear-positive TB cases under the DOTS programs and in general, a successful medical care for 85 percent of all newly smear-positive TB patients (WHO, “Global Tuberculosis Control 2009” 1).

Already in 2003, the Cameroonian NTCP reached its three sub-objectives of annually identifying at minimum 70 percent of TB cases with 73 percent and in 2008 with 93 percent (WHO, “Global Tuberculosis Control: A Short Update”), whereof respectively 70 percent

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29 MDR-TB cases that have been already treated for longer than one month with an SLD are included in the “classical” treatment scheme outlined below (NTCP Cameroon, “Application to the GLC July 2008” 27).
(WHO, “Country Health System Fact Sheet 2006: Cameroon”) and about 76 percent were cured (WHO, “Global Tuberculosis Control: A Short Update”). Furthermore, as a preventive mechanism about 86 percent of all infants below 1 year of age were vaccinated against TB with the BCG-vaccine in 2008, compared to the WHO’s target of 85 percent (UNICEF, “Info by Country: Cameroon: Statistics”).

As other countries in Sub-Saharan Africa, Cameroon has an increasing MDR-TB incidence. Although by the correct implementation of the NTCP, this trend is attempted to be curbed; the increase is possibly due to the following reasons:

1. The economic crisis of the late 80s in Cameroon caused a complete deterioration of the former NTCP. Hence, diagnosis, management, and medical care of TB were individually conducted by the respective physician in consideration of the availability of anti-TB medications.

2. In Cameroon, it is estimated that between 12 and 40 percent of TB patients are resistant against H, while additional resistance against R may be caused by the contemporary treatment regimen.

3. In the current guidelines utilized by the NTCP, no directive is included on the medical treatment of defaults after re-treatment regimen, which offered room for experimental treatment without cure.

Consequently, the NTCP of the Republic of Cameroon is applying a successful alternative standardized treatment regimen for new MDR-TB patients.

3.3 The Dimension of Actors

3.3.1 The Dimension of Actors Derived from the Theoretical Concept of the Policy Analysis Triangle

The dimension of actors is at the core of the theoretical concept of the policy analysis triangle of Walt and Gilson. These may be categorized into individuals, networks, organizations or public institutions, such as the government of a state (Varvasovszky and Brugha 341), and affect the policy process on the international, national, regional or local level. The scope of their impact on the policy process depends on the notion of employed recognized and actual power. The power is formed from combination of personal wealth, individual character, degree of or access to information or authorities, and the context that surrounds the actors (Buse, Mays, and Walt 9/10). Furthermore, power is not solely build
individually, but also relies on external connections with exemplary technical experts and advisors, development institutions, and financial supporters (Walt and Gilson 366).

For assessing the actors, a stakeholder-analysis ought to be conducted. Herein, stakeholders are considered a synonym for actors (Buse, Mays, and Walt 177), in view of their definition: “Stakeholders include those individuals and groups with an interest in an issue or policy, those who might be affected by a policy and those who may play a role in a relation to making or implementing the policy” (Buse, Mays, and Walt 177). Consequently, a stakeholder-analysis is a methodological instrument to identify actors, comprehend their interests, actions and alliances to evaluate their effect by resource allocation on agenda-setting, decision-making or application of a particular policy, especially health policy. Initially, the various elements of a policy have to be assessed (Varvasovszky and Brugha 338, 341). Subsequently, the stakeholders, who are actively engaged with, or positively or negatively influenced by a certain policy process and its content, are to be listed, which entails the decisive opinion of the researcher. Thereafter, the approach of each stakeholder in exercising their power within the policy process has to be evaluated that is linked to their access to physical, e.g. election shares, funds, infrastructure and affiliates, or non-physical political resources, e.g. knowledge and authority in the policy subject, contact with the media and public decision makers. Furthermore, the context determines the influence of each political resource on the policy process. Finally, the interest, stand and dedication of a particular stakeholder to a policy subject condition the application of their political resources and these aspects are evaluated. Hereby, the interests result from the arising (financial) advantages of an actor from the policy. These benefits in-turn shape their stand to the policy that is defined as in favor of, against or neutral. However, the interests of an actor in a certain policy, and thus its stand, are generally not revealed. Likewise, the dedication of an actor to a policy is occasionally characterized via further hidden priorities and this ultimately determines their deployment of political resources (Buse, Mays, and Walt 177-180). When data analysis to the identification of actors, their influencing power, as well as their interests, stands and dedications is finalized, illustrative matrix tables or charts may be created (Varvasovszky and Brugha 341-343).
3.3.2 The Dimension of Actors within the Field of MDR-TB

3.3.2.1 The Dimension of Actors within the Field of MDR-TB on an International Level

The Stop TB Partnership Policy is accordingly reflected in its institutional structures: The Stop TB Partnership Coordinating Board is composed of 34 members from highly TB affected communities and countries as well as the six world-regions, from the WHO, GFATM, donor organizations, NGOs and technical co-operations, e.g. the CDC or the UNION, the private sector, as well as from 7 working groups. These 7 working groups on DOTS Expansion, MDR-TB, TB-HIV, Diagnostics, TB Drug Development, New Vaccines and Advocacy and Communications are subordinated (WHO, “Stop TB Partnership Website: About Us: Coordinating Board”). Moreover, the Stop TB Partnership Policy system includes a Secretariat seated at the WHO for administrative and operational support that is additionally responsible for the following four fields of work: (1) advocacy and interaction, (2) donor procedures, (3) organization, and (4) drug provision via the Global Drug Facility (GDF) (WHO, “Stop TB Partnership Website: About Us: Secretariat”). The hereof arising Working Group on MDR-TB founded in 1999 by WHO – for which it in turn functions as a Secretariat – includes the following four Sub-Working Groups: the Scientific Panel to generate directions for the execution of DOTS-Plus, the Subgroup on Laboratory Issues, the GLC, and the Subgroup on Drug Procurement Issues.

The health-based partnership, the GLC (Gupta et al., “Increasing Transparency in Partnerships for Health” 970/971), assures the execution of the strategic policy framework of section two of the Stop TB Strategy, the Global Plan to Stop TB (2006-2015) and the Global MDR/XDR-TB Response Plan (2007-2008) (WHO, “The Green Light Committee Initiative: FAQ” 2). The WHO set up GLC in 2000 to advance access to and promote correct utilization of the following subsidized SLDs against MDR-TB (Gupta et al., “Increasing Transparency in Partnerships for Health” 970, 972): capreomycin (Cm), cycloserine (Cs), ethionamide (Eto), Km, p-aminosalicylic acid and Pto, as well as the fluoroquinolones, levofloxacin (Lfx) and Ofx (Nathanson et al. 1390, 1392). Further, the GLC is composed of the following five groups of actors: “… academic institutions, civil society organizations, bilateral donors, governments of resource-limited countries …” (Gupta et al., “Increasing Transparency in Partnerships for Health” 970) and the WHO, as a permanent affiliate and the GLC Secretariat. Likewise, the profit-making private sector, e.g. the pharmaceutical producers that

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are responsible for the provision of cost-reduced medications, maintains solely an observer role without decision-making power in the GLC (Gupta et al., “Increasing Transparency in Partnerships for Health” 970/971). At present, the GLC encompasses the following member institutions: Partners in Health (PIH) (chair), CDC, Hospital General de "Francisco J. Muniz", the UNION, KNCV Tuberculosis Foundation, Médecins Sans Frontières (MSF), State Agency for TB & Lung Disease, Latvia, World Care Council (WCC), and the WHO (WHO, “The Green Light Committee Initiative: FAQ” 4). These institutions were chosen from the overriding Stop TB Partnership Working Group on MDR-TB (WHO, “Green Light Committee Initiative: Annual Report 2007” 6). The central tasks of the GLC are to assess applications from government-supported projects for subsidized SLDs, to appraise their compliance to and progress towards the central principles of WHO, to provide technical assistance\(^{31}\) as well as to report to WHO (Gupta et al., “Increasing Transparency in Partnerships for Health” 972). In the application process to the GLC, projects are incorporated under the internationally recognized DOTS-Plus strategy to control MDR-TB and thus must comprise a well-performing DOTS system, a sustainable political devotion, efficient case-finding mechanisms, “… diagnosis of MDRTB through quality-assured culture and drug susceptibility testing (DST) …” (Nathanson et al. 1390), treatment plans with supervision of correct utilization of SLDs, continuous provision of quality-guaranteed SLDs, and notification and information system on MDR-TB control program’s progress and treatment results (Nathanson et al. 1390). The continuation of these requirements and the further compliance to WHO directives is assessed and evaluated by annual field-missions of the GLC, which analogously also ensure technical support (WHO, “Green Light Committee Initiative: Annual Report 2007” 12). Besides, the function of WHO Secretariat is to administratively manage tasks of the GLC, to guarantee that application deadlines are adhered to, to be a central point for contact with projects and to occasionally contribute to technical decisions of the GLC, as well as to choose members of the GLC with sufficient technical know-how. Thus, the WHO is authorized to oversee the access to the SLDs and the implementation of the actions of the GLC. In addition, the member institutions of the GLC are liable to finance their own costs of 50,000 US-dollars annually, whereas WHO tries to support the funding of operational expenditures of members from developing countries. Finally, the GLC consensually recommends MDR-TB control policies in developing countries to WHO; which in turn is also an equal participant in the voting process and

\(^{31}\) Technical assistance is carried out in collaboration with the WHO and its partners (WHO, “Green Light Committee Initiative: Annual Report 2007” 5).
moreover, maintains the right to agree or disagree with these recommendations (Gupta et al., “Increasing Transparency in Partnerships for Health” 970, 972/973). In the beginning of 2007, it was estimated that the GLC annually facilitated treatment with high-quality subsidized SLDs for approximately 10,000 MDR-TB patients of 490,000 MDR-TB global cases per year, whereas without treatment MDR-TB patients are likely to transmit this illness and eventually die. As a result, the GLC had in total approved 69 TB projects including about 30,000 individuals with MDR-TB in 51 countries since 2003 (WHO, “Green Light Committee Initiative: Annual Report 2007” 1, 3).

Following the model of the GLC, the GDF was formed at a conference of the Working Group on DOTS Expansion of the Stop TB Initiative at the end of 2000 (WHO, “Prospectus: Global TB Drug Facility” Preface), whereas it commenced its activities on World TB Day in 2001 (WHO, “Global Drug Facility: Briefing Note”). The Working Group on DOTS Expansion is composed of a secretariat seated at the WHO, a core team and the four thematic subgroups: Public-Private Mix (PPM), Childhood TB, Poverty, and Laboratory Capacity Strengthening that is incorporated into the Global Laboratory Initiative (GLI) (WHO, “Dots Expansion Working Group: About Us”). The GDF was established as a time-limited institution for a duration of ten to 15 years to control local dependencies (WHO, “Global Initiatives: Global Drug Facility: What is the GDF?”) with an overall objective to enhance the access to, and the offer of quality-guaranteed and concessional priced First-line Drugs (FLDs) and SLDs against TB, and to thus assist the DOTS increase within different states. Therefore, the tasks of the GDF are the funding of and the procurement of anti-TB medications to ensure their availability and quality (WHO, “Prospectus: Global TB Drug Facility” Preface, 2); eligibly received by governments and NGOs in cooperation with the corresponding Ministry of Health (WHO, “Global Initiatives: Global Drug Facility: What is the GDF?”) for NTCPs adhering to DOTS (WHO, “Prospectus: Global TB Drug Facility” 8, 11/12). In turn, GDF is exemplary financially supported by the Canadian International Development Agency (CIDA), the UK Department for International Development (DFID), the United States Agency for International Development (USAID), and particularly from UNITAID (WHO, “Global Drug Facility: Briefing Note”) and the GFATM (WHO, “Global Initiatives: Global Drug Facility: What is the GDF?: Facts & Figures”). Furthermore, it supports national systems in efficient medication-administration and service providers in quality-enhancement of anti-TB medications and it creates emergency stocks of FLDs and SLDs (WHO, “The Global Drug Facility: Comparative Advantages” 2). Until 2009, the GDF generated a total assistance of 268 million US-dollars for about 14 million medical treatments
of TB cases in 93 countries. It supplied FLDs to 88 countries and SLDs to 42 countries, of which 17 were highly affected of TB. Finally, 50 beneficiaries of the GFATM were assisted by the GDF (WHO, “Global Initiatives: Global Drug Facility: What is the GDF?: Facts & Figures”).

Notably, the GLC initially approves funding applications for subsidized SLDs of MDR-TB projects following the Stop TB Partnership Strategy (WHO, “The Global Drug Facility: Direct Procurement Service” 1). Thereafter, the GDF is the institution authorized by the GLC to obtain subsidized SLDs against MDR-TB (also via GFATM funds) (WHO, “The Global Drug Facility: Comparative Advantages” 2) of which the quality is assured by the WHO (WHO, “Global Initiatives: Global Drug Facility: What is the GDF?”) as well as to control and coordinate their procurement32 (WHO, “The Green Light Committee Initiative: FAQ” 13). Concessional prices of these drugs are attained via discussions between the GDF and the pharmaceutical industry as well as via collective procurement. Their acquisition is exclusively carried out by the International Dispensary Association (IDA) (WHO, “The Green Light Committee Initiative: FAQ” 7), “... the world’s leading [independent] not-for-profit supplier of affordable pharmaceutical products ...” (IDA, “We Are”), which is mandated by the GDF that in-turn was notified about a projects’ approval by the GLC. In addition, the GDF - in cooperation with the IDA - is in charge of quality-assurance of these SLDs against TB.

The subsidization of the quality-assured SLDs following the GLC’s approval is centrally financed by the mechanisms of UNITAID and the GFATM (WHO, “The Green Light Committee Initiative: FAQ” 3, 8), which covers the majority of funding for TB management (Atun et al. 4). In general, the GFATM acquires, coordinates and controls as well as distributes financial resources via a public-private partnership with the long-term aim of significantly decreasing the incidences of HIV/AIDS, TB and malaria and their morbidity and mortality in developing countries supporting the decrease of poverty under the MDGs (WHO, “The Green Light Committee Initiative: FAQ” 13). Furthermore, in early 2002, the GFATM authorized that demands to them for funding of SLDs against TB as well as their procurement ought to be solely processed by the GLC to advert their mishandling (Nathanson et al. 1395) and accordingly reduce the development of drug resistance. Finally, the GFATM and the GLC jointly evaluate the projects’ outcomes and the achievement of objectives in

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32 Projects not being able or willing to procure SLDs via the GLC, are still allowed to acquire these medications for the usual and thus more cost-intensive market price (Gupta et al., “Increasing Transparency in Partnerships for Health” 974).
view of their decisions on the international control of MDR-TB. The international donor and partner collaboration, UNITAID, supervised and run by WHO was set up to offer financial resources in a continuing, sustainable and foreseeable manner that facilitates an elevated access to and decreases costs of quality-assured medications and medical equipment against HIV/AIDS, malaria and TB (WHO, “The Green Light Committee Initiative: FAQ” 13/14). The Memorandum of Understanding (MOU) to financially support the GLC and the GDF with 4,700 SLDs treatments in 17 nations at the total costs of 20.8 million US-dollars within five years was approved in mid 2007. Additionally, the USAID, the Office of the U.S. Global AIDS Coordinator (OGAC), Eli Lilly (E.LILLY), the Bill & Melinda Gates Foundation (GATES), and the WHO via the Stop TB Strategy offer their financial support to the GLC (WHO, “Green Light Committee Initiative: Annual Report 2007” 13).

At the beginning of 2009, the GDF had supplied FLDs against TB to 89 nations and the GLC had agreed to the utilization of SLDs in 134 projects in 60 nations. Thus, 3 billion US-Dollars were allocated in this year for the fight against TB, whereof about 87 percent were financial resources from the governments, 9 percent of funds were from the GFATM and the remaining 4 percent from further donors. However, the GFATM granted 65 percent of the total financial resources for developing countries. Within the period from 2002 to 2008, which was comprised of eight so-called funding rounds, the GFATM alone passed grants of a total of 3.9 billion US-dollars for TB projects in 102 nations, whereof the African Region received 29 percent followed by the South-East Asian Region and the Western Pacific Region. In the funding rounds 6 to 8, the GFATM financially supported 85 TB control projects. Of these grants, 56 percent were donated to support DOTS programs, while the control of MDR-TB and SLDs received 20 percent, and the remaining resources funded various activities for instance for lung health, for vulnerable populations, for associated TB/HIV infections and for medical care suppliers (WHO, “Global Tuberculosis Control 2009” 3, 41, 62, 74/75). Herewith, the financial support of the GFATM reached in total 23,661 MDR-TB patients or about 79 percent of all MDR-TB cases assisted by the GLC. Besides, in 2007, UNITAID supported the distribution of SLDs in 10 developing countries with above 7 million US-dollars; and further donors provided the following grants the same year (in US-dollars): OGAC - 1,125,000, GATES - 214,700, E.LILLY - 242,264, USAID - 249,481, WHO - 307,404 arising to a total of about 9.3 million US-dollars (WHO, “Green Light Committee Initiative: Annual Report 2007” 3, 19).
3.3.2.2 The Dimension of Actors within the Field of MDR-TB on the National Level of the Republic of Cameroon

In August 2002, the “Decree No. 2002/209” was approved by the Cameroonian President, Paul Biya that replaced the preceding statute of 1995 and re-structured the MoPH of Cameroon. Currently, the MoPH is composed of a Secretariat; three Technical Consultative Organs; a Communication Group; three General Inspections – of Administrative Services, of Medical and Paramedical Services and of Pharmaceutical Services; a Main Administration; a Department of External Services; and Specialized Technical Committees and Mechanisms (see annex 6). The Main Administration encompasses inter alia the Directorate of the Control of the Disease that carries out the following tasks: project cycle management for projects against communicable and non-communicable diseases in collaboration with partners, design and overseeing of the application of direct and indirect epidemiological intervention plans as well as management of epidemiological surveillance. The Directorate is comprised of the three Sub-Directorates of the Control of HIV/AIDS and Sexually Transmitted Diseases, of Endemic Diseases, of Non-Endemic Diseases, and the Department of Epidemiology. Furthermore, the Sub-Directorate of Endemic Diseases observes the implementation of direct and indirect (preventative) measures against endemic diseases and hence, encompasses the three Departments of the Control of Malaria, of the Control of Tuberculosis and of the Control of Onchocerciasis/ River Blindness and Endemic Diseases. Notably, these three departments including their programs are directly attached to the Cabinet of Minister. With regards to the general assignments of the Sub-Directorates, every of these departments monitors and evaluates the integration of health care actions into the overall measures and therefore includes an Office of Prevention, an Office of Program Management, and an Office of Monitoring and Evaluation.

Finally, the Department of External Services is structured into the regional public health delegations, the health districts and public health facilities. These plan, manage and coordinate, implement as well as monitor and report on the health activities in collaboration with the beneficiaries foreseen by the MoPH respective to the administrative levels of Cameroon. The public health facilities are categorized into General Hospitals or 4th Reference Hospitals, Central Hospitals or 3rd Reference Hospitals, Regional Hospitals or 2nd Reference Hospitals, District Hospitals or 1st Reference Hospitals, District Medical Centers, Integrated Health Centers and Ambulatory Care Centers. Besides, there are specialized agencies and technical committees under the MoPH, such as the Pastor Center of Cameroon, the University Hospital, the National Center for Supply of Drugs and Consumables Essential
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Medicines (CENAME), the National Laboratory on Quality and Expertise Control, as well as the Regional Centers of Pharmaceutical Products Supply (CAPP) (République du Cameroun, “Decret No. 2002/209” 2/3, 5/6, 20, 23, 35/36, 38/39, 51-54, 56-60).

The legal basis for health and healthcare in the Republic of Cameroon is *inter alia* defined by the Constitution of Cameroon of 1972, wherein the primary right of health for all citizens is acknowledged, the signing of the Alma-Ata Declaration in 1978 and the adoption of the United Nations Declaration on Health for All in 2000 (Kamgnia 1). At the end of the 1980s, a reform of the Cameroonian Health Sector was launched, which resulted in the approval of the “Declaration of Health Sector Policy” in 1992 and into the “Reorientation of Primary Health Care” in 1993. These lay the foundation for the current structure of the Cameroonian Health Sector, which is presently composed of three levels – central, intermediate and peripheral (see annex 7) (République du Cameroun, “Programme National” 17). Within each administrative level, health care facilities, pharmaceutical institutions and dialogue organizations are included, that can in-turn be divided into public, private and traditional. Of the functional hospitals, 65 percent are public, whereas 35 percent are private, non-profit making compared to the health centers, whereof 79 percent are public and 21 percent are private, non-profit making. In 2007, it was estimated that these health structures are operated in general by one physician per about 13,500 patients and one health worker per approximately 3,000 patients (République du Cameroun, “Stratégie Sectorielle de Santé” 18-24).

Under the supervision and coordination of the MoPH, the Cameroonian health sector is additionally technically and financially supported by international organizations, e.g. the World Bank, the WHO, UNICEF, UNFPA (Soh 119/120), the Global Alliance for Vaccines and Immunization (GAVI), the GFATM, the International Facility of Financing Vaccination, UNITAID, the cancellation of debts within the frame of the HIPC-initiative (République du Cameroun, “Stratégie Sectorielle de Santé” 18-24), by the bilateral donors, for instance France and Germany (Auswärtiges Amt, “Kamerun: Beziehungen zu Deutschland: Entwicklungspolitische Beziehungen”), or NGOs (Soh 120).

Until the economic crisis at the end of the 1980s in the Republic of Cameroon, the MoPH inclusively financed TB case-identification and medical cure, e.g. drugs and hospitalization. Subsequently, amid diminishing funds, this measure was halted (République du Cameroun, “Programme National” 17). About ten years later in 1997, the Cameroonian NTCP was re-instituted (Kuaban and Noeske 155) with regards to the DOTS strategy of WHO and upon policy and technical propositions of the UNION. As the Cameroonian Health
Sector Strategy (HSS) 2001-2010 of the MoPH (modified in 2009) acknowledges TB as a central health problem (see annex 8) (République du Cameroun, “Programme National” 3/4), in the year 2002, the organizational structure of the NTCP was re-arranged.

At present, the NTCP is also operated on the three - national, regional and district administrative – levels (see annex 9). First, on the national level, the NTCP is directly attached to the Minister of Public Health, while the MoPH – in particular its “Department of the Control of Tuberculosis”, of the “Sub-Directorate of Endemic Diseases”, of the “Directorate of the Control of the Disease” – supervises the regulation and execution of, and grants a yearly budget to the NTCP. Parallel to the re-organization of the NTCP, the National Tuberculosis Control Committee (NTCC) and the Tuberculosis Central Technical Group (TB-CTG) were established. The NTCC is positioned under the presiding MoPH that assigns the NTCC-members from further ministries, financial contributors, NGOs and the for-profit sector. Its mission is to outline, implement and monitor the overall strategies and goals of the NTCP, to acquire its funds, and to direct partner efforts in the fight against TB into consistency. Besides, the Consultative Scientific Committee is dedicated to statistical data acquisition and research on TB. The NTCC carries out its mission via the executive TB-CTG on the central level (in turn reporting to the NTCC) that, moreover, plans the yearly TB control activities with the respective costs and the necessary trained human resources considering the HSS on TB. In Cameroon, sputum-smear exams and cultures according to international guidelines are carried out by the two decentralized entities, the CEBEC Baptist Hospital in Douala and MEZAM clinic in Bamenda. Then, the National Tuberculosis Reference Laboratory, which is placed at the “Centre Pasteur du Cameroun (CPC)” in Yaoundé is in charge of conducting quality-guaranteed DST pursuant to international standards, educating laboratory staff, as well as of scrutinizing anti-TB drug-resistances as signs of the success of the NTCP. Further, the CPC is supervised by the WHO/ the UNION Supra-national Reference Laboratory Network for TB based in Antwerp, Belgium and it is in the process of becoming a Regional Tuberculosis Reference Laboratory. Finally, the Chest Service of the 3rd Reference Hospital of Jamot is responsible for adequate medical care for complicated TB cases, medical research and education of health personnel in high-quality case management. Second, on the regional level, provincial units of the Regional Technical

33 In view of the situation that data on surveillance of and response to MDR-TB cases as well as on the number of MDR-TB patients itself is sent by the NTCP of Cameroon to the national WHO office in Yaoundé, Cameroon; this in-turn, however, did not succeed in forwarding these data to the international WHO office in Geneva, Switzerland until today, the data and information provided by the Multidrug and extensively drug-resistant TB (M/XDR-TB): 2010 Global Report on Surveillance and Response of WHO are incorrect (A/N).
Group for the Fight against AIDS and Tuberculosis establish, direct, and assess the execution of yearly budgeted activities of the NTCP. From this information, the Regional Technical Group forms regional action plans and oversees their budget. In addition, it outlines training programs, supervises the stocks of medications against TB and medical materials in collaboration with the regional CAPP, and reports on its activities. Lastly, as the foundation of the NTCP, the district level is responsible for the detection of new TB cases and upholding the referral system to district hospitals for identification, registration and medical care. The Health District Medical Officer supervises the District Unit for Tuberculosis Control, which is charged with project cycle management of TB control action plans - implemented by the staff of the District Hospitals and the DTCs - with the inventory of anti-TB medications and medical and laboratory material, as well as with reporting back quarterly to the Regional Technical Group (Kuaban and Noeske 155-159).

3.3.3 The Outcome of the Stakeholder Analysis of Actors within the Field of MDR-TB

To conclude this section, the following two figures 3 and 4 of actively or passively involved actors - their interests derived from (financial) advantages as well as their influence and power arising from their tangible and/ or intangible resources on the central principles for the treatment of MDR-TB outlined in the Guidelines for the Programmatic Management of Drug-resistant Tuberculosis of WHO on an international and national level - resulting from the stakeholder analysis in annex 10 are displayed. The international actors identified with a high interest as well as high influence/power in these international health policy guidelines are the WHO, the GLC, the GDF, the IDA, the GFATM, UNITAID, the UNION, GTZ and the pharmaceutical industry; accordingly, the actor holding a high interest and a high influence/power operating on the national level of the Republic of Cameroon is the Department of the Control of TB of the MoPH.
3.4 The Dimension of Content

3.4.1 The Dimension of Content Derived from the Theoretical Concept of the Policy Analysis Triangle

Ultimately, the policy content is the feasible outcome of a complex policy process reflecting actors and the surrounding context (Walt and Gilson 366).
3.4.2 The Dimension of Content Derived from the Central Principles of the Treatment of MDR-TB outlined within the “Guidelines for the Programmatic Management of Drug-resistant Tuberculosis” of WHO Applied to the Case Study of the Republic of Cameroon

The Guidelines for the Programmatic Management of Drug-resistant Tuberculosis of WHO direct the following: When MDR-TB is identified, cases can be treated with (a) a standardized MDR therapeutic regime (WHO, “Treatment of Tuberculosis Guidelines” 86), whereby no individual DST is carried out and all MDR-TB cases are treated in the same manner (WHO, “Guidelines for the Programmatic Management” 52), or (b) with an individualized treatment regime (WHO, “Treatment of Tuberculosis Guidelines” 86), founded on the individual’s treatment history and DST (WHO, “Guidelines for the Programmatic Management” 52). Initially, the medications utilized for the treatment of MDR-TB are grouped into the following five categories in order of effectiveness, familiarity and type of medication (WHO, “Treatment of Tuberculosis Guidelines” 84):

- Group 1 are the first-line anti-TB drugs: H, R, pyrazinamide (Z), ethambutol (E), and rifabutin (Rfb) (WHO, “Guidelines for the Programmatic Management” 54). These are most effective and with least adverse effects (WHO, “Treatment of Tuberculosis Guidelines” 84).

- Group 2 SLDs are injectable: Km, Am, Cm, and streptomycin (S) (WHO, “Guidelines for the Programmatic Management” 54) for assumed and proven drug resistance found in the patient’s sputum, whereby S is avoided because of its now common drug-resistance (WHO, “Treatment of Tuberculosis Guidelines” 84).

- Group 3 encompasses the second-line fluoroquinolones: Lfx, moxifloxacin (Mfx), Ofx (WHO, “Guidelines for the Programmatic Management” 54); each patient harboring drug susceptible micro-organisms is administered with one agent (WHO, “Treatment of Tuberculosis Guidelines” 84).

- Group 4 includes the second-line oral bacteriostatics: Para-aminosalicylic acid (PAS), Cs, terizidone (Trd), Eto, Pto (WHO, “Guidelines for the Programmatic Management” 54), generally combined due to cost-effectiveness (WHO, “Treatment of Tuberculosis Guidelines” 84).

- Group 5 are SLDs of undetermined efficacy that are not suggested by WHO: Clofazimine (Cfz), linezolid (Lzd), amoxicillin/clavulanate (Amx/Clv), thioacetazone (Thz), imipenem/cilastatin (Ipm/Cln), clarithromycin (Clr) (WHO, “Guidelines for the Programmatic Management” 54).
On the hierarchical basis of these anti-TB medications, WHO directs to adhere to the following principles by establishing a therapeutic treatment scheme for MDR-TB:

- The usual anti-TB medications administered in a country, the national resistance profile, individual DST (WHO, “Guidelines for the Programmatic Management” 58/59) of H, R, the injectable SLDs and fluoroquinolones (WHO, “Treatment of Tuberculosis Guidelines” 89), and patient’s treatment history determine the therapeutic treatment scheme;
- Each therapeutic treatment plan ought to include at minimum four drugs of Group 1 to Group 4 considering their efficacy;
- One injectable medication is applied for at least six months and at minimum four months after sputum-smear negative laboratory test result;
- During the complete treatment process, Z can be given;
- Medications ought to be administered as single daily dose based on patients’ weight under DOT for the complete treatment duration;
- The least possible treatment duration is 18 months subsequent to sputum-smear negative microscopy;
- Instant and appropriate taking charge of side-effects to diminish treatment failures; and
- Timely identification of drug-resistance and the immediate commencement of the treatment scheme are influential factors on the success rate (WHO, “Guidelines for the Programmatic Management” 58/59).

Therefore, a standardized therapeutic regimen for MDR-TB advised by WHO consists of an intensive phase with at least four medications of each category for at least 6 months and for 4 months after cultures become negative for MDR-TB. The consecutive continuation period lasts for at least 18 months subsequent to a negative culture within the intensive phase, whereas this period may be prolonged up to 24 months depending on case severity. A sputum-smear exam is conducted on a monthly basis until two subsequent negative results, and afterwards in a frequency of every two to three month. Furthermore, monitoring of signs for side-effects ought to be conducted throughout treatment (WHO, “Treatment of Tuberculosis Guidelines” 91).

In the Republic of Cameroon, to diagnose MDR-TB within all suspected cases, such as retreatment or MDR-TB contact cases, initially cultures are conducted in the three laboratories “Centre Pasteur du Cameroun” in Yaoundé, CEBEC Baptist Hospital in Douala and MEZAM clinic in Bamenda (Abena et al., “Preliminary Draft” 16/17). Accordingly when
confirmed, the intensive phase of the standardized treatment regimen for new MDR-TB patients with the habitual abbreviation “4KmGfxPtoHCfzEZ/ 8GfxPtoCfzEZ” is commenced for 4 months by the utilization of Km, Gatifloxacin (Gfx), Pto, H, Cfz, E, and Z as hospital in-patients under DOT at Jamot Hospital in Yaoundé or Dibamba Hospital in Douala. Throughout monthly sputum-smear examinations and cultures are conducted; after four months (following sputum conversion, confirmed by culture), the patient enters the continuation phase; whereas, if positive microscopy, then the intensive phase is extended for maximal two months. If a patient’s sputum culture is positive at the end of the maximum treatment time of the intensive phase, a “classical” treatment scheme for MDR-TB, “6KmLfxPtoCsZ/ 12or18LfxPtoCsZ”, is implemented. During the 8-months continuation period Gfx, Pto, Cfz, E, and Z are administered under ambulatory DOT. Throughout treatment, individual adverse-effects are monitored and if occurring, these are medically cared for. Moreover, herein every two month a sputum-smear exam and culture are conducted. In general, for a duration until month 24 after “cure”, a structured and intensive biological and clinical follow-up is conducted (NTCP Cameroon, “Application to the GLC July 2008” 26/27, 30).

The first results of this standardized treatment regimen for new MDR-TB patients in the Republic of Cameroon since its initiation two years ago are very promising. Among the first group of patients, 96 percent were cured (including four HIV-positive patients); there has not been any treatment defaulters; and solely one patient died during the intensive phase even though being sputum-smear negative (Abena et al., “Preliminary Draft” 14, 19).

For the diagnostic work-up of TB, every suspected patient is charged 1,000 F CFA (1.52 Euros), however when detected the examinations and medications are provided free-of-charge. For this purpose, the Cameroonian NTCP receives its financial resources principally from the GFATM, as well as from the HIPC-initiative, the country office of WHO, the GTZ, the AFD, and the Aide aux Lépreux-Emmaus Suisse (ALES). The Cameroonian government via the main responsible MoPH provides the human resources and the health infrastructure from government funds (Kuaban and Noeske 156/157). At present, SLDs against MDR-TB for Cameroon are ordered from the IDA and/or Svizera via the Damien Foundation (NTCP Cameroon, “Application to the GLC July 2008” 32). Thereafter, the SLDs are distributed on request to the TB-CTG via CENAME to the CAPP, coordinated by the NTCP. Finally, the DTCs apply for the provision of these drugs from CAPP via the approval of the Regional Tuberculosis Control Unit (République du Cameroun, “Programme National” 103). Currently, the SLDs against MDR-TB that are accessible within Cameroon are Am, Ofx,
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ciprofloxacin, Km and Pto. The utilization of Gfx and Pto was recently passed by the Directorate of Pharmacy and Medicine of the MoPH (NTCP Cameroon, “Application to the GLC July 2008” 32).  

4. Discussion

Within the discussion chapter, the three following critical arguments are consecutively debated: the power allocation resulting from the international health policy guidelines for MDR-TB, the relation between therapeutic freedom and the central principles for standardized treatment regimen of MDR-TB of WHO as well as the reasons for the establishment of the power center by international health policy guidelines for MDR-TB.

4.1 The Power Allocation Resulting from the International Health Policy Guidelines for MDR-TB

The first critical argument can be articulated in view of the current power allocation resulting from the international health policy guidelines for MDR-TB of WHO, which was already highlighted by Cullinan in the year 2001 (1124). As described in detail in section 3.3.2.1 and visualized in the fig. 5 “The Established Power Center by International Health Policy Guidelines for MDR-TB” extracted from annex 5 of this master’s thesis, the GLC was set-up by the WHO under the Working Group on MDR-TB of the Stop TB Partnership. Initially, the NTCPs apply for concessional-priced and quality-guaranteed SLDs for the treatment of MDR-TB to the GLC. The GLC solely approves these applications on condition of the conformity of their treatment schemes for MDR-TB with the principles outlined in the Guidelines for the Programmatic Management of Drug-resistant Tuberculosis of WHO. Subsequently, the GDF is authorized by the GLC to control and supervise the procurement of subsidized and quality-assured SLDs against MDR-TB via their exclusive acquisition by the IDA. Most NTCPs in countries with a high MDR-TB burden, particularly transitional and developing countries are primarily funded by the GFATM, which in the beginning of 2002 determined that all demands to them for funding of SLDs against MDR-TB as well as their...

34 Cfz is essential for the treatment regimen of MDR-TB patients that is applied in Cameroon. However, Cfz is habitually utilized to treat leprosy (Van Deun et al., “Short, Highly Effective, and Inexpensive Standardized Treatment” 15) and falls under the group 5 “non-recommended” medications for the treatment of MDR-TB of WHO. Thus, it is internationally hardly accessible for its utilization in the field of MDR-TB (cf. WHO, “Guidelines for the Programmatic Management” 54), and in 2010, it was generally not available for MDR-TB treatments. In addition, as Cfz is not available on the Cameroonian market, it habitually has to be ordered internationally, which hinders its accessibility for MDR-TB patients in Cameroon (A/N).
procurement ought to be solely processed by the GLC. Finally, the access to these SLDs is overseen by the WHO.

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**Figure 5. The Established Power Center by International Health Policy Guidelines for MDR-TB**

As the drugs of complete treatment regimen for one MDR-TB patient cost on average between 16,000 and 19,000 US-dollars in high-income countries (for a detailed graphic on average treatment costs per MDR-TB patient worldwide see annex 11.1) and between 5,000 and 7,000 US-dollars in low-income countries; particularly low-income countries are reliant on executing treatment regimens with concessional-priced and quality-guaranteed SLDs from the GLC or GFATM that cost on average for one MDR-TB case between 1,000 and 2,000 US-dollars (Gupta et al., “Responding to Market Failures” 1049) owing to negotiations between the pharmaceutical industry and the GLC. These lower priced SLDs are solely received via an approved application of the NTCPs by the GLC (Cullinan 1124), while projects not being able or willing to procure SLDs via the GLC, are still allowed to acquire these medications for the usual and thus more cost-intensive market price (Gupta et al., “Increasing Transparency in Partnerships for Health” 974). In early 2001, concerns were raised about the power concentration between the WHO, the GLC, the GFATM, the GDF, and the IDA, as well as consecutively about the interests of these actors and about the transparency of their decisions-making process on the accessibility of SLDs within this global governance system of MDR-TB (Cullinan 1124). First, according to an international expert, the GFATM – by predominantly financing the acquisition of concessional-priced and quality-
assured SLDs for the NTCPs of transitional and developing countries – makes the establishment of national alternative MDR-TB treatment programs virtually impossible, if these do not respect WHO’s Guidelines for the Programmatic Management of Drug-resistant Tuberculosis and do not possess a different donor organization (International Expert 1, “E-Mail: RE: Global Tuberculosis Governance System”). More precisely, this financing of the SLDs creates a one-sided dependency of the NTCPs of transitional and developing countries from the GLC and GFATM that does not permit these countries to manage their MDR-TB policies autonomously (A/N). Second, if - according to this expert - the majority of the salaries of the staff of WHO’s Stop TB Partnership are paid by Northern American organizations, the questions can be raised, which interests are represented, who legitimates and who dominates this established power center (International Expert 1, “E-Mail: RE: Global Tuberculosis Governance System”)? As a further impulse for thought, can this current power allocation by international health policy guidelines for MDR-TB be described as a patronizing behavior of industrial countries dominating in this power center that limits the access to and authorizes the supply of SLDs vis-à-vis transitional and developing countries with the highest MDR-TB burden?

4.2 Therapeutic Freedom and the Central Principles for the Standardized Treatment Regimen of MDR-TB of WHO

The second critical argument can be formulated with regards to the central principles for the standardized treatment scheme of MDR-TB outlined by the Guidelines for the Programmatic Management of Drug-resistant Tuberculosis of WHO that underlie the approval of the provision of subsidized and quality-assured SLDs via the GLC. Hereby, the “therapeutic” or “clinical freedom”, which is characterized as the physician’s choice of treatment in consideration of the medical state of the art that is accumulated by e.g. clinical trials, experience or acceptance, is limited. These components of the medical state of the art are hierarchically ordered by quality and nowadays clinical trials feeding into “evidence-based medicine (EBM)” are found to be from highest quality. Thus, although the data that provides the basis for EBM constantly change and improve, and this information should be the best basis for treatment decisions by individual physicians, this principle is overruled by the concept of standardized treatment regimens (cf. Hart 756). The two reasoning behind the restriction of “therapeutic freedom” are as follows: (a) when physicians ought to administer a treatment solely on a directive formulated from the outcomes of EBM, then there is no more space for the application of other decision criteria for the treatment conception based on
expert opinion, individual experience, accessibility or acceptance; and (b) when a physician has to oblige to an international directive, then his/her individual knowledge on the most effective treatment is questioned and he/she will solely utilize standard treatment regimens for different individual patients (Gerber and Lauterbach 67/68).35 Thus, an obligatory nature of evidence-based directives would not only limit the individual “therapeutic freedom” of a physician, but also the one of therapeutic programs.

In 1948, the first clinical trial that respected methodological standards for indicating effective medications against TB was conducted. Thereafter, further trials that assessed different medications, their combinations, as well as their frequency and period of administration were performed. In this time-period, the British Medical Research Council (BMRC) finally illustrated the effectiveness of a treatment regimen of 18 months for drug-susceptible TB without R - that serves in parallel for the principle that also MDR-TB treatment without R needs to be 18 months long - and a short-course regimen that included R. This initiated its global application recommended by the WHO. In the 1980s, the clinical trials on TB treatment halted almost completely, posing problematic questions about exemplary effective treatments for HIV-TB or MDR-TB patients. Provisional guidelines recommended an eight month-regimen for TB in HIV co-infected individuals. Approximately 20 years later, the UNION carried out a clinical trial on a standardized 6-month treatment regimen for drug-susceptible TB in HIV co-infected individuals, proving its efficacy. In 2008, this finally replaced the 8-month treatment scheme, when also an expert committee of WHO officially concluded that the former treatment scheme cannot be advised any longer (A. Nunn 380).

Now, it is noticed that even though the present “[treatment] of MDR-TB is prolonged, expensive and requires appropriate clinical and laboratory infrastructure” (Lienhardt and Davies 528), the central principles for the standardized treatment scheme of MDR-TB by WHO are also solely based on expert opinions resulting from observational research and individual experience. Therefore, evidence-based results from clinical trials, e.g. as for drug-susceptible TB, are lacking and hence, there is no agreement on the most effective treatment for MDR-TB. Furthermore, due to a relative small proportion of MDR-TB cases compared to drug-susceptible TB, there are simply operational problems in conducting clinical trials to

35 The counter-argument is that international guidelines do not limit “clinical freedom” as these are solely directing the physician to choose an adequate treatment option (Hart 756). In addition, “clinical freedom” can even be strengthened by EBM as any physician can conduct or confide in the statistical outcomes of a research accomplished according to its standards as these are supposed to reflect the reality (Gerber and Lauterbach 60/61).
feed into EBM. Moreover, when this problem is solved by comparisons between different study groups, their heterogeneity with regards to resistance patterns, prior treatment experiences, or prevalence of HIV ought to be considered, and this would limit the validity and generalizability of the evidence provided by such study (Lienhardt and Davies 528, 530). To conclude, “[clinical] trials are likely to remain the gold standard for evidence of efficacy, but their limitations need to be recognized” (A. Nunn 381).

Against this background and in view of the situation that the present international directives for the management of MDR-TB propose lengthy and highly expensive standardized treatments frequently generating severe side-effects and being problematic to apply and observe (Van Deun et al., “Short, Highly Effective, and Inexpensive Standardized Treatment 2, 5) with an overall success-rate only between 54 and 69 percent (cf. Johnston et al., “Treatment Outcomes of MDR-TB”; cf. Orenstein et al., “Treatment Outcomes Among Patients With MDR-TB”); and considering that these guidelines are established via expert opinions in contrast to verification via controlled clinical assessments in accordance with EBM, van Deun et al. conducted a remarkable observational study of which the final results were published in May 2010. Herein, the most successful standardized treatment regimen appeared to be “4(+KmCfzGfxEHZPto/ 5GfxEZCfz” with a minimum duration of nine months. The healing rate among this cohort of 206 MDR-TB patients was 87.9 percent, compared to 221 MDR-TB patients treated within the five 15- to 21-month long ofloxacin-based regimens, which had a success rate varying between 57.1 and 84.2 percent. Moreover, in general the probability of achieving adverse results, e.g. death, default, or failure was about one-third lower in this gatifloxacin-based treatment scheme than in the other five regimens, and in particular the failure-rate was below 1 percent when Gfx was utilized. Finally, the generic medications for this complete scheme merely cost about 225 Euros per MDR-TB patient. Thus, this standardized treatment regimen proves to be very effective and successful, relatively short in time and inexpensive. Therefore, it offers cost-efficient treatment opportunities for developing countries considering the respective HIV-prevalence and susceptibility to SLDs (2-8, 12, 15-19, 30, 38).

In March 2008, the NTCP of Cameroon applied for quality-guaranteed and concessional-priced SLDs for its standardized treatment regimen “4KmGfxPtoHCfzEZ/ 8GfxPtoCfzEZ” for new MDR-TB patients based on this study of van Deun et al.36 from the

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36 The 3-month longer standardized treatment regimen of the Republic of Cameroon is even more reassuring than the 9-month treatment regimen of van Deun et al. for the following reasons: The utilization of
GLC (NTCP Cameroon, “Application to the GLC March 2008”)\textsuperscript{37}, which were to be procured by CENAME and supplied by the TB-CTG to specialized treatment units (NTCP Cameroon, “Application to the GLC July 2008” \textsuperscript{32}). In May 2008, the GLC rejected the application of Cameroon’s NTCP for the first time, as this treatment regimen is not in conformity with the principles outlined in the \textit{Guidelines for the Programmatic Management of Drug-resistant Tuberculosis} of WHO, and as the proof of success of this treatment is insufficient.\textsuperscript{38} However, it was stated that the NTCP of Cameroon may either revise its application with an “experimental” treatment regimen, or may transfer it for approval to the Research Subgroup of the MDR-TB Working Group of WHO (GLC, “Dr H Wang, Yaoundé”). In July 2008, the NTCP of Cameroon submitted a revised application for quality-assured subsidized SLDs for its short-term standardized treatment scheme against MDR-TB with an alternative of a “classical” treatment regimen for MDR-TB re-treatment cases to the GLC (NTCP Cameroon, “Application to the GLC July 2008”). Hereof, respecting its first answer of May 2008, the GLC solely approved the “classical” treatment scheme under several conditions, e.g. addition of further SLDs to the regimen, daily administration of treatment under DOT, implementation of a research project in collaboration with the Research Subgroup of the MDR-TB Working Group of WHO concerning the 12-month treatment scheme or placing all MDR-TB patients under this classical treatment regimen, as well as proof of authorization of import of GLC-supported SLDs (GLC, “Dr F. Ottou, Yaoundé”).

This case supports the second two-folded critical argument with regards to the central principles for the standardized treatment scheme of MDR-TB of WHO. First, the principle of “clinical freedom” of the Cameroonian NTCP and its physicians is limited by rejecting the

\begin{flushright}
\textsuperscript{37}Since 1996, the NTCP of Cameroon collaborates informally together with the Institute of Tropical Medicine in Antwerp, Belgium and van Deun. The former chief of the Cameroonian NTCP, Kuaban, followed closely the successful experiences of van Deun’s different experimental treatment schemes for MDR-TB patients in Bangladesh published in 2004 and 2010. Initially in 2005, he decided to adopt a 21-months long treatment scheme against MDR-TB for Cameroon and in 2008, thus the ‘fortified’ 12-months long treatment regimen against MDR-TB based on the long-term study of van Deun et al. in Bangladesh - after a regional meeting of NTCP Directors, WHO and the UNION in Ouagadougou, Burkina Faso also recommending latter regimen. Subsequently, the NTCPs of Benin and Cameroon adopted this 12-months scheme for the treatment of MDR-TB and other countries envisaged to follow later due to their present financing by the GFATM and in-turn their inability to change their existing treatment regimens against MDR-TB (Noeske, “Personal Interview 2”).
\end{flushright}

\begin{flushright}
\textsuperscript{38}Although, these central principles for the standardized treatment scheme of MDR-TB of WHO were developed in view of the situation of a 20 to 40 percent MDR-TB burden with multiple resistances to FLDs and SLDs in the countries of the former Soviet Union; a situation which differs substantially from the one in Sub-Saharan Africa (A/N).
\end{flushright}
12-month treatment regimen of MDR-TB that was not generated from EBM\textsuperscript{39}, even though the central principles of WHO are also solely based on expert opinions resulting from observational research and individual experience and have an overall success-rate of only 54 to 69 percent. Second, although “[prescribing] presents a clear example of clinical autonomy and the right to prescribe medicines is a major component of clinical freedom” (Britten 479), clearly alternative drugs or durations of treatment of MDR-TB patients are unlikely to be supported by the GLC. This position poses the following problems for the NTCP of Cameroon:

1. Of the recommended SLDs for treatment of MDR-TB, solely the quinolones Ofx and ciprofloxacin, as well as the injectables Km and Amikacin (Am) are prescribed and sold in Cameroon. Furthermore, these drugs are primarily utilized for the treatment of diseases other than TB for a maximum duration of 10 to 14 days (Abena et al., “Preliminary Draft” 6/7, 13). Gfx and Pto need to be procured via the international market.

2. On the international market these drugs are accessible. However, for a long-standing treatment for more than two weeks of MDR-TB patients, the NTCP of Cameroon, a resource-limited country, cannot afford these drugs, if these are not subsidized by the GFATM or the GLC. Thus, their financial accessibility for TB patients is also strongly limited because of their prize.

3. Furthermore, MDR-TB patients in Cameroon cannot afford their treatment, if the GFATM does not pay the follow-up exams that are an essential part of the standardized MDR-TB treatment regimen. On the contrary, each NTCP is only able to receive funds from the GFATM when its treatment scheme was approved by the GLC (Noeske, “Personal Interview 1”).

On the other hand, according to three international experts, there are many countries in which non-standardized treatments of MDR-TB are less successful than in Cameroon or Bangladesh and ultimately lead to the further transmission of MDR-TB. This consecutively endangers the efficacy of current SLDs, and new SLDs are not timely invented. Therefore and since the GLC is statutorily responsible for the adequate management of MDR-TB, it is solely able to approve applications from NTCPs compliant with the recommended central principles of WHO. Other promising treatment schemes are referred to the Research Subgroup of the MDR-TB Working Group of WHO. Also, the cohort study of Cameroon could have been assessed by this institution; however, the NTCP decided against it. They

\textsuperscript{39} With the advice to submit it to the Research Subgroup of the MDR-TB Working Group of WHO (A/N).
knew that randomized studies on MDR-TB treatment would not be feasible in practice in Cameroon and they were aware of internal problems and conflicts\(^40\) (International Expert 2-4, “E-Mail: RE: Questions with regards to Master's Thesis”).

In summary, this paternalistic policy of the established power center by international health policy guidelines for the treatment of MDR-TB vis-à-vis the NTCP of Cameroon, as a representative for performing alternative successful standardized treatment regimen against MDR-TB in resource-limited countries, is criticized.

4.3 The Reasons for the Establishment of the Power Center by International Health Policy Guidelines for MDR-TB

Against this background, the third argument derives from a critical examination of the reasons for the establishment of this power center with the authority to determine the financing process of SLDs utilized for the treatment of MDR-TB. It can be suspected that economical interests within the pharmaceutical market for TB of industrialized nations vis-à-vis transitional and developing countries is a key explanation regarding the power acquisition in decision-making of this group of actors by international health policy guidelines for MDR-TB. This explanation is supported by the fact that the current costs of the drugs of a complete treatment regimen for one MDR-TB patient are on average between 5,000 and 19,000 US-dollars depending on the income-level of the respective country (Gupta et al., “Responding to Market Failures” 1049), whereas the generic drugs of a complete 9-month standardized treatment course based on Gfx in Bangladesh – shown successful by van Deun et al. – solely cost about 225 Euros per MDR-TB patient (van Deun et al., “Short, Highly Effective and Inexpensive Standardized Treatment” 15), and the drugs of a 12-month standardized treatment course based on Gfx in Cameroon – possessing promising results assessed by its NTCP – cost 198 Euros; compared to their costs in the classical standardized treatment course of 1097 Euros (see annex 11.2), which is hence at least five to ten times more expensive depending on the market price determined by demand and supply (NTCP Cameroon, “Application to the GLC July 2008”). As a consequence, it is assumed that the margin of the pharmaceutical industry providing drugs for necessarily treating the estimated 440,000 MDR-TB patients worldwide in the year 2008 alone (Ghandi et al. 1830) with the

\(^{40}\) According to a staff member of the Cameroonian NTCP, this internal problem was observed to be the conflict of interest of certain Cameroonian policy makers, in particular of the national WHO office in Cameroon, that defended their positions by supporting the central principles for the standardized treatment scheme of MDR-TB of WHO. Thus, these officials did not encourage the “experimental” treatment scheme against MDR-TB pursued by the NTCP of Cameroon (A/N).
recommended standardized long-term treatment scheme of WHO and not with alternative short-term treatment regimen of Bangladesh or Cameroon is extremely high\textsuperscript{41}.

On the other hand, pursuant to the three international experts, the suspected key explanation of economical interests in the pharmaceutical market affecting the decision-making of the established global power center is invalid, as the pharmaceutical market for TB, according to them, is found to be minuscule and unprofitable. Correspondingly, they state that the exercise of power of this center in global health politics was derived from the will to satisfactorily ensure the availability of concessional-priced and quality-approved SLDs for the programs according to the central principles of WHO by encouraging the pharmaceutical manufacturers to maintain or increase their production. The trigger for this demand, however, appeared to be the MDR-TB outbreak affecting the United States in 2000, as previously by the mid-1960s the interest of the industrialized countries for the TB problem mostly prevalent in transitional and developing countries had almost extinguished. Thus, as per these international experts, the efficacy of the management of MDR-TB by the GLC is questionable, attributable to the facts that the GLC is an important actor within this closed power center on international level, and it can be understood as rational concern that the global MDR-TB problem should not be compromised by one country’s potentially adverse influence in international politics. In future, this power center ought to open up to foster successful initiatives (International Expert 2-4, “E-Mail: RE: Questions with regards to Master's Thesis”) and “… to adequately meet the growing needs of countries engaging in the management of MDR-TB” (International Expert 2-4, “E-Mail: RE: Questions with regards to Master's Thesis”).

5. **Conclusion and Recommendations**

Within this study, the theoretical policy analysis triangle of Walt and Gilson was utilized to assess the general hypothesis that is implied in this overall research question. Against this policy, the overall research question of this study is confirmed, and thus it is concluded that the access to drugs for MDR-TB patients in the Republic of Cameroon is

\textsuperscript{41} If the mean drug costs for a complete treatment regimen for one MDR-TB patient are considered to be $12,000 \text{US}\$, $[(5,000 \text{US}\$+19,000 \text{US}\$)/2]$, and 440,000 MDR-TB patients need to be treated, then the calculated market volume is 5,280,000,000 \text{US}\$ (12,000 \text{US}\$*440,000 MDR-TB patients), compared to the calculated market volume with a promising short course regimen of about 93,060,000€ (=118,381,885.26 \text{US}\$) $[(198€+225€)/2]*440,000 MDR-TB patients] (A/N).
restricted as a result of these international health policy guidelines, the central principles for
the treatment of MDR-TB patients outlined in the *Guidelines for the Programmatic Management of Drug-resistant Tuberculosis*, of WHO.

Consequently in more detail, within the dimension of the context, the following factors were identified pursuant to the “Scheme for Analyzing Public Policy” of Leichter: The situational factor classified as “Natural disasters” corresponds to the essentially man-made epidemic of TB, in particular the occurrence of MDR-TB in the case study of the Republic of Cameroon. The structural factors primarily considered are the “Political structure”, the “Economic structure”, and the “Social and demographic structure” are consistent to the Cameroonian presidential government within a civilian, non-socialist political regime, underlined by a multiparty system and organized in a centralized political system; to the capitalistic economic system of the Republic of Cameroon with the majority of Cameroonians employed in the agricultural sector, while the service sector contributes mainly to the GDP, and possessing a variety of natural resources, even though being dependent on ODA; as well as to a Cameroonian population having a low life-expectancy, a rising death rate, as well as a decreasing under-five-mortality and fertility rate. The “Cultural factors” principally affecting the access to drugs for MDR-TB patients in the Republic of Cameroon within international health policies are the political norms and values within the relationship of individuals and the Cameroonian government, and cultural pluralism as gender and the stigmatization of TB. The two “Environmental factors” that are crucially important are “Policy and issue diffusion” and “International agreements, organizations and obligations”, which are equivalent to the conditioned policy transfer of the central principles of WHO outlined in its *Guidelines for the Programmatic Management of Drug-Resistant Tuberculosis* to the Cameroonian NTCP, and Cameroon’s dependence on ODA from international donor organizations. Second, within the dimension of process, the agenda-setting of these international health policy guidelines for the treatment of MDR-TB of WHO was initiated by the rising HIV/AIDS pandemic, growing drug-resistances to anti-TB drugs, and the cut back of the health sectors’ budget due to the implementation of the SAPs in transitional and developing countries by the World Bank and the IMF. Therefore, WHO acknowledged TB as a “Global Emergency” in 1993. The policy conceptualization was a process in itself from the first Stop TB Partnership Policy formulated by WHO in 1998 to the contemporary *Guidelines for the Programmatic Management of Drug-resistant Tuberculosis* published by WHO in 2006 and updated in 2008. Further, the stage of policy implementation directed that national NTCPs applied these international health policy guidelines of WHO. The evaluation of this
policy in the Republic of Cameroon demonstrates that the Cameroonian NTCP is supporting an alternative successful standardized treatment regimen “4KmGfxPt0HCfzEZ/8GfxPt0CFzEZ” as the MDR-TB incidence was rising and the GLC was solely able to provide quality-guaranteed and concessional-priced treatment to 1.4 percent of the MDR-TB infected worldwide. Third, within the dimension of actors, the international actors identified with a high interest as well as high influence/power in these international health policy guidelines are the WHO, the GLC, the GDF, the IDA, the GFATM, UNITAID and the UNION; accordingly, the actor holding a high interest and a high influence/power operating on the national level of the Republic of Cameroon is the Department of the Control of TB of the MoPH. Finally, within the dimension of context, the NTCP of the Republic of Cameroon is pursuing the above-mentioned alternative the standardized treatment regimen for new MDR-TB patients with a cure rate of 96 percent.

The conducted analysis of the international health policy guidelines as the central principles of WHO outlined in its Guidelines for the Programmatic Management of Drug-resistant Tuberculosis found the following three critical arguments: First, the current power concentration between WHO, the GLC, the GFATM, the GDF, and the IDA that makes the establishment of national alternative MDR-TB treatment programs not conforming to WHO’s “Guidelines for the Programmatic Management of Drug-resistant Tuberculosis” for transitional and developing countries impossible, in this case in particular for the Republic of Cameroon, as applications to the GLC for concessionally priced and quality-guaranteed SLDs for the treatment of MDR-TB are not approved. Second, these central principles for the standardized treatment scheme of MDR-TB of WHO limit the “therapeutic” or “clinical freedom” of NTCPs, in this study for the Cameroonian NTCP and its physicians, by rejecting alternative treatment regimen for MDR-TB generated form EBM and by rejecting an alternative treatment regimen for MDR-TB patients generated from a randomized study reflecting the highest ranking in EBM. Third, the reasons for the establishment of the power center via international health policy guidelines for MDR-TB are suspected to be the economical interests within the pharmaceutical market for TB of industrialized nations vis-à-vis transitional and developing countries.

With regards to this outcome of the study, the following further recommendations are offered regarding the global commitment to reduce MDR-TB in transitional and developing

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42 Notably, the central principles of WHO are also solely based on expert opinions resulting from observational research and individual experience and have an overall success-rate of only 54 to 69 percent (A/N).
countries: First, the clinical freedom of NTCPs and their physicians in consideration of the medical state of the art has to be accepted and accordingly a more unconditioned authorization for promising alternative (standardized) treatment regimens for MDR-TB patients has to be given and the possibility to recognize successful observational studies by the established power center, particularly in resource-limited settings, is advised. Second, out of the assuring experiences of the 21-months long treatment scheme against MDR-TB and the long-term study of van Deun et al. in Bangladesh, the NTCP of Cameroon adopted the fortified short-term 12-months treatment regimen against MDR-TB. This was reasonable, due to the very sporadic resistances of MDR-TB patients against SLDs. However, in other countries, for instance within the region of the former Soviet Union, an unlimited projection of this promising 12-months treatment scheme is not possible, because of the incomparable situation of frequent resistances of MDR-TB cases against one or more SLDs. Thus, in these countries, either a strong long-term standardized or individualized treatment regimen against MDR-TB utilizing the SLDs proven to be effective is recommended; and the more unconditioned authorization for promising alternative (standardized) treatment regimens for MDR-TB patients in view of the country’s TB drug-resistance profile is suggested to be provided as the standardized treatment regimen against MDR-TB of WHO aims at situations such as in the former Soviet Union region. Third, more unrestrained funding mechanisms, especially for transitional and developing countries, have to be found, when these apply successful alternative treatment schemes against MDR-TB that reduce its occurrence, in order to ensure continuous access to and availability of drugs against MDR-TB.

Already 10 years ago, Cullinan criticized the contemporary power allocation predominantly implemented in transitional and developing countries, which results from international health policies for MDR-TB and the assumed underlying motif of economical interests within the pharmaceutical market for TB of industrial nations. Even though the countries of the former Soviet Union found effective treatment means against MDR-TB, other transitional and developing countries are confronted with the same or a worsened situation as 10 years ago. Thus, in prospect, a change of this system accounting for the above-mentioned recommendations would be highly desirable.
Works Cited


Kuaban, Christopher, Juergen Noeske and Arnaud Trébucq. Personal Interview. 06 Dec. 2010.


---.  Personal Interview 1. 23 Nov. 2010.

---.  Personal Interview 2. 30 Nov. 2010.


Annex 1 List of Search Words

Googlescholar via the Proxy of the University of Groningen
- Pharma Industry AND Influence AND Tuberculosis AND World Health Organization AND Green Light Committee (first 10 pages) (10 Aug. 2010)
- Cameroon and Health Sector from 2005 to 2010 (23 June 2010)
- Armand van Deun (11 Aug. 2010)

PubMed Database
- Multidrug-resistant tuberculosis AND World Health Organization AND Green Light Committee (17 Aug. 2010)
- Multidrug-resistant tuberculosis AND Green Light Committee (17 Aug. 2010)
- Multidrug-resistant tuberculosis AND WHO AND GLC (17 Aug. 2010)
- MDR-TB AND treatment AND alternative (25 Nov. 2010)
- MDR-TB AND treatment AND short (25 Nov. 2010)

The International Journal of Tuberculosis and Lung Disease
- Multidrug-resistant tuberculosis from 2006 to 2010 (18 Aug. 2010)
- Multidrug-resistant tuberculosis AND Green Light Committee (GLC) (18 Aug. 2010)
- All volumes of 2009 and 2010 (19 Oct. 2010)

The Lancet
- Multidrug-resistant tuberculosis from 2006 to 2010 (18 Aug. 2010)
- Multidrug-resistant tuberculosis AND Green Light Committee (GLC) (18 Aug. 2010)

WHO Website
- WHO AND Green Light Committee from 2006 to 2010 (19 Aug. 2010)
- Cameroon Health Sector AND TB (02 July 2010)
Annex 2  Emails from Anonymous International Experts


RE: Global Tuberculosis Governance System
Sunday, August 22, 2010 8:31 PM
From: 111
To: "Natascha Voelz" <natascha.voelz@yahoo.com>

Dear Natascha,

Sorry for not replying. I'm not sure who is on the GLC board these days. I don't get replies from those whom I asked, maybe top secret?

As for your triangle theory: something like that, yes. But maybe more nuanced here and there:
- I wonder if WHO is on top, or CDC Atlanta and other American groups (PIH). The US pay so many salaries at WHO Stop TB these days that they have them in their pocket. But I'm not sure, would have to get the feeling from some honest people in Geneva (they exist!).
- there is also GFATM, more important than GDF which can't even deliver on time regularly, and their prices are not exceptionally low. GFATM can effectively stop countries in their tracks (even for lab in general) if they don't obey and don't have another sponsoring mechanism

I'll try again with some friends in Geneva, touchy?

Best regards,

111

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From: Natascha Voelz [mailto:natascha.voelz@yahoo.com]
Sent: dinsdag 17 augustus 2010 15:26
To: 111
Subject: Global Tuberculosis Governance System

Dear 111,

with regards to the core of my Master’s thesis, which shall be a critical analysis on the access to medicines against MDR-TB, I recently analysed the existing global health - in particular tuberculosis - governance system. Since this is new terrain for me, I would like to kindly inquire if you know a member of the Green Light Committee who might be willing to offer me feedback to the attached draft chapter on the relations of actors and strategies (policies) within this field. For your information, I additionally attached a respective organigram as well as a list of abbreviations.

Furthermore, this chapter arose a few further questions that I would like to pose respectively:
1) Which nationalities are represented by the members of the GLC (is there a statistical breakdown of them)?
2) Would you confirm my abstract thought that a power center or triangle has been established around the GLC (with WHO on the peak and the GLC and GDF on the sides) with regards to access to medicines for MDR-TB? Is there any supporting literature to this critical statement or would you be willing to write two or three sentences about it in an email to me that I may cite?

I am looking forward to your response and thanking you in advance for your support.

Best regards from Yaoundé,
Natascha Voelz

Re: Questions with regards to Master’s Thesis
Saturday, August 28, 2010 9:12 AM
From: 444
To: 222, 333, natascha.voelz@yahoo.com

I agree with the comments of 222 and 333.

444

----- Original Message ----- 
From: 222
To: 333 ; natascha.voelz@yahoo.com
Cc: 444
Sent: Friday, August 27, 2010 11:46 AM
Subject: RE: Questions with regards to Master's Thesis

Natascha,
Find some additional comments in red from my side below.

222

De : 333
Envoyé : jeudi 26 août 2010 19:08
À : natascha.voelz@yahoo.com
Cc : 222, 444
Objet : RE: Questions with regards to Master's Thesis

Natascha
je profite de la proposition de m’exprimer en français pour le faire, en évitant les triangles (et même les carrés).

1)                               What do you think about the present situation that the GLC solely approves applications in compliance with the WHO Guidelines for Programmatic Management of Drug Resistant Tuberculosis and refers all other successful alternative treatment schemes, like the one of van Deun as well as the ones utilized in Cameroon and Benin, to its Scientific Committee while everybody knows that conceiving randomized studies in order to prove their value is in practice almost impossible? As I read in the article of Lienhardt, C., and G. Davies. (“Methodological Issues in the Design of Clinical Trials for the Treatment of Multidrug-resistant Tuberculosis: Challenges and Opportunities.” International Journal of Tuberculosis and Lung Disease 2010: 528-537.), these central principles for the standardized treatment scheme of MDR-TB by WHO with an overall success-rate solely between 54%-69% are also based on expert opinions resulting from observational research and individual experience, in opposition to wished for evidence-based results from clinical trials.

Le monde des MDR est très mouvant et politiquement très sensible. Sans aller trop loin, il y a peu de temps, nous étions assez opposés à détourner l’attention des systèmes de santé de l’organisation correcte du traitement de la tuberculose « banale » vers la prise en charge des MDR. Je connais beaucoup de pays où je trouve anormal de se lancer dans le diagnostic et la prise en charge des MDR alors que le programme contre la tuberculose est un désastre qui fabrique beaucoup plus rapidement des MDR qu’on ne pourra jamais en guérir ! Dans la santé publique, il faut faire des choix ! Le GLC est chargé statutairement de dire si les propositions des pays pour les MDR sont conformes ou non aux recommandations de l’OMS ; je crois que cela a été utile car lors du début du traitement des MDR, on voyait tout et n’importe quoi. Les programmes approuvés par le GLC pouvaient alors bénéficier d’un approvisionnement en médicaments à prix préférentiels négociés par le GLC avec les quelques compagnies pharmaceutiques offrant ces produits (Eli-Lilly, Jacobus, Fatol…). C’était aussi le moyen de protéger l’utilisation des médicaments de seconde ligne/3ème ligne puisque derrière il n’y avait pas de nouveaux produits en vue dans l’immédiat. Donc ce qui sortait des recommandations, comme le protocole du Cameroun ne pouvait être accepté que si le sous-groupe de l’OMS sur la recherche en matière de MDR était d’accord (sous-groupe de l’OMS et non du GLC). Il est faux de dire que seulement les essais cliniques randomisés sont acceptés par ce sous-groupe. Les études de cohortes, comme celles du Cameroun, sont tout à fait acceptées et j’en avais discuté en son temps avec le GLC et le sous-groupe de recherche. Un problème s’est posé pour le Cameroun, lié à l’époque à la grande incertitude pour tout ce qui touchait aux MDR : cela semblait politiquement dangereux de demander l’aval du Comité d’éthique du Cameroun. Les responsables au
Cameroun, comme moi-même, étions persuadé de l’intérêt de cette étude, mais on a décidé de ne pas demander l’avis du Comité d’Ethique du Cameroun de peur d’un refus. Donc nous n’avons pas poursuivi avec le GLC. A présent la situation est différente et nous avons décidé de soumettre cette étude au Comité d’éthique du Cameroun et au GLC car il y a eu un article scientifique accepté dans une revue prestigieuse sur les traitements courts, le nouveau Guide de L’Union qui en parle, les succès intermédiaires au Bénin et au Cameroun. J’espère bien que le Comité d’éthique et le GLC seront d’accord !

2) More specifically, what are the arguments of the opponents of this financing process of concessionally-priced and quality-approved SLDs via the GLC that was set up by the WHO? E.g. - according to you - is there any economical interest of the pharma-industry to be suspected on the decision-making process and the general policies of the GLC? If yes, from whom? Accordingly, is there a gain of industrial countries contrary to developing countries? Consecutively, why is there no rebellion of the health policy/ MDR-TB responsible from developing countries in this context?

Je ne pense pas que l’industrie joue un rôle quelconque dans cette affaire : le marché est minuscule. L’objectif du GLC avec cet approvisionnement en médicaments de seconde ligne était de s’assurer que des produits soient réellement disponibles pour les programmes répondant aux critères OMS. C’était aussi un moyen de regrouper les demandes des pays et de montrer aux fabricants un certain volume pour les inciter à maintenir les productions (Eli-Lilly pour la Capréomycine et la Cyclosérine) ou à en augmenter leur capacité (PASER de Jacobus). Dans un second temps, ce regroupement a permis d’inciter certains génériques à entrer sur ce marché même si c’est encore timide (Mac Leods, Cipla).

Comme le dit, l’industrie a mon sens n’a pas beaucoup d’intérêt pour ce marché peu rentable (Eli-Lilly en avait peut-être un peu au début en finançant le GLC et s’assurant ainsi un marché mais plus pour leur image de marque que par intérêt économique)…on voit d’ailleurs comment les besoins actuels augmentant ont encore du mal à être satisfaits…et ce particulièrement quand vous ne rentrez pas dans la catégorie des programmes approuvés par le GLC !

Il y a un problème industriel avec Novartis qui donne gratuitement la Clofazimine aux programmes Lèpre. Le don perturbe le marché car du coup plus personne n’en fabrique. De la perversité de la charité… Novartis accepte mal que la clofazimine soit utilisée dans la tuberculose parce qu’elle n’a jamais été testée pour cette indication et beaucoup de scientifiques de renom pensent qu’elle ne sert à rien.

La recherche de nouveaux produits pour lutter contre la tuberculose s’est arrêtée au milieu des années 1960 quand l’intérêt pour la tuberculose a presque disparu dans les pays industrialisés. Elle a repris un peu depuis le début des années 2000 car il y a eu une épidémie de MDR aux États-Unis. Le monde est comme cela : on s’intéresse aux problèmes qui touchent les pays puissants. Pourquoi croyez-vous qu’on s’intéresse tant au SIDA et si peu à la mortalité infanto-juvénile en Afrique ?

3) What are the arguments of the proponents of this system?

Je trouve personnellement dommage que le GLC ne soit pas davantage moteur pour stimuler des initiatives. Il reste trop replié sur lui-même. Son utilité devient discutable d’autant que la prise en charge des MDR se rationalise malgré tout. L’OMS considère le niveau mondial et les MDR ne sont pas les mêmes en Russie, à Denver et au Cameroun. L’OMS a du mal à l’admettre mais les pionniers comme au Bangladesh et au Cameroun finiront par faire bouger les choses – j’espère. Les choses changent trop lentement, mais il faut savoir que l’article de Van Deun sur le Bangladesh est uniquement « on-line » et n’est pas encore sorti sur papier.

Je crois que beaucoup de gens qui soutenaient fort le mécanisme du GLC dans les années passées se rendent compte que ce système ne permettra pas de répondre de manière satisfaisante aux besoins croissants des pays qui se lancent dans la prise en charge de la MDR TB. Le système autrefois permettait de s’assurer d’une prise en chargé encadrée dans les pays de et de s’assurer que la qualité des médicaments fournis soit correcte (pour des patients pour lesquels c’est souvent la dernière ligne !) et que ces produits soient préservés pour ce traitement MDR TB.

Il est maintenant temps sur la base de ces expériences d’ouvrir le système…et c’est l’objet de la réflexion en cours par 4 task forces mise en place cette année pour définir le future rôle du GLC. Comme le dit, c’est un sujet hautement politique et on sent clairement que l’avancée du travail de ces task-forces est difficile.

4) Finally, I would like to know if there is any supporting literature to a critical view on the powers of the GLC with regards to my questions?

Don’t know any. Mais une grande réforme du GLC est actuellement en discussion.

Je n’ai jamais rien vu de tel.

Bonne continuation pour votre travail.
Dear 333 and 444,

Could you help me answer the questions raised by Natascha who is writing a master’s thesis? I am available to combine your answers before sending them to her.

Thanks and Kind Regards

222

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De : Natascha Voelz [mailto:natascha.voelz@yahoo.com]
Envoyé : mardi 17 août 2010 16:44
À : 222
Objet : Questions with regards to Master's Thesis

Dear 222,

Herewith, I would like to shortly introduce myself to you: My name is Natascha Voelz and I am currently writing my Master's thesis on “Standardised Short-term Treatment Schemes and Access to Drugs of MDR-TB Patients in Cameroon” in Yaoundé, Cameroon.

 Accordingly, I would like to develop a case study and policy analysis of Cameroon in my thesis and therefore, I initially tried to analyse the existing global health - in particular tuberculosis - governance system. For your information, I attach the resulting organigram on the relation of actors and strategies (policies) within this field.

Moreover, since this is new terrain for me, I would like to pose a few further questions that this chapter aroused:
1) What do you think about the present situation that the GLC solely approves applications in compliance with the WHO Guidelines for Programmatic Management of Drug Resistant Tuberculosis and refers all other successful alternative treatment schemes, like the one of van Deun as well as the ones utilized in Cameroon and Benin, to its Scientific Committee while everybody knows that conceiving randomized studies in order to prove their value is in practice almost impossible? As I read in the article of Lienhardt, C., and G. Davies. (“Methodological Issues in the Design of Clinical Trials for the Treatment of Multidrug-resistant Tuberculosis: Challenges and Opportunities.” International Journal of Tuberculosis and Lung Disease 2010: 528-537.), these central principles for the standardized treatment scheme of MDR-TB by WHO with an overall success-rate solely between 54%-69% are also based on expert opinions resulting from observational research and individual experience, in opposition to wished for evidence-based results from clinical trials.
2) More specifically, what are the arguments of the opponents of this financing process of concessional-priced and quality-approved SLDs via the GLC that was set up by the WHO? E.g. - according to you - is there any economical interest of the pharma-industry to be suspected on the decision-making process and the general policies of the GLC? If yes, from whom? Accordingly, is there a gain of industrial countries contrary to developing countries? Consecutively, why is there no rebellion of the health policy/ MDR-TB responsibilities from developing countries in this context?
3) What are the arguments of the proponents of this system?
4) Finally, I would like to know if there is any supporting literature to a critical view on the powers of the GLC with regards to my questions?

I am looking forward to your response (also possible in French) and thanking you in advance for your support.

Best regards from Yaoundé,

Natascha Voelz
Annex 3  The Pathology of Tuberculosis

Transmission

The infectious agent of TB is typically the *Mycobacterium tuberculosis*, an acid-alcohol resistant rod-bacterium (Harries et al. 23), or occasionally other species from the *M. tuberculosis* complex, the *Mycobacteria africanum* or *bovis*. Due to its slow growth and its glycol-lipids in the cell wall, the *M. tuberculosis* is very resistant against antibiotics or (bio-)chemical drugs. Analogously, individuals are exceptionally tolerant to a TB infection and hence, the mycobacteria can be dormant in the human organism for decades (Renz-Polster, Krautzig, and Braun 468, 471). The transmission is direct; from a human carrier of the TB pathogens to another individual via an airborne droplet infection. Hereby, the disease spreads by coughing, sneezing or speaking (Harries et al. 23) and consecutively, the TB bacteria enter through the respiratory system into the alveoli (Gie 5). A following infection is determined by the quantity of TB pathogens in the air, the duration of exposure (Harries et al. 24) as well as further risk factors. The risk of developing TB increases with the following factors: an elevated age, certain genetic aspects, environmental influences as substance misuse and mal- or deficient nutrition, prior medical conditions e.g. diabetes mellitus, silicosis, malignant lymphomas, renal failure, measles, gastrectomy as well as HIV/AIDS, the socio-economic situation, for instance poverty and thus overcrowding and difficult access to health institutions, migration, single familial status, and by being in close contact with the TB infected (Rieder 66-75, 77-82, 98-107). Consequently about 30 percent of these exposed persons are thereafter infected with TB and about 10 percent develop the illness, mainly within an incubation period from one to three months (Renz-Polster, Krautzig, and Braun 471).

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43 Amid, the mycobacteria have a range of approximately five meters (Renz-Polster, Krautzig, and Braun 471) and may remain in the air for a longer time period when not exposed to direct sunlight (Harries et al. 23/24).

44 Sporadically, in regions with bovine tuberculosis, an infection with the *Mycobacterium bovis* is obtained via animal products containing the TB pathogens such as cow-milk through the digestive system, causing an abdominal TB by the development of the primary focus in the intestines (Harries et al. 24).

45 Genetic aspects, such as being female, having the blood type AB or B, living in a population not frequently exposed to TB or being exceedingly low in weight-for-height, increase the probability of attaining TB (Rieder 72-75).
Stages

The TB illness is divided into the following two stages: primary TB and post-primary TB, also called isolated organ-TB\(^\text{46}\) (Harries et al. 25/26). With reference to primary TB, the mycobacteria reach the individual’s pulmonary alveoli via the intake of breath. In the following weeks, these TB pathogens encapsulate as primary foci therein. Subsequently, these foci expand via the lymphatic system to the closet regional lymph node. Thereafter, lumps grow in the lung tissue, the so-called tubercles, which contain the TB bacteria (Gie 5). The respective course of this communicable disease is dependent on the strength of the individual immune system.\(^\text{47}\) In 90 percent of the TB cases, a robust immune system leads to a complete healing of the primary foci in the lung, commonly without any symptoms of TB. At this stage, however, the mycobacteria included in the foci can spread into different organs. Thus, the patient either lives free of symptoms at all times or – when the strength of his/her immune system decreases – develops a post-primary TB. In general, with a weak immune system, different forms of TB respective to the location of the tubercles can arise, such as caseating pneumonia in the bronchi, exsudative pleuritis in the pleura, miliary TB in the lungs or the meninges (Harries et al. 26). Second, the post-primary TB is commonly an isolated organ-TB that evolves through a temporary immune deficiency, in which the dormant TB bacilli awake (Renz-Polster, Krautzig, and Braun 469), termed a TB-reactivation. Likewise, it may be caused by an exogenous re-infection, signifying a case that previously was concerned with TB and is once more infected. Hereby, a pathologic lesion develops - via the reaction of the immune system - damaging the surrounding tissue and creating cavities. The post-primary TB affects principally, to 85 percent, the lung; however, it can also occur in any other organ, as extra-pulmonary TB (Harries et al. 27).

Types

There are two types of TB differentiated, a latent TB infection or an active TB illness, important for assessing the risks of transmission and of individual disease eruption. With regards to a latent TB infection, the pathogens are dormant in the human organism and hence, an individual with a latent TB infection by definition does not show any illness symptoms. This TB infection type can only be detected by a positive skin or blood test. Finally, a latent TB case cannot transmit TB, since he/she does not spread the foci to the exterior due to a

\(^{46}\) These stages both reflect an active TB disease that should be differentiated from latent TB infection (see below) (A/N).

\(^{47}\) Only five to ten percent of all individuals infected with tubercle bacilli develop overt TB (Renz-Polster, Krautzig, and Braun 468).
sufficient immune system reaction, and hence, a very low bacillary burden. On the other hand, a person with an active TB disease feels ill and shows TB symptoms. Moreover, this type of TB can be detected via mycobacteria in body fluids, e.g. the sputum, blood and urine, as well as via a skin test and chest x-ray. Therefore, the person with active TB has a high bacillary burden may transmit the pathogens to others (CDC, “Basic TB Facts”).

Clinic

Primary TB frequently displays no symptoms; occasionally the patient shows broncho-pulmonary symptoms, as continuous severe cough with blood or sputum, shortness of breath and chest-pains, as well as signs of general malaise, e.g. fever, night sweats, chills and general fatigue (CDC, “Basic TB Facts”). Post-primary TB includes unspecific symptoms, for instance cough, loss of weight, weakness, fatigue, higher temperatures, night sweats, fever, difficulty in breathing (dyspnoea) and blood in the sputum of the cough. Besides, extra-pulmonary TB generates symptoms indistinct to respective other illnesses, e.g. meningeal TB causes additional symptoms similar to meningitis: headache, neck stiffness, impaired consciousness, drowsiness, focal neurological lesions and convulsions, and finally, coma and death (Renz-Polster, Krautzig, and Braun 470).

Diagnosis

The diagnosis is often attained - only after suspicion is raised - by a thorough anamnesis, and by subsequently correctly interpreting clinical signs and symptoms by the physician. To raise suspicion, the risk of obtaining TB should be considered, e.g. exposure to TB infected, to potential TB sources, or access to treatment facilities. Moreover, a tuberculin skin test (‘Mantoux’) or a laboratory blood test (interferon gamma release assay (IGRA)), which displays an immune system response of antigens expressed by tubercle bacilli not shared with most other mycobacteria, may be used to detect sensitization of the host’s immune system, but cannot differentiate between active TB or a latent TB infection (cf. CDC, “TB Elimination: Diagnosis of Tuberculosis Disease”). The Mantoux test is proven to be inexact and insensitive, because a positive test result with reddened skin after two to three days solely partially verifies an overcome primary TB infection (Renz-Polster, Krautzig, and Braun 472). Besides, a chest x-ray (CXR) may help to discover a TB infection (CDC, “TB Elimination: Diagnosis of Tuberculosis Disease”), when mutations in the lung tissue

48 A positive reaction may also be subsequent to a TB vaccination, whereby the immune system has fought the life attenuated Mycobacteria bovis of the BCG vaccine (Renz-Polster, Krautzig, and Braun 472).
become visible. This diagnostic tool is also not entirely specific, as in some TB cases – particularly of HIV-co-infected individuals – the CXR may be normal (Renz-Polster, Krautzig, and Braun 472). Therefore, to confirm TB a bacteriological examination of the sputum, termed sputum-smear test, has to be conducted, preferably followed by a culture. Finally, the sensitivity of the *M. tuberculosis* to anti-TB medications needs to be assessed to predict the response to TB treatment (drug-susceptibility testing (DST)), and to timely detect drug-resistant organisms (CDC, “TB Elimination: Diagnosis of Tuberculosis Disease”).

**Multidrug-Resistant Tuberculosis (MDR-TB)**

MDR-TB is defined as resistance of the *M. tuberculosis* to at least two of the most important anti-TB medications isoniazid (H) and rifampicin (R). It occurs either via selective antimicrobial pressure with single drug treatment allowing naturally occurring drug-resistant mutants to repopulate the TB lesions. If subsequently one active drug is added, mutants resistant to the newly added drug repopulate the TB lesions, resulting in acquired incidence (see fig. A1.1) (Gandhi et al. 1830, 1832). Once a patient is infected with drug-resistant organisms, transmission to other persons never treated with anti-TB medications, is possible; which is referred to as primary resistance (see fig. A1.2) (Weyer 75). This awareness is essential to design the adequate prevention mechanisms and interventions (Gandhi et al. 1833).

While the clinical symptoms of MDR-TB are indistinguishable from drug-susceptible TB (Weyer 75), its medical treatment is significantly more expensive - at times surpassing an annual family income 49, more care-intensive, and carries higher risks for adverse drug effects than for TB cases susceptible to standard TB medications. This results into increased default as well as higher morbidity and mortality rates 50 and is thus less effective. With regards to an early commencement of treatment to decrease mortality and reduce further transmission, initially, active case-finding via rapid testing for the anti-TB medications H and R has to be performed preferably for all TB cases, but in particular for high risk groups - for instance surrounding an MDR-patient, default of first-line treatment course and retreatment (Gandhi et al. 1830, 1834-1836). This verification ought to be anticipated for not including single medications into a generally unsuccessful treatment fostering further drug-resistance (Weyer 74).

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49 The medical treatment of an MDR-TB-patient is about 100 times more expensive than a drug-susceptible TB case (Weyer 75).

50 Mainly the elevated mortality rate is observed during the initial two months prior to case-identification and commencement of treatment (Gandhi et al. 1836).
Each patient with an active TB infection ought to be treated, in view of the facts that the transmission risk is reduced and adequate treatment increases the probability of full healing to above 97 percent (Renz-Polster, Krautzig, and Braun 473). The WHO recommends the following standardized treatment scheme for drug-susceptible and active TB respective to
its DOTS strategy that is usually applied: In the beginning, the intensive phase of at least four months is designed to rapidly destroy the TB pathogens of an active and thus highly infectious case through an antibiotic combination therapy\(^{51}\) frequently initiated as in-patient in hospital. The patient’s contagiousness is dispensed after two consecutively negative sputum cultures being a month apart, whereas the symptoms decrease after approximately two weeks of treatment. Subsequently, the patient is discharged to ambulatory medical care as directly observed treatment (DOT) for six months to two years, namely the continuation phase (Harries et al. 126-127). Finally, subsequent to treatment completion, patients are followed-up for possible signs and symptoms of reappearance suggesting relapse (Weyer 77).

In Cameroon, the two standardized combination treatment schemes against TB within the NTCP are applied according to the patients’ treatment history: new or re-treatment cases. With regards to any newly detected TB cases, first, the 6-month standardized treatment scheme “2{RH}EZ/ 4{RH}” (République du Cameroun, “Programme National” 51) is utilized. During the intensive treatment period of 2 months, a combination of RH as well as Z and E are daily administered to hospital in-patients or under direct observation of treatment (DOT). Thereafter, a sputum-smear exam is conducted; if negative, then, the continuation period is commenced; whereas, if positive, then, the intensive phase is prolonged for one additional month and consecutively the continuation period is begun. Within the continuation period of 4 months RH is given per day on ambulatory basis under DOT. At the end of month 5, the second sputum-smear exam is carried out; if negative, then, treatment is ended after month 6 when a final sputum-smear exam proves healing; whereas, if positive, then, transfer to the standardized therapeutic regime of re-treatment cases (République du Cameroun, “Programme National” 20/21, 49, 51/52). Second, for TB patients, who ought to be retreated, at the beginning of treatment, a sputum-smear examination, cultures and a DST are performed\(^{52}\). If the culture (and the DST) tests negative for MDR-TB, then the retreatment case receives as hospital in-patients or under DOT during the first 2 months of the intensive phase also daily RH, Z and E as well as S, while a third month administration without S is

\(^{51}\) Antibiotic combination therapy is designed to reduce the chance to develop resistance to one antibiotic by providing more antibiotics. The line of antibiotics is dependent on the drug-susceptibility of the \textit{Mycobacterium tuberculosis} (A/N).

\(^{52}\) Cameroon - with the support of GTZ - is in the process of implementing the approach of systematically growing cultures and performing DST for re-treatment cases in the beginning of treatment, considering their risk of 8 to 9 percent to have MDR-TB. Previously, the carrying out of systematic cultures and DST was not possible due to the lack of personnel and equipment, and its execution by only a single laboratory, the “Centre Pasteur du Cameroun” in Yaounde. Currently, systematic cultures and DST are possible since the implementation of two decentralized, additional TB-reference-laboratories within the CEBEC Baptist Hospital in Douala and MEZAM clinic in Bamenda (Noeske et al., “MDR-TB Prevalence”).
added. If the culture (and the DST) confirms MDR-TB, then, the patient is directly assigned to the standardized MDR-TB treatment scheme (see below). Furthermore, at the end of the intensive phase, a sputum-smear exam is performed; if negative, then, the patient is directly assigned to the continuation period; contrary to if positive, then the intensive phase is extended for one additional month and thereafter the continuation period is initiated. The continuation phase of these second category cases lasts five months with treatment through RH and E. Finally, a sputum-smear exam is carried out at the end of month 5; if negative, then, the scheme is finalized after eight months when the last sputum-smear test confirms healing; while if positive, then, a second microscopy proves a chronic illness (République du Cameroun, “Programme National” 54/55). This scheme of re-treatment cases is termed “2{RH}SEZ/ 1{RH}EZ/ 5{RH}E” (République du Cameroun, “Programme National” 54). Besides, the degree and type of side-effects to the anti-TB medications ought to be considered during administration, such as minor adverse effects: nausea, vomiting, dermal reactions, joint pains, fever and/or flu symptoms, and main adverse effects: allergic reactions, hepatitis, anuria, anemia, malfunctioning of the nerve-system, and/or faintness. Thus, consecutively to any form of TB treatment, there are six classifications of outcomes in order of success: cured, completed treatment, treatment failure, defaulter, transfer, and death (République du Cameroun, “Programme National” 58, 85/86).

In general, when MDR-TB is identified, cases can be treated with (a) a standardized MDR therapeutic regime (WHO, “Treatment of Tuberculosis Guidelines” 86), whereby no individual DST is carried out and all MDR-TB cases are treated in the same manner (WHO, “Guidelines for the Programmatic Management” 52), or (b) with an individualized treatment regime (WHO, “Treatment of Tuberculosis Guidelines” 86), founded on the individual’s treatment history and DST (WHO, “Guidelines for the Programmatic Management” 52). Initially, the medications utilized for the treatment of MDR-TB are grouped into the following five categories in order of effectiveness, familiarity and type of medication (WHO, “Treatment of Tuberculosis Guidelines” 84):

- **Group 1** are the first-line anti-TB drugs: H, R, Z, E, and rifabutin (Rfb) (WHO, “Guidelines for the Programmatic Management” 54). These are most effective and with least adverse effects (WHO, “Treatment of Tuberculosis Guidelines” 84).
- **Group 2** SLDs are injectable: Kanamycin (Km), amikacin (Am), capreomycin (Cm), and S (WHO, “Guidelines for the Programmatic Management” 54) for assumed and proven
drug resistance found in the patient’s sputum, whereby S is avoided because of its now common drug-resistance (WHO, “Treatment of Tuberculosis Guidelines” 84).

- Group 3 encompasses the second-line fluoroquinolones: Levofloxacin (Lfx), moxifloxacin (Mfx), ofloxacin (Ofx) (WHO, “Guidelines for the Programmatic Management” 54); each patient harboring susceptible micro-organisms is administered with one agent (WHO, “Treatment of Tuberculosis Guidelines” 84).

- Group 4 includes the second-line oral bacteriostatics: Para-aminosalicylic acid (PAS), cycloserine (Cs), terizidone (Trd), ethionamide (Eto), protonamide (Pto) (WHO, “Guidelines for the Programmatic Management” 54), generally combined due to cost-effectiveness (WHO, “Treatment of Tuberculosis Guidelines” 84).

- Group 5 are SLDs of undetermined efficacy that are not suggested by WHO: Clofazimine (Cfz), linezolid (Lzd), amoxicillin/clavulanate (Amx/Clv), thioacetazone (Thz), imipenem/cilastatin (Ipm/Cln), clarithromycin (Clr) (WHO, “Guidelines for the Programmatic Management” 54).

On the hierarchical basis of these anti-TB medications, WHO directs to adhere to the following principles by establishing a therapeutic treatment scheme for MDR-TB:

- The usual anti-TB medications administered in a country, the national resistance profile, individual DST (WHO, “Guidelines for the Programmatic Management” 58/59) of H, R, the injectable SLDs and fluoroquinolones (WHO, “Treatment of Tuberculosis Guidelines” 89), and patient’s treatment history determine the therapeutic treatment scheme;

- Each therapeutic treatment plan ought to include at minimum four drugs of Group 1 to Group 4 considering their efficacy;

- One injectable medication is applied for at least six months and at minimum four months after sputum-smear negative laboratory test result;

- During the complete treatment process, Z can be given;

- Medications ought to be administered as single daily dose based on patients’ weight under DOT for the complete treatment duration;

- The least possible treatment duration is 18 months subsequent to sputum-smear negative microscopy;

- Instant and appropriate taking charge of side-effects to diminish treatment failures; and
Timely identification of drug-resistance and the immediate commencement of the treatment scheme are influential factors on the success rate (WHO, “Guidelines for the Programmatic Management” 58/59).

A standardized therapeutic regimen for MDR-TB consists of an intensive phase with at least four medications of each category for at least 6 months and for 4 months after cultures become negative for MDR-TB. The consecutive continuation period lasts for at least 18 months subsequent to a negative culture within the intensive phase, whereas this period may be prolonged up to 24 months depending on case severity. A sputum-smear exam is conducted on a monthly basis until two subsequent negative results, and afterwards in a frequency of every two to three month. Furthermore, monitoring of signs for side-effects ought to be conducted throughout treatment (WHO, “Treatment of Tuberculosis Guidelines” 91).

With regards to prophylaxis, particularly exposure prevention is essential, which includes an assessment of the patient’s environment and identification of further TB infected individuals (Renz-Polster, Krautzig, and Braun 473). Subsequently, solely for persons at risk because of its severe side-effects, an immunization with the Bacille-Calmette-Guerin (BCG) live attenuated vaccine can be carried out (Harries et al. 212/213). Finally, a regular chemoprophylaxis with the antibiotic H over the time-period of half to a year is recommended for immune deficient patients, e.g. with HIV/AIDS and infants below one year of age (Renz-Polster, Krautzig, and Braun 473); however considering contacts to proven MDR-TB, whereby H chemoprophylaxis is obviously ineffective.
Annex 4  Statistical Data on Cameroon

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**Demographic Indicators**

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</thead>
<tbody>
<tr>
<td>Total population (millions)</td>
<td>1990°</td>
<td>12.2</td>
<td></td>
<td></td>
<td>4.2</td>
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<tr>
<td></td>
<td>2008°</td>
<td>19.01</td>
<td></td>
<td></td>
<td>4.767</td>
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<tr>
<td>Population under 18 (thousands)</td>
<td>2008°</td>
<td>9,142</td>
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<td></td>
<td>1,106</td>
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<tr>
<td>Population under 5 (thousands)</td>
<td>2008°</td>
<td>3,016</td>
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<td>Annual rate of natural increase of the population (%)</td>
<td>1990–2000°</td>
<td>2.6</td>
<td></td>
<td></td>
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<tr>
<td></td>
<td>2000–2008°</td>
<td>2.3</td>
<td></td>
<td></td>
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<tr>
<td>Annual no. of births (thousands)</td>
<td>1990</td>
<td>..</td>
<td></td>
<td></td>
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</tr>
<tr>
<td></td>
<td>2008°</td>
<td>704</td>
<td></td>
<td></td>
<td>58</td>
</tr>
<tr>
<td>Crude birth rate (births per 1,000 population per year)</td>
<td>1990°</td>
<td>42</td>
<td></td>
<td></td>
<td>14</td>
</tr>
<tr>
<td></td>
<td>2008°</td>
<td>37</td>
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<td></td>
<td>12</td>
</tr>
<tr>
<td>Total fertility rate (births per woman)</td>
<td>1990°</td>
<td>5.9</td>
<td></td>
<td></td>
<td>1.9</td>
</tr>
<tr>
<td></td>
<td>2008°</td>
<td>4.6</td>
<td></td>
<td></td>
<td>1.9</td>
</tr>
<tr>
<td>Life expectancy at birth (years)</td>
<td>1990°</td>
<td>55</td>
<td></td>
<td></td>
<td>77</td>
</tr>
<tr>
<td></td>
<td>2008°</td>
<td>51</td>
<td></td>
<td></td>
<td>68</td>
</tr>
<tr>
<td>Healthy life expectancy at birth (years)</td>
<td>1990</td>
<td>..</td>
<td></td>
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<td></td>
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<tr>
<td></td>
<td>2007°</td>
<td>45</td>
<td></td>
<td></td>
<td>59</td>
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<tr>
<td>Crude death rate (deaths per 1,000 population per year)</td>
<td>1990°</td>
<td>13</td>
<td></td>
<td></td>
<td>11</td>
</tr>
<tr>
<td></td>
<td>2008°</td>
<td>14</td>
<td></td>
<td></td>
<td>9</td>
</tr>
<tr>
<td>Under 5 mortality rate (per 1,000 live births per year)</td>
<td>1990°</td>
<td>149</td>
<td></td>
<td></td>
<td>9</td>
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<td></td>
<td>2008°</td>
<td>131</td>
<td></td>
<td></td>
<td>4</td>
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<tr>
<td>Adult Literacy Rate (% aged 15 and above)</td>
<td>1990°</td>
<td>55</td>
<td></td>
<td></td>
<td>99.9</td>
</tr>
<tr>
<td></td>
<td>2003-2008°</td>
<td>68</td>
<td></td>
<td></td>
<td>99.9</td>
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</table>

**Economic Indicators**

<table>
<thead>
<tr>
<th>Indicator</th>
<th>Year</th>
<th>Value</th>
<th>(G)</th>
<th>(A)</th>
<th>(N)</th>
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<tbody>
<tr>
<td>Total GDP (US$ billions)</td>
<td>1990</td>
<td>..</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>2007°</td>
<td>20.7</td>
<td></td>
<td></td>
<td>388.4</td>
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<tr>
<td>GDP per capita (US$)</td>
<td>1990°</td>
<td>1,000</td>
<td></td>
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<td>1,187</td>
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<td></td>
<td>2007°</td>
<td>1,116</td>
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<td>82,480</td>
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<tr>
<td>GDP per capita annual growth rate (%)</td>
<td>1970-1990°</td>
<td>3.3</td>
<td></td>
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<td>3.2</td>
</tr>
<tr>
<td></td>
<td>1990-2008°</td>
<td>0.7</td>
<td></td>
<td></td>
<td>2.5</td>
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<tr>
<td>Average annual rate of inflation (%)</td>
<td>1990-2008°</td>
<td>4</td>
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<td></td>
<td>4</td>
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<tr>
<td>Population living below the international poverty line of $1.25 a day (%)</td>
<td>1992-2007°</td>
<td>33</td>
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<td></td>
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<tr>
<td>ODA inflow in millions (US$)</td>
<td>1990°</td>
<td>475</td>
<td></td>
<td></td>
<td>14.81</td>
</tr>
<tr>
<td></td>
<td>2007°</td>
<td>1,933</td>
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### Health Indicators

<table>
<thead>
<tr>
<th>Description</th>
<th>Year</th>
<th>Value</th>
<th>Reference</th>
</tr>
</thead>
<tbody>
<tr>
<td>Central government expenditure allocated to health (%)</td>
<td>1998-2007°</td>
<td>3</td>
<td>(N*) 5</td>
</tr>
<tr>
<td>Central government expenditure allocated to military defense (%)</td>
<td>1998-2007°</td>
<td>10</td>
<td>(N*) 17</td>
</tr>
<tr>
<td>Central government expenditure on health as % of total expenditure on health</td>
<td>2003*</td>
<td>28.9</td>
<td>..</td>
</tr>
<tr>
<td>Private expenditure on health as % of total expenditure on health</td>
<td>2003*</td>
<td>71.1</td>
<td>..</td>
</tr>
<tr>
<td>Per capita government expenditure on health (US$ at average exchange rate)</td>
<td>2003*</td>
<td>11</td>
<td>(N 2006°) 3,780</td>
</tr>
<tr>
<td>Health system statistics (Density per 1,000 population)</td>
<td>2004*</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Physicians</td>
<td></td>
<td>0.19</td>
<td>0.2</td>
</tr>
<tr>
<td>Nurses</td>
<td></td>
<td>1.6</td>
<td>1.1</td>
</tr>
<tr>
<td>Pharmacists</td>
<td></td>
<td>0.04</td>
<td>..</td>
</tr>
<tr>
<td>Lab technicians</td>
<td></td>
<td>0.11</td>
<td>..</td>
</tr>
<tr>
<td>Public and environmental health workers</td>
<td></td>
<td>0.00</td>
<td>..</td>
</tr>
<tr>
<td>Health management and support workers</td>
<td></td>
<td>0.36</td>
<td>..</td>
</tr>
<tr>
<td>Infants with low birth weight (%)</td>
<td>2003-2008°</td>
<td>11</td>
<td>(N*) 5</td>
</tr>
<tr>
<td>Under-fives suffering from moderate and severe underweight (NCHS/WHO)</td>
<td>2003-2008°</td>
<td>19</td>
<td>(N*) -</td>
</tr>
<tr>
<td>Estimated number of people living with HIV (thousands)</td>
<td>2007°</td>
<td>540</td>
<td>(G) 644</td>
</tr>
<tr>
<td>Estimated adult (aged 15-49) HIV prevalence rate (%)</td>
<td>2007°</td>
<td>5.1</td>
<td>(N*) 0.1</td>
</tr>
</tbody>
</table>

### Tuberculosis Profile of Cameroon

<table>
<thead>
<tr>
<th>Description</th>
<th>Year</th>
<th>Value</th>
<th>Reference</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prevalence rate associated with tuberculosis (per 100,000 population)</td>
<td>1990*</td>
<td>163</td>
<td>..</td>
</tr>
<tr>
<td></td>
<td>2008†</td>
<td>150</td>
<td>(A) 475</td>
</tr>
<tr>
<td>Incidence rate associated with tuberculosis (per 100,000 population)</td>
<td>1990*</td>
<td>..</td>
<td>..</td>
</tr>
<tr>
<td></td>
<td>2008†</td>
<td>190</td>
<td>..</td>
</tr>
<tr>
<td>Number of tuberculosis cases</td>
<td>2003*</td>
<td></td>
<td>..</td>
</tr>
<tr>
<td>All tuberculosis forms</td>
<td></td>
<td>16478</td>
<td></td>
</tr>
<tr>
<td>New pulmonary tuberculosis, sputum-smear positive</td>
<td></td>
<td>10661</td>
<td></td>
</tr>
<tr>
<td>Retreatment tuberculosis cases</td>
<td></td>
<td>1217</td>
<td></td>
</tr>
<tr>
<td>Other tuberculosis forms</td>
<td></td>
<td>4600</td>
<td></td>
</tr>
<tr>
<td>Number of tuberculosis cases</td>
<td>2008*</td>
<td></td>
<td>..</td>
</tr>
<tr>
<td>All tuberculosis forms</td>
<td></td>
<td>25125</td>
<td></td>
</tr>
<tr>
<td>New pulmonary tuberculosis, sputum-smear positive</td>
<td></td>
<td>14232</td>
<td></td>
</tr>
<tr>
<td>Retreatment tuberculosis cases</td>
<td></td>
<td>1420</td>
<td></td>
</tr>
<tr>
<td>Other tuberculosis forms</td>
<td></td>
<td>9473</td>
<td></td>
</tr>
<tr>
<td>Tuberculosis and HIV</td>
<td>2008*</td>
<td></td>
<td>..</td>
</tr>
<tr>
<td>Tuberculosis among HIV-positive tested persons</td>
<td></td>
<td>7211</td>
<td></td>
</tr>
<tr>
<td>New pulmonary tuberculosis among HIV-positive tested persons</td>
<td></td>
<td>3924</td>
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</tr>
</tbody>
</table>
### MDR-TB (%)

- MDR-TB among all new tuberculosis cases: 1.7% in 2007
- MDR-TB among previously treated tuberculosis cases: 8.3%

### Top ten causes of death (%)

<table>
<thead>
<tr>
<th>Cause</th>
<th>2002*</th>
<th>2007</th>
<th>2008†</th>
</tr>
</thead>
<tbody>
<tr>
<td>All causes</td>
<td>100</td>
<td>100</td>
<td></td>
</tr>
<tr>
<td>HIV/AIDS</td>
<td>21</td>
<td>24</td>
<td></td>
</tr>
<tr>
<td>Lower respiratory infections</td>
<td>14</td>
<td>17</td>
<td></td>
</tr>
<tr>
<td>Malaria</td>
<td>8</td>
<td>11</td>
<td></td>
</tr>
<tr>
<td>Diarrheal diseases</td>
<td>6</td>
<td>8</td>
<td></td>
</tr>
<tr>
<td>Perinatal conditions</td>
<td>5</td>
<td>7</td>
<td></td>
</tr>
<tr>
<td>Cerebrovascular disease</td>
<td>4</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td>Ischaemic heart disease</td>
<td>4</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>Road traffic accidents</td>
<td>2</td>
<td>3</td>
<td></td>
</tr>
<tr>
<td>Tuberculosis</td>
<td>2</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td>Whooping Cough</td>
<td>2</td>
<td>2</td>
<td></td>
</tr>
</tbody>
</table>

### Death rate associated with tuberculosis (per 100,000 population)

- 2002*: 19
- 2007: 39
- 2008†: 93

### Tuberculosis cases detected under DOTS (%)

- 2003†: 73
- 2008†: 93

### Tuberculosis cases cured under DOTS (%)

- 2002*: 70
- 2006*: 74

### Treatment outcomes of notified new pulmonary tuberculosis, sputum-smear positive (%)

- Cases evaluated: 98.5 in 2003‡
- Treatment success: 73
- Treatment failure: 1
- Death: 5
- Lost to follow-up: 19
- Transferred out: 2

### Treatment outcomes of notified new pulmonary tuberculosis, sputum-smear positive (%)

- Cases evaluated: 99.9 in 2007†
- Treatment success: 76
- Treatment failure: 1
- Death: 7
- Lost to follow-up: 11
- Transferred out: 5

### Treatment outcomes of notified pulmonary tuberculosis, sputum-smear positive (%)

- Cases evaluated: 71.4 in 2003‡
- Treatment success: 75
- Treatment failure: 2
- Death: 5
- Lost to follow-up: 17
- Transferred out: 3

### Treatment outcomes of notified pulmonary tuberculosis, sputum-smear positive (%)

- Cases evaluated: 97.4 in 2007†
- Treatment success: 64
- Treatment failure: 2
- Death: 9
- Lost to follow-up: 15
- Transferred out: 7

### 1-year-old children immunized against TB (% BCG vaccination)

- 2008*: 86

---

Kuaban and Noeske 157-160
† UNDP, “Human Development Report 2009”
° UNICEF, “Info by Country: Cameroon”
♣ UNICEF, “Info by Country: Norway”
♦ WHO, “Cameroon Health Profile”
♂ WHO, “Country Health System Fact Sheet 2006: Cameroon”
†† WHO, “Global Tuberculosis Control: A Short Update”
‡‡ WHO, “TB Country Profile: Cameroon”
Annex 5  Policies and Actors Regarding the International Health Policy Guidelines for MDR-TB
Annex 6  Organigram of Central Elements of the MoPH of the Republic of Cameroon
Annex 7  Organigram of the National Health Sector of the Republic of Cameroon

Annex 8  The Health Sector Strategy (HSS) 2001-2015 of the MoPH of the Republic of Cameroon

On 5th May 2006 in Kribi in Cameroon, the MoPH of Cameroon and its technical and financial associates adopted a Sector Wide Approach (SWAp) for the Cameroonian Health Sector considering:

• the mutual interest and dedication of the central associates, namely the MoPH, WHO, World Bank, Germany, and France;
• the political determination to reach the MDGs and the objectives of the Poverty Reduction Strategy (PRS) for Cameroon;
• the encouragement of critical educated health staff;
• and the increase of the budget for the health sector.

Accordingly, the SWAp was designed for inter alia initiating:

• a modified HSS including its operationalization;
• an official partnership harmonization and collaboration structure;
• and a modified health sector budget.

In 2009, the revised HSS 2001-2015 of the MoPH was adopted and designed in consistency with the MDGs, the Poverty Reduction Strategy Paper (PRSP) for Cameroon of 2007, and the preceding HSS 2001-2010 approved in 2001. Its central purpose is to support the reduction of poverty via the enhancement of the socio-health conditions of the Cameroonian citizens. Thus, its overall objective is to develop each health entity with regards to their support to the accomplishment of the MDGs. Following, the specific goals for 2015 are:

• direct 80 percent of the 178 Cameroonian health districts to finalize at least their initial phase of advancing to functioning health districts;
• direct all central and intermediate health entities to realize their support and appeal;
• decrease the morbidity of vulnerable groups by one-third;
• decrease the mortality rate of children under five years by one-third;
• and decrease the maternal mortality rate by two-fifths.

Accordingly, these specific goals are based on the MDGs 1, 4, 5, 6 and 7 and ought to be achieved via the following five strategies:

1. Strengthening of the existing health system;
2. Exercise respective activities within the health districts;
3. Creation of a functional referral system to the consecutive health entity on a vertical level;
4. Strengthening of associations and connections in the health sector;
5. Initiation of demand.

These strategies are implemented in four priority areas of the Cameroonian health system:
- The child, adolescent and maternal health
- The fight against illnesses
- The enhancement of health
- The development of health districts.

Within the priority area of “The fight against illnesses”, the interventions against malaria and TB are considered, and the comprehensive management of TB is one element. Hence, the measures of prevention, case-identification, care for patients with HIV-TB, as well as monitoring of resistance against anti-tuberculosis medications (République du Cameroun, “Stratégie Sectorielle de Santé” 73) are carried out regarding MDG 6 to “[combat] HIV/AIDS, Malaria and other Diseases” (UN, “United Nations Millennium Development Goal 6”), more particularly target 6.3 to “[have] halted by 2015 and begun to reverse the incidence of malaria and other major diseases” (UN, “United Nations Millennium Development Goal 6”). Subsequently, the following five results shall be achieved in 2015:

1. A BCG-vaccination rate of at least 80 percent in each health district;
2. A case-identification rate of pulmonary smear-positive TB of at least 70 percent from estimates per year;
3. Clinical care for at least 98 percent of identified cases;
4. A cure rate of 85 percent;
5. An increased rate of HIV-TB patients are physically active and sporty.

In total the HSS encompasses a budget of 1,258,624 million F CFA for the period between 2009 and 2013. Hereof, for the second priority area 277,333 million F CFA are foreseen, and the “Fight against malaria and tuberculosis” receives 157,457 million F CFA (République du Cameroun, “Stratégie Sectorielle de Santé” x, 2/3, 20, 55, 59, 72/73, 75, 85, 101).
Annex 9 Organigram of the NTCP of Cameroon
# Annex 10 Stakeholder Analysis

<table>
<thead>
<tr>
<th>LEVEL</th>
<th>STAKEHOLDER</th>
<th>Category</th>
<th>Involvement in the Issue</th>
<th>CHARACTERISTICS</th>
<th>Interest in the Issue</th>
<th>Position</th>
<th>Level of Commitment</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Influence / Power</td>
<td>(Financial) Advantages</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Tangible and/or Intangible Resources</td>
<td>Outcome</td>
<td>Outcome</td>
<td></td>
</tr>
</tbody>
</table>
| International | WHO International Organization | Actively Involved | Tangible Resources:  
- Finances for national health sectors  
- Infrastructure (Secretariat: Oversee the access to the SLDs and the implementation of the actions of the GLC and the GDF)  
- Member institution of GLC  
Intangible Resources:  
- Technical expertise  
- Legitimacy  
- Political decision-making | High | - Conceptualization of DOTS and DOTS-Plus  
- Perception via achievements of MDGs related to health (including the reduction of MDR-TB), accumulating to political power in decision-making (domination) and legitimacy  
- Advocacy and interaction  
- Donor procedures  
- Dependency of transitional and developing countries  
- Fostering the pharmaceutical market via global drug provision | High | Support | High |

GLC

International Organization (Part of WHO)

Actively Involved

Tangible Resources:  
- Finances of donors and members (50,000 US-dollars/year)  
- Infrastructure  
- Member institution of

High

- Execution of DOTS-Plus  
- Financial advantages  
- Perception via achievements in providing access to and assuring compliance with correct

High

Support

High

---

53 Pursuant to the theoretical concept, the category of a stakeholder can be the following: Individual, Network, National or International Organization, Part of an International or National Organization, Public Institution or Government (A/N).

54 Pursuant to the theoretical concept, the involvement in the issue is divided into: Actively Involved, Passively Involved, Positively or Negatively Influenced (A/N).

55 Pursuant to the theoretical concept, the position of a stakeholder is either in support of, or opposed, or neutral to the policy (A/N).

56 Pursuant to the theoretical concept, the level of commitment to a policy is classified into: High, Low, or Medium (A/N).

57 Pursuant to the theoretical concept, an outcome is classified into: High, Low, or Medium (A/N).
<table>
<thead>
<tr>
<th>Organization</th>
<th>Role</th>
<th>Tangible Resources</th>
<th>Intangible Resources</th>
<th>Support</th>
<th>Description</th>
</tr>
</thead>
</table>
| WHO          | Members (PIH, CDC, IUATLD, WCC, Hospital General Muniz, KNCV, MSF, State Agency Latvia, WHO) | - Expertise  
- Legitimacy  
- Political decision-making via voting | utilization of quality-assured and subsidized SLDs against MDR-TB of national supported programs  
- Indirect fostering the pharmaceutical market via facilitation of treatment with SLDs | High Support High |
| GDF          | International Organization (Part of WHO) | Actively Involved | Tangible Resources:  
- Finances  
- Infrastructure  
- Member institution of WHO | Intangible Resources:  
- Expertise  
- Legitimacy | High |
|              |      |                   | - Execution of funding as well as coordinate and control drug procurement of SLDs of DOTS-Plus  
- Financial advantages  
- Perception via achievements in enhancing the access to and the offer of quality-guaranteed and concessional priced FLDs and SLDs against TB; via their funding, procurement, ensuring their availability and quality  
- Indirect fostering of pharmaceutical market via acquisition of SLDs by IDA | High Support High |
| IDA          | International Organization | Actively Involved | Tangible Resources:  
- Infrastructure  
- Exclusive mandate by GDF | Intangible Resources:  
- Expertise | High |
|              |      |                   | - Exclusive acquisition of concessional –priced and quality-guaranteed SLDs  
- Indirect fostering of pharmaceutical market | High Support High |
| GFATM        | International Organization (Donor) | Actively Involved | Tangible Resources:  
- Major acquiring, coordinating and controlling as well as | Intangible Resources:  
- Perception via achievements international control of MDR-TB, accumulating to political | High Support High |
<table>
<thead>
<tr>
<th>Donor</th>
<th>Organization (Donor)</th>
<th>Actively Involved</th>
<th>Tangible Resources:</th>
<th>Intangible Resources:</th>
<th>Support</th>
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<th>Medium</th>
<th>High</th>
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</thead>
<tbody>
<tr>
<td>UNITAID</td>
<td>International Organization (Donor)</td>
<td>Actively Involved</td>
<td>Tangible Resources:</td>
<td>- Major Financing of GLC and GDF in a continuing, sustainable and foreseeable manner</td>
<td>High</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Intangible Resources:</td>
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<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>- Legitimacy (supervised and run by WHO)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>- Access to political decision-making of the GLC (MOU) and GDF</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>- Access to drug procurement via the GDF</td>
<td></td>
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<td>High - Perception via facilitation of access to and decrease costs of quality-assured SLDs for the reduction of MDR-TB</td>
<td>High</td>
<td>Support</td>
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<td></td>
<td></td>
<td>- Fostering the pharmaceutical market</td>
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<tr>
<td>USAID</td>
<td>Government Organization (Donor)</td>
<td>Actively Involved</td>
<td>Tangible Resources:</td>
<td>- Financing of GLC and GDF</td>
<td>Medium</td>
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<td>Intangible Resources:</td>
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<td></td>
<td></td>
<td>- Access to political decision-making of the GLC and GDF</td>
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<td></td>
<td>Medium - Perception of respective government via funding of SLDs for GDF and GLC for the reduction of MDR-TB</td>
<td>Medium</td>
<td>Support</td>
<td>Medium</td>
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<td>Tangible Resources:</td>
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<td></td>
<td>- Access to political decision-making of the GLC</td>
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<td></td>
<td>Medium - Perception via achievements international control of MDR-TB</td>
<td>High</td>
<td>Support</td>
<td>Medium</td>
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<td>- Fostering the pharmaceutical market</td>
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<td>Donor Organization (Donor)</td>
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<td>Intangible Resources:</td>
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<td>Perception via achievements international control of MDR-TB</td>
<td>Perception via achievements international control of MDR-TB</td>
<td>Perception of respective government via funding of SLDs for GDF for the reduction of MDR-TB</td>
<td>Perception of respective government via funding of SLDs for GDF for the reduction of MDR-TB</td>
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<td>E.LILLY International Organization (Donor)</td>
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<td>Tangible Resources: - Financing of GLC</td>
<td>Intangible Resources: - Access to political decision-making of the GLC</td>
<td>Medium</td>
<td>High</td>
<td>Support</td>
<td>Medium</td>
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</tr>
<tr>
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<td>Intangible Resources: - Access to political decision-making of the GLC</td>
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<td>High</td>
<td>Support</td>
<td>Medium</td>
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<tr>
<td>CIDA Government Organization (Donor)</td>
<td>Actively Involved</td>
<td>Tangible Resources: - Financing of GDF</td>
<td>Intangible Resources: - Access to political decision-making of the GDF</td>
<td>Medium</td>
<td>Medium</td>
<td>Support</td>
<td>Medium</td>
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<td>DFID Government Organization (Donor)</td>
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<td>Tangible Resources: - Financing of GDF</td>
<td>Intangible Resources: - Access to political decision-making of the GDF</td>
<td>Medium</td>
<td>Medium</td>
<td>Support</td>
<td>Medium</td>
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<tr>
<td>World Bank International Organization (Donor)</td>
<td>Passively Involved</td>
<td>Tangible Resources: - Finances for the health sector</td>
<td>Low</td>
<td>Low</td>
<td>Neutral</td>
<td>Low</td>
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<tr>
<td>IMF International Organization (Donor)</td>
<td>Passively Involved</td>
<td>Tangible Resources: - Finances for the health sector</td>
<td>Low</td>
<td>Low</td>
<td>Neutral</td>
<td>Low</td>
<td></td>
<td></td>
</tr>
<tr>
<td>UNICEF International Organization (Donor)</td>
<td>Passively Involved</td>
<td>Tangible Resources: - Finances for the health sector</td>
<td>Low</td>
<td>Low</td>
<td>Neutral</td>
<td>Low</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Donor/Actor</td>
<td>Organization</td>
<td>Level of Involvement</td>
<td>Tangible Resources</td>
<td>Intangible Resources</td>
<td>Advantages/Disp.</td>
<td>Support</td>
<td>Opposition</td>
<td></td>
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<tr>
<td>UNFPA</td>
<td>International Organization (Donor)</td>
<td>Passively Involved</td>
<td>Tangible Resources: - Finances for the health sector</td>
<td>Low - Perception via achievements in meeting the MDGs (including TB reduction)</td>
<td>Low</td>
<td>Neutral</td>
<td>Low</td>
<td></td>
</tr>
<tr>
<td>GAVI</td>
<td>International Organization (Donor)</td>
<td>Passively Involved</td>
<td>Tangible Resources: - Finances for the health sector</td>
<td>Low - Perception via achievements in TB reduction</td>
<td>Low</td>
<td>Neutral</td>
<td>Low</td>
<td></td>
</tr>
<tr>
<td>International Facility of Financing Vaccination</td>
<td>International Organization (Donor)</td>
<td>Passively Involved</td>
<td>Tangible Resources: - Finances for the health sector</td>
<td>Low - Perception via achievements in TB reduction</td>
<td>Low</td>
<td>Neutral</td>
<td>Low</td>
<td></td>
</tr>
<tr>
<td>The UNION</td>
<td>International Organization</td>
<td>Actively Involved</td>
<td>Intangible Resources: - Technical expertise and policy proposition for the re-institution of NTCP of Cameroon</td>
<td>High - Short, highly effective and inexpensive standardized treatment of MDR-TB for its reduction</td>
<td>High</td>
<td>Support</td>
<td>High</td>
<td></td>
</tr>
<tr>
<td>GTZ</td>
<td>Bilateral Cooperation (Donor)</td>
<td>Actively Involved</td>
<td>Tangible Resources: - Finances for the health sector, particularly MDR-TB program Intangible Resources: - Technical expertise</td>
<td>High - Providing a short, highly effective and inexpensive as well as replicable standardized treatment of MDR-TB for its reduction</td>
<td>High</td>
<td>Opposition</td>
<td>Medium</td>
<td></td>
</tr>
<tr>
<td>Pharmaceutical Industry</td>
<td>International Actor</td>
<td>Actively Involved</td>
<td>Tangible Resources: - Finances - Infrastructure - Exclusive production of SLDs, conditioned usage of SLDs for NTCPs by WHO Intangible Resources: - Access to political decision-makers - Technical expertise</td>
<td>High - Financial advantages through conditioned usage of SLDs for NTCPs by WHO</td>
<td>High</td>
<td>Support</td>
<td>High</td>
<td></td>
</tr>
<tr>
<td>National</td>
<td>Minister of Public Health</td>
<td>Actively Involved</td>
<td>Tangible Resources: - Government and GF finances for funding the</td>
<td>High - Advantages - Financial advantages - Advocacy and liaison with</td>
<td>High</td>
<td>(Limited) Support</td>
<td>Medium</td>
<td></td>
</tr>
</tbody>
</table>

58 Opposition, only to the exclusive support of the GLC and GFATM of the treatment regimen against MDR-TB outlined in the central principles of WHO’s Guidelines for the Programmatic Management of Drug-resistant Tuberculosis (A/N).
<table>
<thead>
<tr>
<th>Department of the Control of Tuberculosis of the MoPH</th>
<th>Government Department</th>
<th>Actively Involved, Negatively Influenced</th>
<th>Tangible Resources:</th>
<th>Medium</th>
<th>Advantages</th>
<th>High (Limited) Support</th>
<th>Medium</th>
</tr>
</thead>
<tbody>
<tr>
<td>NTCC Public Institution</td>
<td>Actively Involved</td>
<td>Tangible Resources:</td>
<td>Medium</td>
<td>- To outline, implement and monitor the overall</td>
<td></td>
<td></td>
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</tr>
</tbody>
</table>

- NTCP of Cameroon
- Infrastructure
- Intangible Resources:
  - Legitimacy
  - Representation of Cameroon
  - National political decision-maker and responsible in (MDR-)TB
- Expertise
- Access to media

- International organizations and further nation-states
- National responsible of direct and indirect measures against MDR-TB; integrating into national health policy
- Perception of the Cameroonian peoples in the reduction of MDR-TB

Disadvantages
- Dependency on international organizations from industrial countries (patronizing) in selecting national program on MDR-TB
<table>
<thead>
<tr>
<th>Institution</th>
<th>Involvedness</th>
<th>Tangible Resources:</th>
<th>Intangible Resources:</th>
<th>Support</th>
</tr>
</thead>
<tbody>
<tr>
<td>Consultative Scientific Committee</td>
<td>Passively Involved</td>
<td>Infrastructure: - Infrastructure - Technical expertise - Legitimacy</td>
<td>Access to MoPH (located under MoPH) Technical expertise Legitimacy</td>
<td>Low</td>
</tr>
<tr>
<td></td>
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</tr>
<tr>
<td>Consultative Scientific Committee</td>
<td>Actively Involved</td>
<td>Tangible Resources: - Infrastructure - Technical expertise - Legitimacy</td>
<td>Access to NTCC (located under MoPH) Technical expertise Legitimacy</td>
<td>Medium</td>
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<tr>
<td>Centre Pasteur du Cameroun</td>
<td>Actively Involved</td>
<td>Tangible Resources: - Infrastructure (including National TB Reference Laboratory) - Finances from MoPH and patients</td>
<td>Limited access to national decision-maker Technical expertise Legitimacy</td>
<td>Medium</td>
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<tr>
<td></td>
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<tr>
<td>CEBEC Baptist Hospital Douala</td>
<td>Actively Involved</td>
<td>Tangible Resources: - Infrastructure - Finances from patients and Baptist church</td>
<td>Conducting quality-guaranteed sputum-smear exams, cultures and DST</td>
<td>Low</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Strategies and Goals of the NTCP</th>
<th>Support</th>
</tr>
</thead>
<tbody>
<tr>
<td>To acquire its funds</td>
<td>(Limited) Support</td>
</tr>
<tr>
<td>To direct partner efforts in the fight against TB into consistency</td>
<td>Low</td>
</tr>
</tbody>
</table>

- Low |
- Medium |
- High |
- Limited |

Statistical data acquisition and research on TB |
Execution of mission of NTCC |
Standardizing quality-guaranteed procedures for sputum-smear exams, cultures and DST by supervising 2 subordinated laboratories |
Educating laboratory staff |
Evaluating anti-TB drug-resistances to determine success of the NTCP |
<table>
<thead>
<tr>
<th>Institution</th>
<th>Type</th>
<th>Involved</th>
<th>Tangible Resources:</th>
<th>Intangible Resources:</th>
<th>Support</th>
<th>(Limited) Support</th>
<th>Medium Support</th>
</tr>
</thead>
<tbody>
<tr>
<td>MEZAM Clinic Bamenda</td>
<td>Private</td>
<td>Actively</td>
<td>- Limited access to national decision-maker</td>
<td>- Technical expertise - Legitimacy</td>
<td>Low</td>
<td>Low (Limited)</td>
<td>Low</td>
</tr>
<tr>
<td></td>
<td>Institution</td>
<td>Involved</td>
<td>- Finances from patients</td>
<td></td>
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<td></td>
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<td></td>
<td>Intangible Resources:</td>
<td>- Limited access to national decision-maker - Technical expertise - Legitimacy</td>
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<tr>
<td>Chest Service of the 3rd Reference Hospital of Jamot</td>
<td>Public</td>
<td>Actively</td>
<td>Tangible Resources:</td>
<td></td>
<td>Low</td>
<td>Low</td>
<td>Neutral-Opposed</td>
</tr>
<tr>
<td></td>
<td>Institution</td>
<td>Involved</td>
<td>- Infrastructure</td>
<td></td>
<td></td>
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<td></td>
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<td></td>
<td>- Finances from MoPH and patients</td>
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<td></td>
<td></td>
<td>Intangible Resources:</td>
<td>- Limited access to national decision-maker - Technical expertise - Legitimacy</td>
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<tr>
<td>Regional Technical Group for the Fight against AIDS and Tuberculosis</td>
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<td>Actively</td>
<td>Tangible Resources:</td>
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<td>Medium</td>
<td>Medium</td>
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<tr>
<td></td>
<td>Institution</td>
<td>Involved</td>
<td>- Infrastructure</td>
<td></td>
<td></td>
<td></td>
<td>Medium</td>
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<td></td>
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<td></td>
<td>- Access to national decision-maker (direct to TB-CTG and CAPP) - Technical expertise - Legitimacy</td>
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<td>Medium</td>
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<td></td>
<td></td>
<td>Medium</td>
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<tr>
<td>Provincial Units of the Regional Technical Group for the Fight</td>
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<td>Actively</td>
<td>Tangible Resources:</td>
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<td>Low</td>
<td>(Limited) Support</td>
</tr>
<tr>
<td></td>
<td>Institutions</td>
<td>Involved</td>
<td>- Infrastructure</td>
<td></td>
<td></td>
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<td></td>
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<td>- Intangible Resources:</td>
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<td></td>
<td></td>
<td></td>
<td>- Limited access to national decision-maker (access to Regional Technical Group)</td>
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<tr>
<td>Role</td>
<td>Status</td>
<td>Actively Involved</td>
<td>Tangible Resources:</td>
<td>Intangible Resources:</td>
<td>Medium</td>
<td>- Supervises the District Unit for Tuberculosis Control</td>
<td>Medium</td>
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<td>----------------------------------------------------------------------</td>
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<tr>
<td>Health District Medical Officer</td>
<td>Individual in Public Sector</td>
<td>Actively Involved</td>
<td>Finances from MoPH - Technical expertise - Legitimacy</td>
<td>- Supervises the District Unit for Tuberculosis Control</td>
<td>Medium</td>
<td>Neutral</td>
<td>Medium</td>
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<tr>
<td>District Unit for Tuberculosis Control</td>
<td>Public Institution</td>
<td>Actively Involved</td>
<td>Infrastructure - Technical expertise - Legitimacy - Limited access to national</td>
<td>- Limited access to national political decision-makers (access to Regional Technical Group) - Legitimacy</td>
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<td>Low</td>
<td>Low</td>
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<tr>
<td>Public, Private and Traditional Institutions</td>
<td>Actively Involved, Negatively Influenced</td>
<td>Tangible Resources:</td>
<td>- Finances from MoPH and patients - Infrastructure - Intangible Resources: - Legitimacy - Limited access to national political decision-maker - Expertise to plan, manage and coordinate, implement as well as monitor and report on the health activities in collaboration with the beneficiaries</td>
<td>Advantages - Financial advantages - Advocacy and liaison with MoPH - Perception of the Cameroonian beneficiaries in the reduction of MDR-TB - Detection of new TB cases and upholding the referral system for identification, registration and medical cure - Implement TB control action plans</td>
<td>Low</td>
<td>Advantages</td>
<td>Low</td>
</tr>
<tr>
<td>Low Opposed</td>
<td></td>
<td></td>
<td>Disadvantages - Limited clinical freedom of national entities in choice of treatment regimen - Implementation of sub-</td>
<td>Disadvantages - Limited clinical freedom of national entities in choice of treatment regimen - Implementation of sub-</td>
<td>Low</td>
<td>Neutral-Opposed</td>
<td>Low</td>
</tr>
<tr>
<td>Public Institution</td>
<td>Actively Involved</td>
<td>Tangible Resources:</td>
<td>Intangible Resources:</td>
<td>Medium</td>
<td>optimal treatment regimen</td>
<td>Support</td>
<td>(Limited) Support</td>
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</tr>
<tr>
<td>CENAME Public</td>
<td>Actively Involved</td>
<td>- Finances from MoPH</td>
<td>- Legitimacy</td>
<td></td>
<td>Distribution of drugs against TB</td>
<td>High</td>
<td>(Limited) Support</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Infrastructure</td>
<td>- Access to national political decision-maker</td>
<td></td>
<td>Collaboration with CAPP and the TB-CTG</td>
<td></td>
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<tr>
<td></td>
<td></td>
<td>- Expertise</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>CAPP Public</td>
<td>Actively Involved</td>
<td>- Finances from MoPH</td>
<td>- Legitimacy</td>
<td></td>
<td>Distribution of drugs against TB</td>
<td>High</td>
<td>(Limited) Support</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Infrastructure</td>
<td>- Access to national political decision-maker</td>
<td></td>
<td>Process of applications for the provision of drugs against TB</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Expertise</td>
<td></td>
<td></td>
<td>Collaboration with CENAME and the TB-CTG</td>
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</table>
Annex 11  Average Drug Costs per MDR-TB Patient of Standardized Treatment Regimens

Annex 11.1  Figure A.3. Average Drug Costs per MDR-TB Patient of Standardized Treatment Regimens Worldwide

(Qtd. in Gupta et al., “Responding to Market Failures” 1049).

Annex 11.2  Tables A.1. and A.2. Average Drug Costs per MDR-TB Patient of Standardized Treatment Regimens in Cameroon

Drugs and costs for the short course regimen

<table>
<thead>
<tr>
<th>Drugs</th>
<th>Average Daily Dose (&gt;55kg)</th>
<th>Nº/ Day</th>
<th>Nº of Days per Patient</th>
<th>Nº of Vials/Tablets per Patient</th>
<th>Unit Cost (Euro)</th>
<th>Total Costs per Patient (Euro)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Kanmycin, 1000mg</td>
<td>1000mg</td>
<td>1</td>
<td>120</td>
<td>120</td>
<td>0.196</td>
<td>23.52</td>
</tr>
<tr>
<td>Gatifloxacin, 400mg</td>
<td>400mg</td>
<td>1</td>
<td>360</td>
<td>360</td>
<td>0.12</td>
<td>43.20</td>
</tr>
<tr>
<td>Clofazimim, 100mg</td>
<td>100mg</td>
<td>1</td>
<td>360</td>
<td>360</td>
<td>0.03</td>
<td>10.80</td>
</tr>
<tr>
<td>Prothionamide, 400mg</td>
<td>250mg</td>
<td>3</td>
<td>360</td>
<td>1080</td>
<td>0.04</td>
<td>43.20</td>
</tr>
<tr>
<td>Isoniazid, 300mg</td>
<td>300mg</td>
<td>1</td>
<td>120</td>
<td>120</td>
<td>0.006</td>
<td>0.72</td>
</tr>
<tr>
<td>Ehtambutol, 400mg</td>
<td>1200mg</td>
<td>3</td>
<td>360</td>
<td>1080</td>
<td>0.025</td>
<td>27.00</td>
</tr>
<tr>
<td>Pyrazinamide, 400mg</td>
<td>1600mg</td>
<td>4</td>
<td>360</td>
<td>1440</td>
<td>0.0145</td>
<td>20.88</td>
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<tr>
<td>Syringe</td>
<td>10ml</td>
<td>1</td>
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<td>120</td>
<td>0.14</td>
<td>16.80</td>
</tr>
<tr>
<td>Dest. Water</td>
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<td>1</td>
<td>120</td>
<td>120</td>
<td>0.14</td>
<td>16.80</td>
</tr>
</tbody>
</table>

Drugs and costs for the short course regimen

<table>
<thead>
<tr>
<th>Drugs</th>
<th>Average Daily Dose (&gt;55kg)</th>
<th>Nº/ Day</th>
<th>Nº of Days per Patient</th>
<th>Nº of Vials/Tablets per Patient</th>
<th>Unit Cost (Euro)</th>
<th>Total Costs per Patient (Euro)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Capreomycin</td>
<td>1g</td>
<td>1</td>
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<td>180</td>
<td>0.22</td>
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<td>Levofloxacin, 250mg</td>
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<td>720</td>
<td>2160</td>
<td>0.13</td>
<td>280.80</td>
</tr>
<tr>
<td>Prothionamide, 250mg</td>
<td>750mg</td>
<td>3</td>
<td>720</td>
<td>2160</td>
<td>0.04</td>
<td>86.40</td>
</tr>
<tr>
<td>Cycloserine, 250mg</td>
<td>750mg</td>
<td>3</td>
<td>720</td>
<td>2160</td>
<td>0.13</td>
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</tr>
<tr>
<td>Pyrazinamide, 400mg</td>
<td>1600mg</td>
<td>4</td>
<td>720</td>
<td>2880</td>
<td>0.0145</td>
<td>41.76</td>
</tr>
</tbody>
</table>

(Qtd. in NTCP Cameroon, “Application to the GLC July 2008”).
Annex 12  Summary of the Observational Study of van Deun et al. “Short, Highly Effective and Inexpensive Standardized Treatment of Multidrug-resistant Tuberculosis”

The observational study Short, Highly Effective and Inexpensive Standardized Treatment of Multidrug-resistant Tuberculosis of van Deun et al. assessed the outcomes of six different standardized treatment schemes on sequential cohorts of 486 enrolled new MDR-TB patients possessing an HIV-negative status in the resource-poor setting of Bangladesh from May 1997 to December 2007. All six standardized treatment regimens included a fluoroquinolone, Km and Pto, as well as promising FLDs and Cfz. The schemes were applied according to international principles, e.g. observance of treatment compliance through hospitalization during the intensive period and DOT in the continuation phase, surveillance of treatment effect via regular sputum-smear laboratories, and a two year follow-up period subsequent to healing. The most successful standardized treatment regimen was “4(+)KmCfzGfxEHZPto/5GfxEZCfz” with a minimum duration of nine months. Respectively, the intensive phase with the administration of Km, Cfz, Gfx, E, H, Z and Pto encompasses a minimum duration of four months until culture conversion is reached. The continuation phase includes a 5-month long treatment with Gfx, E, Z and Cfz. Consecutively, the healing rate among this cohort of 206 MDR-TB patients was 87.9 percent, compared to 221 MDR-TB patients treated within the five 15- to 21-month long ofloxacin-based regimens, which possessed a success rate from 57.1 to 84.2 percent. Moreover, in general the probability of achieving adverse results, e.g. death, default, or failure was about one-third lower in the gatifloxacin-based treatment scheme than in the other five regimens, and in particular the failure-rate was below one percent when Gfx was utilized. Even though, frequent minor side-effects also occurred in the scheme administering Gfx; these were commonly controllable, not leading to a halt of treatment. In addition, all the 206 MDR-TB patients in this cohort concluded the gatifloxacin-regimen in the maximum time of one year. Furthermore, compared to the ofloxacin-based treatment scheme, it did not cause further acquired drug-resistance. Finally, the generic medications for this complete scheme solely cost about 225 Euros per MDR-TB patient. Thus, this standardized treatment regimen proves to be very effective and successful, relatively short in time and inexpensive. Therefore, it offers cost-efficient treatment opportunities for developing countries considering the respective HIV-prevalence and susceptibility to SLDs (2-8, 12, 15-19, 30, 38).
K. J. Seung critized the utilization of H and Cfz in the standardized treatment regimen for MDR-TB in Bangladesh, as MDR-TB strains are proven resistant to the FLD, H, and no clinical evidence is existing on the effectiveness of Cfz in humans. Hence, he proposes, if possible, to exchange these two medications with PAS and Cs (231). In response to this criticism, van Deun et al. acknowledge the missing clinical proof of the efficacy of H and Cfz against MDR-TB. However, the researchers justify this standardized treatment by the significant fraction of MDR-TB strains that show H susceptibility (fostered via the utilization of Cfz) and its support against adverse outcomes. Furthermore, the recommended exchange medications PAS and Cs possess a high probability of initiating severe side-effects that ought to be closely monitored and treated, and are especially expensive, which in-turn lower the treatment opportunities in developing countries (232). Finally, H and Cfz show relatively few adverse-effects, are accessible, and frequently utilized by health personnel in low-income countries. These advantages and the above mentioned disadvantages of further anti-tuberculosis medications guided their decision to include H and Cfz in the standardized treatment regimen for MDR-TB in Bangladesh (Van Deun et al., “Results of a Standardised Regimen for MDR-TB” 561).