EQUITABLE ACCESS TO ESSENTIAL MEDICINES FOR NONCOMMUNICABLE DISEASES IN THE CARIBBEAN



A RAPID ASSESSMENT REPORT



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Acknowledgements

This report was prepared by independent consultant, Dr. Rian Extavour and reviewed by the Healthy Caribbean Coalition (HCC) team and the PAHO team including Dr. Begona Sagastuy (Consultant Medicines and other Health Technologies, PAHO/WHO, Caribbean Subregional Program Coordination), Dr. Elisa Prieto (past NCDs and Mental Health Subregional Advisor) and Ms. Sheryl Dennis (acting NCDs and Mental Health Subregional Advisor). The Case Studies section was researched and written by Tara Lisa Persaud, HCC Our Views Our Voices Technical Advisor.

The Healthy Caribbean Coalition expresses its gratitude to members of various non-governmental organizations, health professionals and health administrators who provided information and facilitated interviews for this report:

- Mr. Everton Anderson and staff of the National Health Fund, Jamaica
- Mr. Francis Burnett, Organization of Eastern Caribbean States Pharmaceutical Procurement Service
- Dr Christine Chin, Cancer Society of the Bahamas
- Ms. Michelle Daniel, Heart and Stroke Foundation of Barbados
- Mr. Andrew Dhanoo, Diabetes Association of Trinidad and Tobago
- Ms. Juanita James, Antigua and Barbuda Diabetes Association
- Dr. Paula Michele Lashley, Deputy Dean -clinical, Lecturer in child health, Paediatric Consultant, Faculty of medicine, University of West Indies, Cave Hill Campus
- Dr Karen Sealey, Trinidad and Tobago NCD Alliance
- Dr Dingle Spence, Senior Medical Officer, Hope Institute, Kingston, Jamaica
- Dr Asante Van West-Charles-Le Blanc, Physician, Victoria Clinic, Trinidad and Tobago
- Dr Charles Preston, Advisor, Regulatory Systems Strengthening for Medicines and Other Health Technologies, PAHO/WHO
- Dr Gustavo Mery, Advisor, Health Systems and Services (Bahamas, Turks and Caicos), PAHO/ WHO

Abbreviations / Acronyms

CARICOM

CARPHA

CCS

CDAP

CRS

DPH

EML

MAP

MBS

NCD

NF

NGO

NLC

NPDP

NRT

NSAP

OECS

PAHO

PEN

PHA

PPS

UN USA USD WHO

JADEP

Caribbean Community
Caribbean Public Health
Country Capacity Survey
Chronic Disease Assistan
Caribbean Regulatory Sys
Department of Public Hea
Essential Medicines List
Jamaica Drugs for the El
Multisectoral Action Plan
Medical Benefits Scheme
Noncommunicable Disea
Non-Formulary
Non-Governmental Orgar
Non-Latin Caribbean
National Prescription Dru
Nicotine replacement the
National Strategic Action
Organization of Eastern C
Pan American Health Org
Package of Essential Non
Public Hospitals Authorit
Pharmaceutical Procurer
United Nations
United States of America
United States Dollar
World Health Organizatio

Agency

- nce Programme
- rstem
- ealth
- lderly Programme
- n (also called National Strategic Action Plan)
- е
- ise
- nization
- ug Plan
- erapy
- Plan (also called Multisectoral Action Plan)
- Caribbean States
- ganization
- ncommunicable disease interventions
- ty
- ment Service

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1. Executive Summary

In the Caribbean, noncommunicable diseases (NCDs) are the leading causes of mortality, morbidity, and disability. This burden results in losses in household income, productivity and reduced gross domestic product. In response to this situation, there has been increasing recognition of the urgent need to tackle NCDs, as reflected in various mandates at the global, regional and subregional levels. While primary prevention of NCDs is a key objective of these mandates, the burden of disease related to NCDs cannot be reduced without access to safe, effective, guality, and affordable essential medicines for NCD treatment. Unfortunately access to these essential medicines is generally poor in most low- and middle-income countries. The Healthy Caribbean Coalition (HCC) recognizes the challenge of NCDs in the Caribbean and the need for sustainable, equitable access to essential NCD medicines. Therefore, HCC embarked on this project aimed at providing an overview of the state of access to noncommunicable disease (NCDs) medicines in the Caribbean.

This characterization applied a variety of methods, including literature review, desk reviews of country situations, and interviews. It is a first of its kind for the region and represents an initial step towards consolidating knowledge in this area, which may inform policy makers, donors, non-profit organizations, and citizens. Some aspects need further study and/or more direct analysis, therefore this report may be used to point to future research directions.

Thirteen CARICOM states were included in the study, with a focus on essential medicines for cancer, cardiovascular diseases, diabetes, chronic respiratory diseases, mental neurological diseases, palliative care, tobacco cessation treatment and alcohol abuse. The report is structured according to the World Health Organization's (WHO) Roadmap for Access to Medicines. Vaccines. and Other

Health Products 2019-2023 framework. Key findings are described below.

Cross cutting health system structure elements: Governance, Financing, Health workforce and Information systems.

Access to essential medicines and other health products relies on a well-functioning health system, which requires four crosscutting elements: governance, financing, health workforce and information systems.

Governance: Good governance of pharmaceuticals relies on the presence and implementation of legislative frameworks and national medicines policies to ensure appropriate selection, use, and removal of medicines that no longer pose a favourable benefit-risk balance or satisfy quality standards. This review found that 12 of 13 Member States had a national NCD plan or policy, and only one had a national medicines policy. Although Member States may refer to the Caribbean Pharmaceutical Policy of 2013 for adoption or for adaptation of draft medicines policies, the resulting national policies should be accessible to stakeholders, including the public. National strategic multisectoral plans for NCDs varied in articulation of strategies to ensure access to quality, safe and effective medicines, highlighting the need for more alignment with national medicines policies. Although the Member States all have legislation that governs pharmaceuticals (directly and indirectly), these appear in different arms of governance and Acts, which may create challenges in the streamlining, updating and/or enforcement of policies and procedures. Notable is that there is no differentiation between children and adults within any of the plans or policies referred to above, even though appropriate prescribing for children may differ to that of adults.¹

Financing: Inadequate or insufficient financing for medicines and pharmaceutical systems is a common challenge to CARICOM health national expenditure on health products, systems. This is further weakened by high prices, and inadequate pricing policies for generics and biosimilars to ensure controls. Public health expenditure is low on average throughout CARICOM, but out-of-pocket expenditure is high (over 50% total health expenditure). Although NCD medicines are provided free or at reduced costs in publicprivate arrangements in CARICOM, insufficient financing and high prices lead to low volumes. stock-outs, and subsequent increases in direct spending by patients. Additional information on pharmaceutical expenditure (public and private), and price analyses for NCD medicines using standardized methods are needed to understand the impact of current policies and procedures, and to identify solutions to ensure appropriate expenditure.

Health workforce: The Caribbean is characterized for having an undersupply of health workforce, including pharmacists, primarily due to migration. Pharmacists are key to ensuring access to and appropriate use of medicines and vaccines, but available information on pharmacist density in CARICOM indicates unequal distribution in the region ranging from 0.09 pharmacists per 10 000 to 6.64 in 2018. The differences in pharmacy gualifications and roles undertaken also adds to differences in the type of service provided to patients. Harmonization of pharmacy education, training, and practice is key to ensuring persons who use NCD medicines are guided appropriately, and that the management of the dispensary meets the standards for Good Pharmacy Practice. The availability of pharmacists with required competence is also dependent on financing and good governance / regulation.

Health Information Systems: Health information systems are essential to provide insight on

availability of medicines in health facilities. pharmacovigilance, and outcomes. Decision makers who were interviewed identified the lack of integrated health information systems as one of the main challenges they are facing for guaranteeing access to NCD medicines. Health information systems in CARICOM vary in maturity and stage of transitioning from manual to digitised systems. Health information pertaining to access to medicines is formatted and processed differently, and is not readily communicated within national systems or divisions. Hence the generation of information remains intensive and inefficient as it largely relies on periodic surveys, census, and other ad hoc studies, instead of being routinely collected, analysed and archived for use by multiple divisions. Information products, such as electronic lists of registered medicines or procurement lists, are generated, but not routinely, and these are often outdated and unavailable to the public.

Ensuring the Quality, Safety, and Efficacy of health products

Regulation of Medicines: The scope of regulatory systems is extensive and resource-intensive, which poses a challenge to CARICOM countries in the regulation of medicines. National regulatory authorities are responsible for assessing medicines prior to authorization for sale or use in the country, but more than half of CARICOM states lack NRAs, and low fees make development of regulatory systems untenable. Countries that lack NRAs rely on gualification of suppliers, such as via the OECS Procurement Services, but this process does not include assessment of the quality, safety or efficacy of the proposed medicines prior to market entry. This leaves the onus on procurers to monitor the guality of the products on the market, which is beyond their inherent scope or function, which trends related to NCDs and their risk factors, conflicts with the WHO's recommendation to

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separate assessment of quality, safety and efficacy of medicines from procurement.

Quality, Safety, Efficacy: The Caribbean Public Health Agency (CARPHA) with support from PAHO houses two divisions that assist Member States with evaluation of medicines prior to marketing (Caribbean Regulatory System, CRS), and with testing the quality of medicines (Medicines Quality Control and Surveillance Department, MQCSD)². More than one third of the medicines reviewed and recommended by the CRS are NCD medicines including insulin and medicines for cancer, and risk-based testing of medicines by the MQCSD prioritizes essential NCD medicines. In addition, the CRS' VigiCarib³ network enables collection of case reports for regional and international vigilance, and for notification of substandard / falsified medicines in CARICOM. However, Member States and procurement agencies need to increase utilisation of the CRS and the MQCSD to support regulatory functions of market authorisation, pharmacovigilance, and market surveillance and control.

Improve Equitable Access

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covered in this study use a list of essential medicines (i.e. a VEN list) or a national drug formulary based on the WHO Model List of Essential Medicines. A checklist of 178 essential NCD medicines was used to compare with public sector procurement lists (including awards lists or price guides), or with national lists of essential medicines where procurement lists were not available, as a proxy for availability. Of the 178 medicines selected, an average of 61.6% were included on the lists examined. When analysed by category, from highest to lowest, essential medicines were found for: cardiovascular disorders (79%), chronic mental / neurological disorders (73%), respiratory conditions (75%), to revisit and reassess intellectual property palliative care (67%), diabetes (59%), cancer (45%), and nicotine replacement therapy (14%). Medicines recommended in guidelines for medicines. alcohol use disorders were not considered as

essential medicines, and none were included in the reviewed lists. Government officials and civil society representatives interviewed confirmed that many of the NCD medicines are available, but they also reported occasional stock outs. Various factors were reported to contribute to stock outs, including limited financing, poor demand monitoring and forecasting, lack of inventory management, and late payment of suppliers. The introduction of public-private programmes to ensure NCD medicines are available free or at reduced cost in CARICOM remains an important avenue to ensuring equitable access, but health information and adequate financing are also key to ensure an appropriate, sufficient and sustainable supply for these programmes to have impact.

Management of Intellectual Property: Towards ensuring access to affordable medicines, CARICOM Ministers of Health established in 2003 a Technical Advisory Group (TAG) on Trade-Related Intellectual Property Rights (TRIPS), which was mandated to assess the situation of the drug registration systems, and patent and related issues. One of the main conclusions of a study published in 2009 was that all the Essential NCD Medicines: All 13 countries countries had patent (intellectual property) Acts but seven of them were considered obsolete and needed to be replaced, and that the inclusion of TRIPS flexibilities was uneven across the region. This situation was also seen in 2012 in a PAHO report that showed that out of 11 countries under study, none had incorporated the Bolar exception in their national legislation, 6 had included compulsory licencing, and 3 considered provisions for parallel imports. Since TRIPS came into force and following the Doha declaration, several bilateral and regional trade agreements have tended to set even higher standards for intellectual property (IP) protection. There is a need for CARICOM states Acts, TRIPS flexibilities and the implementation of solutions that support access to affordable **Research and Development:** Population-specific and solutions to support equitable access. research on the safety and quality of medicines These strategies should include strengthening used by the populations, and procedures to ethical reviews and oversight of clinical trials, assess risk-benefit analyses are needed to setting of standards for regulation of local determine which medicines work best in local manufacturing and production, and the study populations. Research into the public health of adverse events in specific populations. needs in the context of NCDs, clinical efficacy Collaborations with academic institutions, and safety of NCD medicines in CARICOM, the international organizations and donors are availability of NCD medicines, factors affecting also important strategies. All of which will also their utilization and real-world effectiveness of require robust regulatory frameworks, reliable NCD medicines in CARICOM are all necessary to health information systems, appropriately inform the development of relevant approaches trained personnel and sustainable financing.

Key Recommendations

- challenges and lines of action for access to NCD medicines.
- on the state of patent acts and TRIPS flexibilities.
- barriers in the Caribbean.
- harmonization of pharmacy education.
- essential medicines, quality standards and procurement lists.
- CARPHA Caribbean Regulatory System.
- surveillance that are integrated with NCD medicines programmes.
- treatment guidelines for priority NCDs.

1. High-Level Commitments are needed to ensure equitable access to essential medicines, in light of an updated Caribbean Pharmaceutical policy to identify

2. Enhance access to NCD Medicines through Affordable Pricing policies, and equitable financing. Current information on pharmaceutical spending is needed, and a study

3. Conduct in-depth studies on the effectiveness of the various NCD medicine programmes in facilitating equitable access to NCD medicines and reducing financial

4. Determine the current pharmacist-population density and distribution in CARICOM, and identify strategies to promote more equitable distribution of pharmacists, and

5. Strengthen health information systems to routinely generate information products related to access to NCD essential medicines, such as publicly available lists of

6. Strengthen regional regulation of marketing authorization or approval of NCD medicines through standardized processes of evaluation, such as the review by the

7. Establish strong pharmacovigilance systems, and risk-based post-market

8. Increase rational use of NCD medicines by updating national EMLs and standard

9. Review and include appropriate essential medicines from the World Health Organization's Model List of Essential Medicine for Children to ensure that the priority health care needs of CARICOM children are also being considered.

2. Introduction

The Healthy Caribbean Coalition (HCC) is the only alliance of health and non-health focussed civil society organisations (CSOs) in the Caribbean working to address the prevention and control of noncommunicable diseases (NCDs). Access to high guality medicines for NCDs is a significant challenge for people living with NCDs in the Caribbean. This report is to provide an overview of the state of access to NCD medicines in the Caribbean. The report uses a variety of different methodologies including document reviews, desk reviews of country situations, and interviews. It is a first of its kind for the region and represents an initial step towards consolidating knowledge in this area, which can inform policy makers, donors, non-profit organizations, and citizens. Some aspects require further study and/or more robust analysis, which are identified in this report to inform future research directions.

2.1 The Burden of Noncommunicable Diseases in the Caribbean: An Economic and **Development Challenge**

The lack of access to health care and universal health coverage is one of the fundamental challenges that countries in the Americas face, as this translates to millions of people who are unable to receive the health care needed to live healthy and prevent disease.⁴ Bearing this in mind, in 2014, the Member States of the Pan American Health Organization (PAHO) adopted the Strategy for Universal Access to Health and Universal Health Coverage,⁴ and the following year they endorsed the adoption of a Sustainable Development Goal (SDG) aimed at achieving universal health coverage by 2030. Yet, universal health access and universal health coverage remain a distant reality for many countries where the burden of noncommunicable diseases (NCDs) and its

increasing costs threatens the sustainability of health systems and the health of populations. In the Caribbean, the four major NCDs cardiovascular diseases (CVDs), diabetes, cancer, and chronic respiratory diseases remain leading causes of mortality, morbidity and disability. In 2016, NCDs were responsible for 76.8% of all deaths in the subregion. Moreover, 38.1% of all NCD deaths occurred in persons under 70 years of age, and people in the Caribbean had the highest probability of premature death (i.e. between the ages of 30 and 70 years) from any of the 4 major NCDs, compared to other subregions of the Americas.⁵ This burden results in losses in household income, productivity and reduced gross domestic product (GDP). As an example, the Pan American Health Organization (PAHO) in collaboration with Harvard University estimated that NCDs and mental health conditions will lead to a USD\$17 billion loss in Jamaica, which is equivalent to an annual GDP reduction of 3.9% over the 15-year period of 2015 to 2030.6 This economic impact is particularly challenging for Small Island Developing States (SIDS), where NCDs have the potential to reverse developmental and economic gains, while the rising costs of health services associated with NCDs threaten the achievement of Universal Health.

In response to this situation, there has been increasing recognition of the urgent need to tackle NCDs, as reflected in the growing mandates at the global, regional and subregional levels. The Heads of State and Government of the Caribbean Community (CARICOM) convened the first NCD summit in the world in September 2007, and signed the Port of Spain Declaration (POSD),⁷ aimed at uniting to stop the epidemic of NCDs, and establishing a series of mandates and commitments to achieve its goals.

Following the 2007 POSD and the landmark In line with the strong linkages with economic Political Declaration of the first United Nations growth and development, NCDs are explicitly High Level Meeting (UNHLM) on NCDs in 2011,⁸ reflected in the sustainable development Member States endorsed the World Health goals (SDGs), which include a goal on health Organization (WHO) Global Action Plan for the (SDG 3) and targets related to reducing Prevention and Control of NCDs 2013-2020,⁹ and premature mortality from NCDs by one third the Pan American Health Organization (PAHO) by 2030 through prevention and treatment, and Regional Plan of Action for the Prevention and promoting mental health and wellbeing. Control of NCDs 2013-2020.¹⁰ Both action plans 2.2 Context of Access to Essential call for the implementation of a set of very cost-NCD Medicines: Mandates and effective and feasible interventions and policy options to address NCDs and their risk factors Challenges (RFs), including the so-called WHO "Best Buys", While primary prevention of NCDs is a key which were recently updated and adopted by objective, the burden of disease related to the World Health Assembly in May 2017.¹¹ They NCDs cannot be reduced without access to also provide a clear accountability framework safe, effective, quality, and affordable essential to measure impact by 2025, as defined by the medicines and technologies for NCD treatment. 25 indicators and 9 voluntary targets of the Unfortunately access to these chronic disease WHO Global Monitoring Framework (WHO GMF), medicines is generally poor in most low- and including a 25% relative reduction in premature middle-income countries. mortality from the 4 major NCDs by 2025.

In an effort to accelerate progress, countries further endorsed 4 time-bound commitments as part of the Outcome Document of the 2014 High Level UN General Assembly to review progress on NCDs, which include, by 2025: 1) Consider setting national NCD targets for 2025; 2) Consider developing national multisectoral policies and plans to achieve the national targets by 2025; and by 2016: 3) Reduce risk factors for NCDs building on guidance set out in the WHO Global NCD Action Plan: and 4) Strengthen health systems to address NCDs through people-centred primary health care and universal health coverage, building on guidance set out in the WHO Global NCD Action Plan. Moreover, countries adopted a set of 10 progress indicators, measured through the WHO Country Capacity Survey (CCS) and other WHO tools, to assess the realization of these 4 time-bound commitments, including at the Third UN High-level Meeting on NCDs in 2018.

Essential medicines are defined by WHO as "medicines that satisfy the priority health needs of the population"¹² and as a result, are crucial to promoting health and achieving sustainable development. Throughout this document, when essential medicines are referenced, a broad concept that considers the quality, safety, effectiveness, and affordability of the medicines is applied. Access to essential medicines is a complex construct that is influenced by various factors including manufacturing practices, the robustness of regulatory systems, health systems and related infrastructure, affordability, procurement practices, the reliability of supply chains, detection and monitoring of pharmaceutical quality, medication safety and usage patterns.¹³

The importance of access to medicines and technologies for NCD is directly highlighted in the mandates and accountability frameworks outlined above and summarized in Table 1.

Table 1: Key Global, regional, subregional mandates and accountability framework

Year	Accountability Framework	Description	Reference to access to medicines and other health technologies		Year	Accountability Framework	Description	Reference to access to medicines and other health technologies
2007	Port of Spain Declaration ⁷	The 2007 Declaration of Port of Spain, "Uniting to stop the epidemic of chronic NCDs," resulted from a historic and unprecedented effort by Heads of Government of CARICOM who recognized the devastating burden and consequences of noncommunicable diseases (NCDs) on their citizens and the need to respond at the highest political level. The Port of Spain Declaration (POSD) comprises 15 mandates monitored by 26 indicators reflecting commitments to action in key areas including risk factor reduction and health promotion; improving quality of care; the development of appropriate legislative frameworks and the establishment of NCD commissions or similar entities to provide an "all of society" response to NCD prevention and control efforts.	No specific mention of medicines and other health technologies for NCDs.		2013WHO Global Action Plan for Prevention and Control of NCDs 2013 – 2020°201320132013PAHO NCD Action Plan10	 Six objectives (abridged): 1. To raise the priority of NCD prevention and control in global, regional and national agendas and internationally agreed development goals. 2. To strengthen national capacity, leadership, governance, multisectoral action and partnerships 3. To reduce modifiable risk factors and underlying social determinants through health promoting environments. 4. To strengthen and orient health systems to address the prevention and control of NCDs and the underlying social determinants. 5. To promote and support national capacity for high-quality research and development. 	Two voluntary global targets refer to medicines and health technologies: At least 50% of eligible people receive drug therapy and counselling to prevent heart attacks and strokes. An 80% availability of the affordable basic technologies and essential medicines, including generics, required to treat major noncommunicable diseases in both public and private facilities.	
2011	Political Declaration of the High-level Meeting of the General Assembly on the Prevention and Control Non communicable Diseases ⁸	The General Assembly in its resolution A/RES/65/238 PDF Document decided that the high-level meeting of the General Assembly on the prevention and control of noncommunicable diseases shall be held on 19 and 20 September 2011 in New York and that the high-level meeting shall address the prevention and control of noncommunicable diseases worldwide, with a particular focus on developmental and other challenges and social and economic impacts, particularly for developing countries	Promote access to comprehensive, cost effective and affordable medicines, including generics. Strengthen health infrastructure for procurement, storage and distribution of medicines. Encourage alliances and networks for development of new medicines, vaccines, diagnostics and technologies.				 6. To monitor trends and determinants of NCDs and evaluate progress in their prevention and control. The four lines of action are: Multisectoral policies and partnerships for NCD prevention and control; NCD risk factors and protective factors; Health system response to NCDs and risk factors; and NCD surveillance and research. 	Access to medicines is included within the third strategy as specific objective 3.2 "Increase access to and rational use of essential medicines and technologies for screening, diagnosis, treatment, control, rehabilitation, and palliative care of NCDs."

Year	Accountability Framework	Description	Reference to access to medicines and other health technologies
2013	WHO NCD Global Monitoring Framework (GMF) ¹⁴	Comprised of 9 voluntary targets aimed at combatting the 4 main NCDs, and accelerating action against leading risk factors. These targets include access to essential NCD medicines, drug therapy counselling, reduction in tobacco use, and reduction in harmful use of alcohol.	80% availability of the affordable basic health technologies and essential medicines, including generics, required to treat major noncommunicable diseases in both public and private facilities
2014	United Nations Second High- Level Meeting on NCDs ¹⁵	By the terms of a wide-ranging draft resolution — the meeting's outcome document — Governments committed to address NCDs as a matter of priority in national development plans, for which they agreed to consider setting national targets for 2025, by 2015, and by 2016, to reduce risk factors and underlying social determinants for those diseases. They aimed, by 2016, to strengthen and orient health systems to address prevention and control issues through people-centred primary health care and universal health coverage.	Promote the use of the TRIPS provisions to promote access to medicines. Promote the development and dissemination of appropriate, affordable and sustainable transfer of technology for the production of medicines and other health technologies.
2015			Targets (3.8 and 3b) and more broadly in at least six additional SDG targets (3.1, 3.2, 3.3, 3.4, 3.5, 3.7).
2018	United Nations Third High- Level Meeting on NCDs ¹⁷	Commitment to implement a series of WHO-recommended policies to prevent and control of NCDs - such as public education and awareness campaigns to promote healthier lifestyles, vaccinating against HPV virus to protect against cervical cancer and treating hypertension and diabetes.	Promote increased access to affordable, safe, effective and quality medicines and diagnostics and other technologies, reaffirming the World Trade Organization Agreement on TRIPS.

All the agreed international and regional mandates that address the management of NCDs acknowledge the importance of access to safe, affordable, and guality essential medicines and other health technologies in the management of NCDs. However, despite these strong mandates, and widespread agreement, approximately two billion people do not have access to essential medicines globally.¹³ In its mid-point evaluation of the progress achieved in the implementation of the NCD-GAP, the WHO identifies key shortcomings including the need for more work in the management of NCDs in primary care, the inclusion of vulnerable groups (including multiple age-groups), a need for greater investment in research, and a lack of clear guidance as to how countries can establish effective multisectoral responses.¹⁸ In addition, rising costs of medicines and rapidly changing markets for health products translate into an increased pressure to all health systems' capacity to provide access to essential medicines. This is more glaring when considering the rise of NCDs that require long-term pharmaceutical treatment and the financial burden this presents to governments and patients.¹⁹

These challenges are also experienced in the Caribbean, particularly in the context of sustainable health financing and the need for research. According to the WHO 2020 NCD Progress Monitor only 2 of the 14 CARICOM PAHO/WHO Member States that participated reported full implementation of the progress indicator for:²⁰

"Provision of drug therapy, including glycaemic control, and counselling for eligible persons at high risk to prevent heart attacks and stroke, with emphasis on the primary care level."

2.3 The Healthy Caribbean Coalition

The Healthy Caribbean Coalition (HCC) was formed in 2008, arising from the 2007 Port of Spain Declaration by Heads of Government of the Caribbean Community on noncommunicable diseases. The coalition is an umbrella organisation of civil society organisations working to reduce the NCD burden in the Caribbean region, that promotes and advocates for the involvement of civil society in the all-ofsociety, whole-of-government, multisectoral response which is essential for NCD prevention and control, in the framework of relevant national, regional, and international plans and frameworks. The work of the HCC is underpinned by five strategic pillars: accountability, capacity development, communication, sustainability, and advocacy.²¹

The HCC recognizes the challenge of NCDs in the Caribbean and the need for sustainable, equitable access to essential NCD medicines. The Coalition has identified as one of its eight advocacy priorities a call for increasing equitable access to quality and affordable essential medicines. For countries in the region to act for increased access to medicines, it is fundamental to understand the current situation of availability of NCD medicines. Hence, HCC embarked on this rapid characterization that is expected to inform on possible solutions and strategies for improvement and identify information gaps for future action.

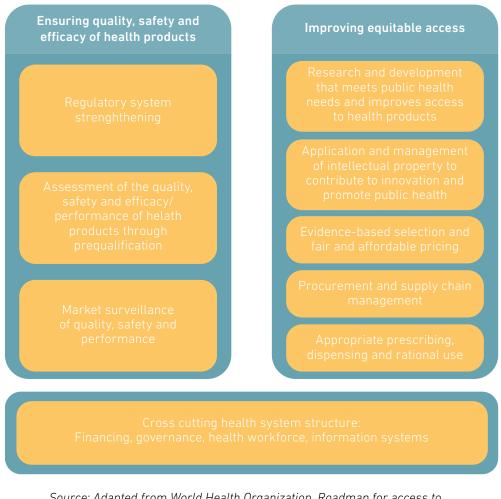
3. Methods

3.1 General Considerations

This report is structured according to the different strategic areas and cross cutting health system lines laid out in WHO's Roadmap for Access to Medicines, Vaccines, and Other Health Products 2019-2023 framework (**Figure 1**) which has two interlinked strategic areas: (a) ensuring the quality, safety and efficacy of health products, and (b) improving equitable access to health products. These

areas are supported by four cross-cutting operational areas of health systems: financing, governance, health workforce and information systems.¹⁹ This framework was selected for its comprehensiveness, to enable identification of areas and activities that countries in the region should strengthen in conjunction with the work that is being done globally.

Figure 1: WHO's strategic areas and activities for Access to Essential Medicines



Source: Adapted from World Health Organization. Roadmap for access to medicines, vaccines, and other health products 2019-2023. Geneva: World Health Organization; 2019

The CARICOM states included in the study were: diseases. In addition, medicines for palliative Antigua and Barbuda, Bahamas, Barbados, care, tobacco cessation and alcohol abuse Belize, Dominica, Grenada, Guyana, Jamaica, were included. To characterize the availability Saint Kitts and Nevis, Saint Lucia, Saint Vincent of medicines for NCDs in the region, a review and the Grenadines, Suriname and Trinidad and of the most current, publicly available national Tobago. Excluded States were: Haiti - due to procurement lists and/or essential medicines language barriers, and Montserrat - as a British lists was undertaken to provide a snapshot overseas territory. of medicine availability. A list of indicator medicines was developed and used to compare The characterization was done virtually with national procurement lists or national whereby information was sourced mainly from essential medicines lists, where available. the academic literature, online documents, Indicator medicines were included considering desk reviews and websites of governments the following:

and international agencies. This information was complemented with semi-structured interviews with public health professionals and representatives of civil society organizations. These interviews took place in June 2019 and the detailed guide used is available in **Appendix** 2. A total of ten interviews were done with representatives of the following organizations:

- Barbados Drug Service
- Drug Inspectorate, Ministry of Public Health, Guyana
- National NCD Focal Point, Ministry of Public Health, Guyana
- Jamaica
- Essential medicines for palliative care Senior Medical Officer, Hope Institute, were assessed separately from cancer medicines as these may be used in National Health Service, Jamaica and critical care for other NCDs (e.g. seizures). OECS Pharmaceutical Procurement These products included analgesics, anti-Service (PPS). emetics. laxatives. antibiotics (Access Group antibiotics or WHO PEN 2020), and Antigua and Barbuda Diabetes Association electrolyte infusions
- Cancer Society of the Bahamas
- In the absence of essential medicines in Heart and Stroke Foundation of Barbados the WHO EML for the treatment of harmful • T&T NCD Alliance, with input from the use of alcohol, two medicines were noted Diabetes Association of Trinidad and in the treatment guidelines for harmful use Tobago. of alcohol by the American Psychological The NCDs considered for this study were: Association.²⁴ These were not counted cancer, cardiovascular diseases, diabetes, as essential medicines but the lists were respiratory disease, and mental or neurological checked for their inclusion.

- Inclusion in the 22nd WHO List of Essential Medicines 2021²² and/or the WHO Package for Essential Noncommunicable (PEN) Diseases for primary health care 2020²³
- Used in the treatment of five of the major types of NCDs: diabetes, cardiovascular, respiratory, cancer (including medicines for palliative care), and mental conditions (including neurological disorders)
- Used in the treatment of smoking cessation, including nicotine replacement therapy

The final list was reviewed and approved by of availability for this report relied on these members of the board of the Healthy Caribbean Coalition prior to the assessment and consisted of 178 medicines - Appendix 1. This list was compared with available public sector procurement lists of non-Latin Caribbean (NLC) countries, excluding overseas territories, Aruba and Puerto Rico. Where the procurement lists were not available, the most recent versions of national lists of essential medicines or national formularies were used. The WHO Global EML,²⁵ an online database of national essential medicines lists, was used as a source, along with websites of the ministries of health and/ or procurement agencies, including the OECS' Pharmaceutical Procurement Service.²⁶

3.2 Limitations of the Assessment

There are limitations to the methodology used to compile this report that are worth mentioning. These are discussed below, but in general, include the fact that it was not possible to visit each of the countries studied and so the assessments had to be done virtually, using online documents, websites, and virtual interviews to gather information. In addition, the lack of standardized, current information (public or otherwise) made it difficult to draw generalizable conclusions.

A primary source of data and focus for this report were procurement lists and national medicines lists, but these have limitations. Most of the lists reviewed were developed prior to 2021 and lacked standardized formats. In addition, the policies and procedures used to develop and update national essential medicines lists and public procurement lists vary, including the frequency of the revisions. The inclusion of a pooled procurement agency assists with identifying procured products for public sectors in the OECS countries, but it does not reflect private sector procurement. The assessment

procurement lists and did not involve a physical assessment of stock on hand at public or private health facilities. Hence, the information reflects expected availability for procurement for public sector, but not a real-time review of physical availability. The assessment of medicines that would be reimbursable by private medical insurance plans in the Caribbean was beyond the scope of this assessment.

It was not feasible to determine real-time availability of essential NCD medicines in the private sectors of the various countries in a virtual approach, as it would have required surveys of private pharmacies in each country or online publication of the inventories of several private pharmacies in each country. However, in countries with programmes that extend access to publicly procured NCD medicines into the private sector, the listed medicines would be included on procurement lists, and distributed via private pharmacies.

Finally, the absence of national medicines policies restricted the identification of policies to documents available at the time. Therefore, the assessment provides an overview of published data and perspectives, but it does not provide a comprehensive assessment of all aspects of country pharmaceutical systems, or the processes used to develop the lists reviewed. The interviews with patient advocacy groups provided important, qualitative information but cannot be considered representative of all patients' experiences in the given country due to convenience sampling.

4. Findings

4.1 Cross Cutting Elements of **Health Systems**

4.1.1 Governance

Governance and stewardship are fundamental Out of the 13 countries under study, 10 (77%) to improving access to universal health. This had a current national health policy and 12 (92%) is particularly important when talking about had a NCD plan/policy or strategy, of which 7 medicines because weak governance produces (53%) are past their end dates - Tables 2-3. inefficiencies and waste, and it can also make Only 1 country had a current pharmaceutical systems vulnerable to corruption and abuse. policy, which may be interpreted as a decline The existence of national health policies, in comparison to 2007 when 7 CARICOM strategies and plans play an essential role countries had a national medicines policy.29 in defining a country's vision, direction, and However, given the fact that the region has a priorities to advance towards universal health.²⁷ Regional Pharmaceutical Policy since 2013,³⁰ For several decades, WHO has been advocating this framework may have guided policy actions for countries to develop national health at national level regarding pharmaceuticals.

Table 2: National frameworks for health, NCDs and medicines

Total Countries §

Countries with a current national health plan no earlier than 2016

Countries with a current national NCD plan/p earlier than 2016

Countries with a current national medicine p expired no earlier than 2016

Source: <u>WHO Country Planning Cycle Database³¹ and MoH webpages</u>

8: Antiqua/Barbuda, Bahamas, Barbados, Belize, Dominica, Grenada, Guvana, Jamaica, St Kitts/ Nevis, St Lucia, St Vincent and the Grenadines, Suriname, Trinidad and Tobago

policies. The Organization has also promoted, since 1975, the development of national drug policies and more recently, 2011, the adoption of multisectoral policies, strategies and plans to address NCDs.^{8,28}

	13	100%
n/policy/strategy or that it expired	10	77%
policy/strategy or that it expired no	12	92%
olan/policy/strategy or that it	1	8%

Out of the 10 countries that had a national health policy, only 7 were publicly available on tobacco cessation or the reduction in harmful the respective webpages or in the WHO Country Planning Cycle Database. Of those 7 countries, 86% had goals or targets related to NCDs, 71% related to medicines, and 57% had both (NCD targets and medicines).

Regarding NCD policies and plans, all had at least one strategic line or target related to increasing the availability and access to medicines but varied in the extent to which they define strategies for access to essential NCDs and their rational use. For example:

- Antigua and Barbuda: "List of Available Essential Medicines for NCDs from MBS and OECS/PPS updated and available"³²
- Grenada: "Increase access to and rational use of essential medicines and technologies for treatment, rehabilitation, and palliative care of CNCDs."33
- Suriname: "Strengthening of regulation to improve access to safe, affordable and efficacious NCD medicines"³⁴
- Trinidad and Tobago: "An 80% availability of the affordable basic technologies and essential medicines, including generics required to treat major noncommunicable diseases in both public and private facilities"³⁵

Components for access to medicines used in use of alcohol were not commonly found in the NCD strategic plans. However, all NCD strategies recognized tobacco use and harmful use of alcohol as risk factors. In addition, most countries had policies for the management of mental health or tobacco control, which included strategies for smoking cessation and the harmful use of alcohol. In Table 3 some of the components and strategies for access to NCD medicines in the revised national strategic action plans are outlined. Where an aspect was not described in the national NCD plan, but it was addressed in a mental health strategy, this was noted as 'mhs' in the table. Similarly where a medicine access indicator was not clearly specified in the NCD strategic plan, but it was framed within another national policy, this was noted with a symbol.



The proposal for the Caribbean Pharmaceutical Policy was presented at the Eighteenth Meeting of Chief Medical Officers (CMOs) on 19 May 2010 and at the Nineteenth Meeting of the Caucus of CARICOM Health Ministers in September 2010. The ministers agreed that a decision should be taken on this matter at the next COHSOD meeting, to be held in April 2011, when the policy was finally approved.

The goal of the Caribbean Pharmaceutical Policy is to guide Caribbean countries in ensuring:

- medicines; and
- professionals and consumers.

There is no available evaluation of this policy, hence there is no information on its implementation and achievements.

Policy. Washington, DC: PAHO, 2013.

Box 1: Caribbean Pharmaceutical Policy

• Rational use: therapeutically sound and cost-effective use of medicines by health Table 3: Components for Access to Essential NCD Medicines Specified in National Strategic Action Plan for NCDs

Aspect	ANT	BHS	BBD	BEZ	DCA
Period Applicable	2015-19	2017-22	2015-19	2013-23	n/a
Treatment of 4 Major NCDs	Yes	Yes	Yes	Yes	¥
Therapies for Mental Health / Conditions	mhs	mhs	mhs	mhs	mhs
Tobacco Cessation Therapies	No ¥	No ¥	No ¥	No ¥	
Alcohol abuse Treatment	No ¥	No ¥	Yes	No	
Revision or review of EML / Formulary (i)	No ¥	Yes	Yes	No ¥	¥
Use of generic medicines (ii, iii)	No ¥	No ¥	Yes	Yes	¥
Supply Chain / Procurement review (ii, iii, iv)	Yes	No ¥	Yes	No	¥
Pharmacy Legislation / Policies / Governance (i-iv)	Yes	Yes	Yes	Yes	¥
Standard Treatment Guidelines / Prescribing (i)	Yes	Yes	Yes	Yes	¥
Drug Use Reviews (i)	Yes	No ¥	No ¥	Yes	¥
National Subsidized or Free NCD Medicines Programme (ii, iv)	Yes	Yes	Yes	Yes	¥
Percent covered in any national policy	63% (7/11)	55% (6/11)	91% (9/11)	63% (7/11)	n/a
Percent specified in NCD or MH plan	100%	100%	100%	91%	73%

Key: ANT – Antigua/Barbuda, BHS – Bahamas, BBD – Barbados, BEZ – Belize, DCA – Dominica, GRN – Grenada,
GUY – Guyana, JCA – Jamaica, SKN – St. Kitts / Nevis, SLU – St Lucia, SVG – St Vincent and the Grenadines, SUR –
Suriname, TTO – Trinidad and Tobago

mhs – National mental health policy exists which addresses treatment of conditions; n/a – not assessed

GRN	GUY	JCA	SKN	SLU	SVG	SUR	TT0
2013-17	2013-20	2013-18	2013-17	2017-25	2017-25	2015-20	2017-21
Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
mhs	mhs	Yes	mhs	mhs	mhs	mhs	mhs
No	Yes	Yes	No ¥				
No	No ¥	Yes	No ¥	No	No ¥	No	No ¥
No ¥	Yes	Yes	No ¥				
Yes	Yes	Yes	Yes	Yes	No ¥	No ¥	No ¥
Yes	Yes	Yes	No ¥	No ¥	Yes	No ¥	No ¥
Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
No ¥	Yes	No ¥	No ¥	No ¥	Yes	No ¥	No ¥
Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
63% (7/11)	91% (10/11)	91% (10/11)	55% (6/11)	55% (6/11)	82% (9/11)	45% (5/11)	63% (7/11)
73%	100%	100%	100%	91%	100%	91%	100%

¥ - Not specified in NCD plan as a strategy but found in other national policies, regional formulary policy or country profile
 (i - iv): WHO Framework Elements: (i) Rational selection and use of EMs; (ii) Affordable prices; (iii) Sustainable

(i – iv): WHO Framework Elements: (i) Rational selection a financing; (iv) Reliable health and supply systems.

The WHO Framework Convention on Tobacco database, 7 of the 13 CARICOM countries were Control's report on the global tobacco epidemic noted as having tobacco cessation therapies 2021 Web Annex VI: Global Tobacco Control available in pharmacies, 6 reported smoking Policy Data provided an overview of the cessation support was available, and 5 had availability of nicotine replacement therapy included NRT in the national essential medicines and availability of smoking cessation support lists – Table 4.³⁶ in various health settings by country. In the

Table 4: Programs to facilitate access to medicines (including NCD medicines) in selected Countries

Country	NCD Medicine Access Program Description	NRT in Pharmacies
Antigua and Barbuda	Universal access in public sector Medical Benefits Scheme	No
Bahamas	Universal access in public sector National Prescription Drug Plan	Yes
Barbados	Special Benefit Service of Barbados Free essential NCD medicines via Barbados Drug Service in public and private facilities / pharmacies.	
Belize	Universal access in public sector	No
Dominica	Universal access in public sector	No
Grenada	Universal access in public sector	No
Guyana	Universal access in public sector	Yes
Jamaica	Jamaica Drugs for the Elderly Programme (JADEP) National Health Fund (NHF) Government of Jamaica (GOJ) Card	Yes (on prescription)
St Kitts and Nevis	Universal access in public sector	Yes
St Lucia	Universal access in public sector	Not reported
St Vincent and the Grenadines	Universal access in public sector	No
Suriname	Universal access in public sector	Yes
Trinidad and Tobago	Universal access in public sector Chronic Disease Assistance Programme	Yes

Although most countries under study do not for storage and distribution, and Acts related have a current medicines policy, and the to medicines registration) - Table 5. This poses National Strategic Action Plans for NCDs a challenge whereby policies and procedures generally do not specify policies for access to for the regulation of pharmaceuticals are not treatments for tobacco cessation or harmful streamlined, and may result in duplication use of alcohol, all the countries have legislation of work, inefficiencies, gaps in regulatory for pharmaceuticals, which appear in different oversight, and omissions during revisions and/ arms of governance (e.g. public procurement or during strategic development. policies, pharmacy practice regulation, policies

Country	General Health	Medicines Specific	Other Sectors
Antigua and Barbuda	Public Health Act - 1957	Antibiotics and Therapeutic Substances Act, 1951; Medical Act, 1938 Pharmacy Act, 1995 Misuse of Drugs Act, 1974	
Bahamas	Health Services Act- 2002	Pharmacy Act- 2009 Pharmacy Regulations 2010 Dangerous Drugs (Dispensing of Narcotics) - Rules Dangerous Drugs Act - Chapter 228 Precursor Chemicals - Chapter 228A Penicillin Act - Chapter 229	Tariff Act Industrial Property Act
Barbados	Health Services Act of Barbados (Cap. 44) - 1969	Drug Services Act – 1980 Pharmacy Act Pharmacy (Compounding and dispensing of drugs and poisons) (Amendment) Regulations,1993	Customs and Tariff Act, Section 19 VAT Act
Belize	Public Health Act, Chapter 40, 2011	The Chemists and Druggists Act, Chapter 311, 1940, The Antibiotics Act, Chapter 33, 1948, The Food and Drugs Act, Chapter 291, 1953, The Misuse of Drugs Act, Chapter 103, 1990, and Subsidiary Laws	

Key: NRT – *nicotine replacement therapy*

Table 5: Main Legislation for Public Health Services and Pharmaceuticals in selected Countries

Country	General Health	Medicines Specific	Other Sectors
Dominica	Hospitals and Health Care Facilities Act, 2002	Medical Act of 1938 Dangerous Drugs Act of 1938 Pharmacist Profession Bill, 2004	Environmental Health Services Act, 1997
Grenada	Public Health Act, 1990	Pharmacy Act (Cap 241) of 1987, Medical Products (Regulations) Act, 1995, Drug Abuse (Prevention and Control) Act, 1992, Food and Drugs Law, 1986 Antibiotics Act	
Guyana	Ministry of Health Act (2005) Regional Health Authorities Act (2005)	Antibiotics Act, 1952; revised 1998; Pharmacy and Poisons Ordinance Act of 1956, Food and Drugs Act, 1971, revised in 1998, Narcotics Drugs and Psychotropic Substances (Control) Act, 1988 Pharmacy Practitioners Act of 2003	
Jamaica	National Health Services Act, 1997	Pharmacy Act and Regulations, 1975 Food and Drugs Act and Regulations Dangerous Drugs Act, and Regulations, 1948 Precursor Chemicals Act	
St Kitts and Nevis	Public Health Act Cap. 9.21	Medical Act of 1938 Drug (Prevention and Misuse) Act of 1986. Pharmacy Bill, 2000	

4.1.2 Financing

Health financing is a core function of health was 3% of the GDP (Table 6), which is below systems that can enable progress towards the recommended proportion of 6%.² The PHE universal health. The Caribbean region has low of Suriname was closest to the recommended public health expenditure (PHE) levels, where proportion at 5.3%.³⁷ the average PHE in CARICOM countries for 2018

Table 6: Domestic General Government Health Expenditure (% of GDP)

Country/Region	2000	2010	2011	2012	2013	2014	2015	2016	2017	2018
Latin America & Caribbean	3.08	3.63	3.66	3.65	3.78	3.81	4.20	4.10	4.21	
Antigua and Barbuda	2.52	2.95	2.78	2.82	3.02	2.90	2.61	2.14	2.13	2.9
Bahamas, The	1.92	2.80	2.87	2.84	2.83	2.61	2.87	3.02	2.53	3.1
Guyana	2.07	1.69	1.88	2.05	2.40	2.67	2.25	3.24	2.96	3.7
Jamaica	3.19	3.04	3.00	2.85	3.23	3.04	3.58	3.67	3.87	2.9
St. Lucia	1.87	1.92	1.97	2.27	2.33	2.17	2.19	2.17	2.23	2.1
Suriname	3.04	2.13	1.92	1.88	2.02	2.01	3.39	3.89	3.65	5.3
Barbados	2.76	3.62	3.35	4.30	3.81	3.29	3.19	3.14	3.00	2.9
Grenada	1.78	2.54	2.62	2.48	2.34	2.15	1.95	2.16	2.03	1.7
Belize	2.09	3.83	3.64	3.50	3.75	3.32	4.10	4.09	3.84	3.9
St. Kitts and Nevis	1.96	1.99	1.95	2.03	1.98	2.02	1.98	2.30	2.35	2.5
St. Vincent and the Grenadines	3.00	2.70	2.53	2.91	2.84	2.68	2.63	2.73	2.89	3.1
Dominica	3.28	3.28	3.15	3.40	3.21	3.32	3.57	3.41	3.82	4.3
Trinidad and Tobago	1.57	2.45	2.35	2.38	2.60	2.63	3.11	3.53	3.71	3.4
CARICOM average	2.39	2.69	2.62	2.75	2.80	2.68	2.88	3.04	3.00	3.2

Data from database: World Development Indicators³⁸

Last Updated: 09/24/2021

average for 2018 was 35% of total health

Table 7: Out-of-pocket expenditure (% of current health expenditure)

Country/Region	2000	2010	2011	2012	2013	2014	2015	2016	2017	2018
Latin America & Caribbean	38.4	31.8	30.4	30.0	29.1	28.7	28.3	28.7	28.2	30.1
Antigua and Barbuda	23.3	25.5	26.4	28.1	27.0	27.8	26.0	31.7	35.0	29.5
Bahamas, The	21.2	28.4	28.4	28.7	28.6	30.1	26.9	27.7	31.0	27.2
Guyana	39.4	38.1	42.2	38.6	41.6	44.4	45.2	45.2	46.3	46.5
Jamaica	35.1	23.9	24.5	25.3	24.3	24.0	23.1	23.5	24.2	23.2
St. Lucia	33.5	35.9	36.8	35.3	35.0	33.9	30.8	29.1	31.0	32.4
Suriname	59.7	49.5	50.7	53.7	54.6	50.3	52.5	49.2	52.4	54.5
Barbados	42.8	36.7	38.3	39.7	38.6	37.2	39.7	29.9	32.5	32.3
Grenada	29.0	24.8	23.4	21.3	18.4	21.1	18.9	17.9	17.2	17.1
Belize	52.6	55.2	55.5	55.4	56.5	52.9	54.3	48.2	47.8	48.5
St. Kitts and Nevis	27.3	32.2	32.7	31.9	33.0	33.8	33.3	33.2	31.2	28.4
St. Vincent and the Grenadines	57.3	46.6	44.8	44.7	43.2	42.8	41.3	41.7	39.8	43.9
Dominica	15.4	23.6	27.2	28.3	27.9	29.0	22.0	21.8	26.4	19.9
Trinidad and Tobago	58.9	54.8	55.6	51.7	52.1	47.6	47.0	49.1	44.8	46.3
CARICOM average	38.1	36.6	37.4	37.1	37.0	36.5	35.5	34.5	35.3	34.6

Data from database: <u>World Development Indicators</u>³⁸ Last Updated: 09/24/2021

In contrast, out of pocket expenditure is very expenditure, it can represent over 50% of total high in several countries. Although the regional health expenditure in some countries – Table 7.

products, such as medicines, is essential to understand pharmaceutical spending considering that health products represent a in the CARICOM countries. Updated and high proportion of health spending.^{39,40} According to WHO, pharmaceutical expenditure⁴¹ is the third largest functional expenditure item of health spending after inpatient and outpatient care.42 Hence, some of the main financing challenges faced by health systems worldwide countries published a National Health Accounts are: inadequate financing of health products, payment of unnecessary high prices for health products, and ineffective use of policies for can be generalized for CARICOM. generic and biosimilar medicines.

Sufficient and adequate financing of health Unfortunately, further information is needed comparable information on public and private pharmaceutical expenditure for the region was not available in the databases of the main international organizations (e.g. WHO, World Bank, OECD). However, since 2010 at least 5 reports which provide some information about pharmaceutical expenditure, but no conclusions

Table 8: Pharmaceutical spending according to most recent National Health Accounts Reports

	Barbados 2012-2013	Dominica 2010 - 2011	Guyana 2016	St. Kitts and Nevis 2011	Trinidad and Tobago 2015
NCD expenditure	23% of total health spending was spent on NCDs.	Information not available	34% of total health expenditure was spent on NCD's.	Information not available	21% of total health expenditure was on NCDs"
Total Heath spending by function or by type of service	The purchase of drugs and medical goods represented 11% of recurring health spending by type of service	1% of total health expenditure by provider was spent at pharmacies	Pharmaceuticals accounted for 5% of total health spending by function.	9% of total health expenditure was spent at pharmacies.	Pharmaceuticals represented 27% of recurrent health spending by inputs. It was the second largest expenditure after compensation of employees, 35%.
Out of pocket expenditure (OOP)	Pharmacies accounted for 16% of household 00P.	Pharmacies accounted for 2% of household 00P.	Pharmacies accounted for 59% of household OOP.	Pharmacies accounted for 15% of household 00P.	Pharmacies accounted for 49% of household 00P.

Sources:

Barbados https://www.hfaproject.org/barbados-2012-13-health-accounts-report/

Dominica https://www.hfgproject.org/dominica-2010-2011-national-health-accounts-hiv-subaccounts/

Guyana https://www.hfgproject.org/guyana-health-accounts-2016/

St. Kitts and Nevis. https://www.hfgproject.org/saint-kitts-nevis-2011-national-health-accounts-hiv-subaccounts/ Trinidad and Tobago: http://www.health.gov.tt/images cms/2019/20190325-HAR/Trinidad Tobago Health Accounts Main Rpt.pdf

Several CARICOM countries have implemented programmes or arrangements to dispense NCD medicines at no cost or at reduced costs to patients. However, as noted in the interviews conducted with civil society, non-beneficiaries such as migrants, visitors, and regional workers are unable to access medicines provided under special NCD programmes or benefit schemes. An in-depth study on the effectiveness of these type of programmes in facilitating access to NCD medicines by reducing financial barriers would be of interest to inform policy.

4.1.3 Human Resources

Itiswidelyrecognizedthatforcountriestoachieve their health goals, sufficient, appropriately gualified personnel are fundamental to provide the required services to meet the health needs of the population.⁴ However, WHO estimates that there will be a global shortage of 18 million health workers by 2030 and that inequities will persist regarding their availability, distribution and guality.43

Small developing states, like Caribbean countries, are particularly vulnerable to this situation. The region is characterized for having an insufficient supply of trained health workers. This is particularly true for nurses with nursing vacancy rates averaging 40%.44

One of the main reasons behind this shortage is the migration of nurses to more developed observed within the region, for example in 2018 Trinidad and Tobago reported having 6.64 countries, such as Canada, the United States of America, and the United Kingdom.⁴⁵ In a pharmacists per 10 000 population, whereas study conducted by the Pan American Health Guyana reported a density of 0.09 per 10 000. Organization (PAHO 2019) in 26 countries of the The decision makers interviewed during this Caribbean, of the 573 health workers surveyed assessment noted that the lack of pharmacists (39% nurses), 341 or 59.5% indicated that they at the point of dispensing, when needed, is one would migrate if given the opportunity. The of the challenges faced by the health system. top five reasons that health care professionals It is also important to highlight that the from the Caribbean would migrate were: better qualifications to practice pharmacy vary working or employment conditions (45%), significantly across the region according to better financial or economic opportunities local capacity for education and training. For (25%), availability of education or training

opportunities (15%), too much bureaucracy in local systems (8%), and others (7%).⁴⁶

Pharmacists are key health care professionals required to ensure access to medicines and vaccines. Although their functions have evolved throughout the years, and they vary across countries, pharmacists' main role remains the dispensing of medications. With the expanding roles, pharmacists increasingly provide direct (pharmaceutical) care and counselling to patients, and support the procurement and supply of medicines.⁴⁷

CARICOM profiles in the WHO Global Health Observatory indicate that over 65% of its Member States have less than 5 pharmacists per 10 000 population and 36% have less than 1.41 Distribution of this workforce generally correlates with population and economic level as shown by Monaco, Belgium, Finland and Japan, which have the highest pharmacist densities per 10 000 (with 26.3, 19.4, 19.2 and 18.9 respectively), in comparison with Niger, Uganda, Burundi and Madagascar, which have the lowest reported densities (less than 0.02).48

The availability of updated information of pharmacist-population density in the Caribbean varies significantly. Of the 12 CARICOM countries that reported this information to WHO, only 6 had information updated within the past 5 years - Table 9. Unequal distribution is also Table 9: Pharmacists Density in CARICOM countries (last available year)

Country	Year	Pharmacists per 10,000
Antigua and Barbuda	2007	1.79
Bahamas	2011	5.62
Barbados	2005	9.08
Belize	2017	6.76
Dominica	2001	2.58
Grenada	2016	6.8
Guyana	2018	0.09
Jamaica	2016	0.22
Saint Lucia	2017	4.37
St Vincent and the Grenadines	2004	3.32
Suriname	2019	0.36
Trinidad and Tobago	2018	6.64

Source: WHO Global Health Observatory⁴⁹

example, to register as a pharmacist in Jamaica or in Trinidad and Tobago, a Bachelor's degree in Pharmacy is required. Registered pharmacists who do not have the degree remain registered. but new pharmacists entering the profession are required to have completed the undergraduate degree. In comparison, in Grenada, an associate degree or certificate is acceptable to register as a pharmacist. It is noted that in Jamaica, Guyana, and Trinidad and Tobago, there are tertiary education institutions that offer pharmacy degrees, whereby pharmacy certification, or associate degrees are offered in other countries.

4.1.4 Information Systems

Timely, accurate and guality information is essential for decision-making, policy monitoring and implementation, and for establishing accountability. Consequently, systems that provide such information have been considered as fundamental to all health systems. Comprehensive, up-to-date information systems are key when considering access to NCD medicines because these may provide insight on trends including NCD incidence and their risk factors, national expenditure on health products, availability of medicines in health facilities, prescribing patterns, utilization by patients, and the safety and quality of medicines (pharmacovigilance).

CARICOM countries have a long history of working on health information systems and have identified their development as a priority in their efforts to advance towards universal access to health and universal health coverage.^{50,51} Health information systems of CARICOM countries are at varying stages of maturity and in the governments' efforts to move from predominantly manual to automated systems. Ultimately, the region faces common challenges and goals regarding information systems for health and it is why the Caribbean Council for Human and Social Development (COHSOD) and the OECS Council of Ministers have endorsed a road map of actions aimed at having regional capacity enhanced to generate and use quality data and evidence for more effective policy, programs and monitoring.⁵²

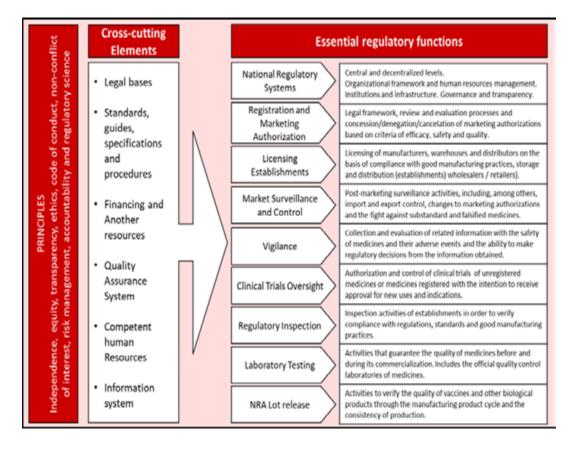
Regarding access to medicines, decisions makers that were interviewed identified the lack of integrated health information systems as one of the main challenges they are facing. Health data related to access to medicines is processed in a variety of formats and is not readily shared across units. Hence the generation of information requires intensive

work because it largely relies on data from may not have strong regulatory controls. surveys, census, and other ad hoc studies. Regulatory systems also help with affordability through their analysis of generic medicines for Information products, such as electronic lists of authorization. If they are operating efficiently, registered medicines or procurement lists, are they make decisions on accountable and generated, but not routinely, and are not always transparent timelines, ensuring access for available for the general population. patients.

4.2 Ensuring Quality, Safety and

PAHO and WHO have done much work in this **Efficacy of Health Products** area, including developing a set of recommended regulatory functions that countries should 4.2.1 Regulatory System Strengthening aim to have. The functional areas include legal and organizational frameworks, market Regulatory systems are a foundational, but authorization, licensing of establishments, often neglected, part of the health system. market surveillance and vigilance, inspections, They ensure that medicines and other health laboratory testing, clinical trials regulation, and technologies are safe, guality, and effective for vaccine lot release. These are underpinned by patients and are becoming even more important cross cutting principles such as independence, with the globalization of manufacturing and flexibility, transparency, and risk management distribution of health products in places that - Figure 2.53

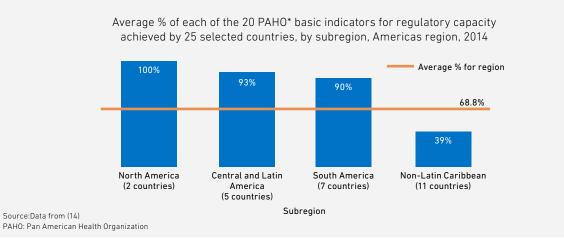
Figure 2: Elements and functions of Regulatory Systems



These functions are resource intensive, and this poses a challenge for small Caribbean non-Latin Caribbean achieved 39% compared countries. PAHO's data show that the Caribbean has the lowest regulatory capacity in the region of the Americas. On 20 basic indicators of regulatory capacity, such as existing policies

and programs for key regulatory functions, the to 90% or more by all the other sub-regions of the Americas.⁵⁴ This highlights a profound disparity in access to guality, safe, and effective medicines, including NCD medicines.

Figure 3: Regulatory Capacity in CARICOM countries



Additional PAHO data show a strong correlation between population size and regulatory capacity. and between absolute gross domestic product (GDP) and regulatory capacity. The smaller the population and/or GDP, the lower the regulatory capacity.⁵³ This means there are fewer human resources and financial resources to support and sustain regulatory agencies.

Several countries in the Caribbean do not have regulatory authorities, including those of the OECS. Others have regulatory authorities that do not perform the various recommended functions, and/or do not perform them efficiently or fully. For example, there are only 6 countries that require regulatory evaluation of a product for sale or use in the country prior to market authorization (Belize, Guyana, Haiti, Jamaica, Suriname, and Trinidad and Tobago). Furthermore, these market authorization processes are prone to backlogs in assessment of products and long review timelines that compromise access to products by patients

and create an uncertain business environment for companies.

Another detractor is the size of the market. Companies are less attracted to selling their products in places where there are lower sales volumes, and where there are fewer incentives to comply with stronger regulation, when applied. This also affects the fees that companies are willing to pay for regulatory review. These are called "user fees" and are typically a major way that regulatory authorities finance their activities. However, fees in the Caribbean are some of the lowest in the world, averaging anywhere from USD\$50-150 per product application compared to millions of dollars charged by the United States of America, based on the type of product. Caribbean regulatory systems cannot sustain basic operations or develop adequate solutions with such low fees.

All these challenges create a situation where Caribbean governments are particularly vulnerable to quality problems with their medicines, including NCD medicines. For Policy, which calls for a regional approach to example, if there is less active ingredient or no regulation, and they appointed a committee active ingredient (which are common guality of pharmaceutical policy advisors (called TECHPHARM) in 2014.³⁰ This committee has problems) in products used in high volumes for public or private health programs, it could been operational since 2017. The CRS provides have deleterious effects for population health. recommendations of quality-assured essential medicines for market authorization and WHO's research has suggested that about 10% of the products on markets of low- and procurement in CARICOM. The product must middle-income countries are substandard already be approved in a PAHO-designated or falsified.⁵⁵ However, these numbers are reference regulatory authority (same list used likely higher when there is limited regulatory by the PAHO Strategic Fund), and the CRS verifies capacity. The literature also reports practices the product is the same. This adds efficiency where manufacturers send products overseas to the process including by using fewer human under "for export only" policies. These products resources and faster timelines to process are not regulated to the same degree as those because the product has already been approved authorized for the domestic market.⁵⁶ Even by a larger and more resourced authority.⁵⁸ products from well-known companies may be The entire process is electronic and once the made to different standards depending on the product is favourably verified, the technical intended destination. For example, a product information is transferred to focal points in intended for a less lucrative or under-regulated each CARICOM government to facilitate their decision-making. The CRS also helps mitigate destination may include a cheaper active pharmaceutical ingredient, different set of small market challenges. It offers a single portal of entry to the 17 million persons in CARICOM, excipients, and/or be manufactured in a lower cost manufacturing plant than one going to a using a single set of standards, known timelines highly attractive and regulated country in North and published results. This offers an attractive America or Western Europe. business climate to companies. Products must be included on the WHO EML, of which about PAHO has recommended an approach to 95% are available in generic form, or approved regulatory system strengthening in the by TECHPHARM, and the categories include Caribbean that focuses on the most critical pharmaceuticals, vaccines, and biotherapeutic functions of market authorization and postproducts, including "biosimilars".

market surveillance, and that uses strategies like working together, pooling of resources, sharing information, and adopting efficiencies to do more with less.⁵⁷ This has resulted in a major initiative between PAHO, CARICOM, CARPHA, and others, with funding from the Bill and Melinda Gates Foundation, to establish a sub-regional system for regulation of medicines and other health technologies called the "Caribbean Regulatory System" (CRS), managed as a regulatory unit in CARPHA.

CARICOM Ministers of Health endorsed the CRS as part of the Caribbean Pharmaceutical

There have been 195 medical products recommended by the CRS to CARICOM governments up to the end of September 2021, including 75 NCD medicines (38%). Of these, 52% are immunomodulators and/or antineoplastics for cancer (39 products) – Figure 4.59 Most of these NCD medicines are generics, which creates opportunities for speedy access to more affordable, quality-assured medicines, particularly for cancer, as the CRS' reports summarise the quality, safety and efficacy characteristics of these products.

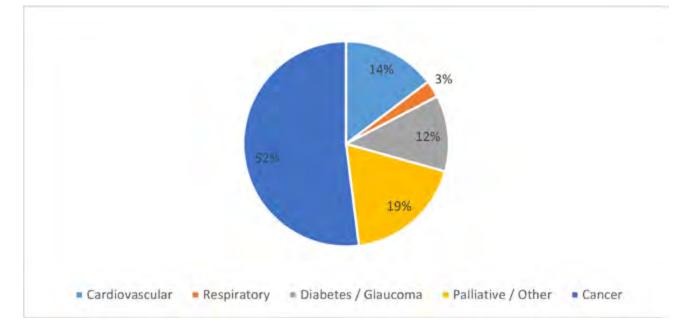


Figure 4: NCD Medicine Groups Recommended by CARPHA-CRS (2017-Sept. 2021)

Although the selection of medicines submitted for review by companies to the CRS is driven by the CRS' recommended products, or expedited business or marketing objectives, there may be opportunities for additional efforts to increase the number of NCD products, including in other areas such as cardiovascular and endocrine agents. For example, manufacturers with reference authority approved products in critical areas may be invited to submit products to the CRS. However, national authorities would also need to utilize the recommendations in procurement decisions for this to be viable and sustainable.

Uptake of the CRS' recommendations by CARICOM may be improved. Guyana has been a leading adopter of this initiative and automatically recognizes CRS recommended products for marketing authorization within 1-2 weeks of CRS recommendation, and without additional requests for technical information. Other countries such as Jamaica have also granted market authorization to CRS recommended products, but the process still requires additional information. To date,

procurers have not fully availed themselves of access by granting priority for procurement, or by taking other policy actions to favour these products in selection processes.

4.2.2 Assessment of the quality, safety, and efficacy/performance of health products through pregualification

WHO evaluates the quality, safety and efficacy of certain classes of pharmaceuticals for procurement by United Nations (UN) agencies, and for accelerated registration by national regulatory authorities. Medicines for HIV, tuberculosis, malaria, reproductive health, and biologics including vaccines, and more recently biosimilars including insulin are included. This program, named the "WHO Pregualification Programme"60 focuses on manufacturers of medicines that may not otherwise have been reviewed by reference regulatory authorities, including generic versions of these products. WHO encourages the governments to utilize pregualified medicines to accelerate market authorization and procurement. This will the CRS submits reports to global databases facilitate decision-making through sharing of at the WHO for pharmacovigilance and for confidential documentation (e.g. inspection and substandard / falsified products for further assessment reports) with regulators via the analysis and follow up. This step helps to WHO Collaborative Procedure for Accelerated increase the awareness of safety and quality Registration and a secured platform.⁶⁰ issues related to medicines both globally and regionally. It also allows regulators in Although there are no national regulatory the Caribbean to identify common trends in authorities in the Caribbean that actively medicines with similar safety or quality reports. participate in this program, the CARPHA/ enabling greater vigilance of the local market.

CRS engages in the Collaborative Procedure for accelerated registration of pregualified Medicines with suspected quality issues may be submitted to CARPHA's Medicines Quality medicines and vaccines, on behalf of CARICOM Member States. Since initiating this procedure Control and Surveillance Department (MQCSD), in 2017, the CRS has recommended 31 WHO formerly the CARPHA Drug Testing Laboratory, pregualified medicines, mostly for HIV.59 for quality control testing on behalf of Member States.⁶² The administration of medicines Although the WHO prequalification programme does not include treatments for all NCDs. quality testing laboratories is particularly the inclusion of insulin and two biosimilars resource-intensive, and as a result, many (trastuzumab and rituximab), provides another Caribbean countries do not have functional pathway for access to affordable, gualitylaboratories. In July 2018, the MQCSD launched assured medicines that are usually expensive. a risk-based post-market surveillance program to collaborate with Member States to identify 4.2.3 Market surveillance of quality, potentially problematic products for testing.

safety, and efficacy

During the pilot of the PMS programme from The CRS also performs another core regulatory July 2018 to November 2019, the MQCSD tested function to support CARICOM Member 50 samples of 19 medicines (mostly oral dosage forms), of which 39 samples of 13 NCD States: pharmacovigilance and post-market surveillance through a regional network medicines were tested: 9 cardiovascular, 2 anticalled "VigiCarib". This is a function that is diabetic, and 2 for mood disorders. In January 2020 the programme expanded to invite all particularly limited in the individual countries Member States to submit medicines for testing. of CARICOM, with some governments using paper-based reporting systems, and few Testing in 2020 under the PMS programme involved 17 samples of metformin (2nd guarter), with clearly defined protocols or dedicated 19 samples of warfarin (3rd guarter), and 10 staffing to monitor, assess and/or implement samples of amoxicillin-clavulanic acid tablets regulatory actions against potentially harmful products in the market. VigiCarib provides (4th guarter). Ten of the 46 samples tested (21%) an electronic reporting system that receives failed to meet the international specifications. reports of suspected adverse drug reactions, Reports of the failed products were sent to the respective Member States for further review adverse events following immunization, and and regulatory action, where needed. 63-66 reports of substandard and/or falsified and/or unregistered (SF) medicines from governments, The respective Member States are encouraged providers, patients, and industry in the to report the finding to the CRS for entry into Caribbean, for analysis and recommendations the VigiCarib database and to WHO's GSMS for regarding regulatory action.⁶¹ When reguested,

substandard and/or falsified medical products, but this is not routinely done by all Member States. As an accredited drug quality testing laboratory, the MQCSD may be better utilised by countries, but it is currently limited in its scope of full compendial testing of oral and topical dosage forms with international testing methods (e.g. United States Pharmacopeia). Further, the lack of reporting of failed products to the regional mechanism under CRS reduces the ability of other countries with similar products to prioritize these products for riskbased monitoring and testing.

4.3 Improving Equitable Access

4.3.1 Evidence based selection and fair and affordable pricing

WHO recommends that all countries should have a national list of essential medicines. This is a list of carefully selected medicines that correspond to the priority health needs of a country, which may guide government procurement and prescribing.

Several of the countries covered in this study use a list of essential medicines (commonly

called a VEN list – vital, essential, necessary devotes a significant number of resources to medicines) or a drug formulary based on the developing its list and updates it every 2 years. WHO Model List of Essential Medicines. These However, information on the last time that local lists should ideally comprise of cost-effective lists were updated and if they are aligned with medicines that show favourable benefit-risk Standard Treatment Guidelines used in the ratios based on current evidence, and address country was varied. Table 10 identifies the most the needs of the majority of the population, recent editions reviewed in this report. thereby informing procurement for public Although national EMLs identify the agreed sector. Although the lists are based on the list of medicines based on national treatment WHO Model List of Essential Medicines, which guidelines, additional factors may influence is revised every two years, the national EMLs which ones are procured for a given period. As in the region are not revised as often. In WHO's a result, public sector procurement lists provide online database of national EMLs, compiled in a more current overview of NCD medicines 2019, the publication years of lists of CARICOM procured for use. Where a national procurement countries ranged from 2007 to 2014.67 WHO

Category (N)	Barbados PRL 18-20	Belize EML 09-11	Guyana EML 20-22	Jamaica PL 19-23	OECS-PPS PL 19-21	Suriname EML 2021	Trinidad and Tobago PL 20-21	Average Availability
	Count (%)	Count (%)	Count (%)	Count (%)	Count (%)	Count (%)	Count (%)	Avg (%)
Cancer (65)	12 (15.4)	10 (15.4)	36 (55.4)	44 (67.7)	18 (27.7)	32 (49.2)	52 (80.0)	29.1 (44.8)
CVD (33)	20 (60.6)	25 (75.8)	28 (84.8)	30 (90.9)	24 (72.7)	26 (78.8)	29 (87.9)	26.0 (78.8)
Diabetes (8)	4 (50.0)	4 (50.0)	5 (62.5)	6 (75.0)	5 (62.5)	5 (62.5)	4 (50.0)	4.7 (58.9)
Ment / Neuro (23)	15 (65.2)	19 (82.6)	16 (69.6)	18 (78.3)	17 (73.9)	14 (60.9)	18 (78.3)	16.7 (72.7)
NRT (1)	0	0	0 ¥	0 ¥	0	1 (100)	0 ¥	0.1 (14.3)
Palliative (39)	15 (38.5)	30 (76.9)	31 (79.5)	27 (69.2)	28 (71.8)	27 (69.2)	25 (64.1)	26.1 (67.0)
Respiratory (9)	7 (77.8)	5 (55.6)	6 (66.7)	8 (88.9)	7 (77.8)	6 (66.7)	8 (88.9)	6.7 (74.6)
Total Medicines (178)	73 (41.0)	93 (52.2)	122 (68.5)	132 (74.7)	99 (55.6)	111 (62.4)	136 (76.4)	109.6 (61.6)

Key: ¥ - List includes bupropion (counted in mental health medicines). EML – national list of essential medicines (or equivalent); N – number of medicines; NRT – nicotine replacement therapy; PL – procurement list; PPS – Pharmaceutical Procurement Services; PRL – price guide for procurement list; TTO – Trinidad and Tobago.

Table 10: National Essential Medicine Lists or Formularies

	Bahamas	Barbados	Belize	Guyana	Jamaica	OECS	Suriname	Trinidad and Tobago
EML	Essential Drug List	Barbados National Drug Formulary	Belize Drug Formulary and Therapeutics Manual	National Essential Medicine List	V.E.N. List of drugs, medical sundries, and raw materials	Regional Formulary Manual	National Medicines List (NGK)	V.E.N. list
Last Updated	UKN	2018	2009	2020	2016 UKN		2020 (est. 2012)	2010
Publicly Available	Yes	No (new list not public)	Yes	No	Yes (new list not public)	No	Yes	Yes
Mechanisms to Align the EML with STGS	UKN	No	Yes	Yes	Yes	Yes	UKN	Yes
Formal Committee for the Selection of Products	Bahamas National Drug Council	National Formulary Committee	National Formulary Committee	National Medicines Policy Committee	National Formulary Committee	OECS/PPS Technical Advisory Committee	National Medicines List Committee	National Drug Advisory Committee

Key: UKN - Unknown ; V.E.N. – Vital, Essential, Necessary

Sources:

A. WHO Pharmaceutical Country Profiles

B. Webpages of Ministries of Health, OECS-PPS

Table 11: Inclusion of HCC Essential NCD medicines in national procurement lists or national essential medicines list

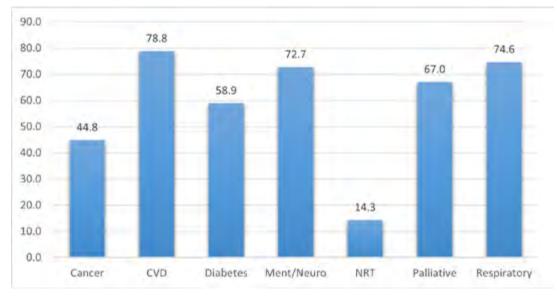
list could not be found for a country, the national EML was checked as an alternate source or proxy for inclusion of the listed essential NCD medicines. This was applied to Belize, Guyana and Suriname. Seven lists were reviewed: one regional procurement list for the OECS (6 CARICOM states), three national EMLs, and three national procurement lists – **Table 11**. The list found for the Bahamas was specific to the National Prescription Drug Plan for medicines provided in non-institutional settings. This list was not included in the table as it did not reflect procurement of medicines used in secondary and tertiary care settings, but the number of medicines found is presented in the country profile in Appendix 3.

Of the 178 essential medicines for NCDs defined by HCC, an average of 110 medicines (61.6%) were included on the various lists examined from the selected countries –**Table 11**. Percent availability by country ranged from 41% to 76%. Categories with greatest availability were (14%) – Figure 5. cancer, cardiovascular and palliative care.

As showed in Table 11, nicotine replacement therapy(NRT), which is used in the management of smoking cessation, was included in one national EML. However, three national procurement lists included bupropion, an antidepressant which may also be used in tobacco cessation. None of the medicines recommended for the treatment of the harmful use of alcohol by the APA were included in any of the national lists. However, magnesium sulphate, which is used in treatment of alcohol withdrawal was generally available on lists reviewed.

Just over 61% of the essential NCD medicines were identified among the reviewed medicines lists. When analysed by medicine category, over 70% of the HCC medicines for cardiovascular conditions (79%), respiratory disorders (75%), and mental / neurological conditions (73%) were included in the reviewed lists. The lowest available categories of medicines were for cancer (45%) and nicotine replacement therapy

Figure 5: Percent of Essential HCC medicines in national procurement lists or national essential medicines list according to medicine category



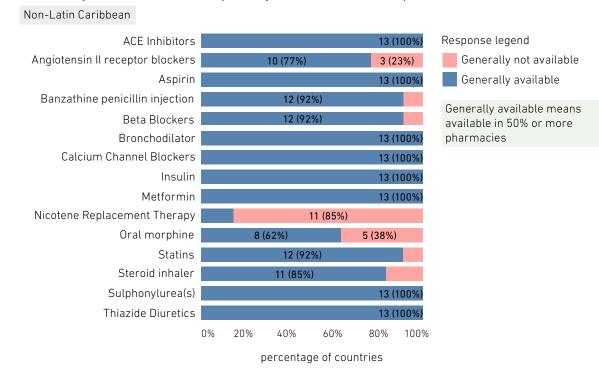
Key: CVD – cardiovascular, Ment/Neuro – mental health / neurological, NRT – nicotine replacement therapy

There are no published analyses of the prices documentation can be shared related to WHO's of NCD medicines in the Caribbean in the favourable review of these products. The CRS peer-reviewed literature, and there are few participates in the Collaborative Procedure data sources. Some procurers list the prices and can be an important intermediary in the of medicines that they purchase in terms of assessment of these products in the Caribbean. price per unit, but these are often calculated 4.3.2 Procurement and supply chain differently across jurisdictions, making it difficult to compare. What is known from these management data sets, such as the OECS/PPS prices per unit. Procurement and supply chain management is that generic versions of NCD medicines such are critical topics in access to medicines, and as for diabetes or for high blood pressure are especially so in the Caribbean because most relatively inexpensive because many of these countries rely on national, guasi-national, or products have been around for a long time and sub-regional procurement for their public there are generic versions available.

sectors. Some of the macro level factors that Cancer medicines can be much more expensive governments must wrestle with include small because in some cases they are innovator volumes of sale (and decreased incentives for products and represent the latest technologies, industry to supply- affecting availability and such as monoclonal antibodies, which are called price), as well as quality. Various strategies "biotherapeutic products" because they are have been adopted to manage these problems, produced from biological sources rather than and for example, the OECS developed a pooled synthesized chemicals. These more expensive procurement mechanism in 1986. It is known products may put strains on pharmaceutical as the Pharmaceutical Procurement Service budgets and it may be why there is less (PPS) and pools smaller markets together for a procurement of them. In response, there has total of 500 000 to achieve economies of scale been an increasing push for countries to acquire that, for example, help it realize cost savings of generic versions of biotherapeutic products, approximately USD\$4 million annually.⁶⁹ called "biosimilars", because they can be much In the Country Capacity Survey 2019, PAHO less expensive. For example, the global average studied the availability of NCD medicines in cost of trastuzumab, a biotherapeutic that treats the non-Latin Caribbean shown in Figure 6. breast cancer, is USD\$20,000 while the generic In the CCS, all countries reported general version is generally about 65% cheaper.⁶⁸

availability (in more than 50% of pharmacies) However, these biosimilars are more of ACE inhibitors, aspirin, bronchodilators, complicated to regulate that pharmaceutical calcium channel blockers, insulin, metformin, generics and being able to ensure quality sulphonylureas and thiazide diuretics. Other versions is critical. Even the most well-resourced medicines that were reported as generally regulatory systems have been challenged available in more than 75% of the countries were by the regulation of biosimilars. Caribbean angiotensin II receptor blockers, benzathine governments, with their limited regulatory penicillin injection, beta blockers, statins and capacity, will need to develop strategies for steroid inhalers. In alignment with an earlier quality assurance. WHO has launched a pilot observation, nicotine replacement therapies, program to pregualify selected biosimilar which are excluded from public sector products - trastuzumab and rituximab procurement lists of the countries under study, (primarily for non-Hodgkin's lymphoma and were reported as generally not available.⁷⁰ chronic lymphocytic leukemia) through its The CCS did not include medicines for mental Collaborative Procedure so that key confidential disorders, or palliative care.

Figure 6: PAHO Country Capacity Survey 2019: Disease Management and Availability of NCD Medicines in Non-Latin Caribbean countries



Availability of medicinces in the primary care facilities of the public sector

Although stakeholders interviewed for this report confirm that many of these medicines are available, they also reported that stock outs occasionally happen. They raised a variety of commonplace factors that lead to stock outs, including: limited financing, poor demand monitoring and forecasting, lack of inventory management, late payment to suppliers, lack of strict enforcement of drug policies (pricing), unregulated distribution channels, inefficient selection processes, irrational prescribing, lack of networked information systems, and limited human resources capacity. It was noted that Caribbean countries have long recognized the need to strengthen supply chain management across the region, hence in 2004 a Regional Network of Pharmaceutical Procurement and Supply Management Authorities (CARIPROSUM) was created with the mission "To promote the continuous availability of affordable pharmaceutical products meeting standards in

safety, quality and efficacy, for Caribbean public health program and services, through intercountry and regional cooperation".⁷¹

Another challenge is quality. Ideally, the National Regulatory Authority should authorize all products for legal sale in the market before they can be procured. However, many countries in the Caribbean do not have their own regulatory authorities to ensure guality, safety, and efficacy of products, and some procurers fill that role for the public sector (e.g. in the OECS). Often, procurers use a system that pregualifies manufacturers and suppliers for tender. Once pregualified, any of their catalogued products may be supplied if selected for purchase, thereby by-passing the assessment of the quality, safety or efficacy of each medicine. Hence, procurers using this approach are unable to assure the quality of the medicines procured. Typically, quality

related documentation such as certificates of Fund addresses guality by requiring that all good manufacturing practices, or certificates products are the same versions approved in of pharmaceutical product are not requested one of PAHO's designated reference authorities. at the product level, despite this being a good Therefore, manufacturers must be willing to practice. Procurers are not generally set up or offer the same version to PAHO, whose internal staffed to review this information as regulators technical team verifies the product is the same are, and furthermore, WHO recommends that (note: the CARPHA/CRS approach is modelled procurement should be separated from quality, after PAHO's Strategic Fund). efficacy, and safety reviews because of the All PAHO Member States can procure through

All PAHO Member States can procure through the Fund if they have a signed an agreement with PAHO. As of July 2020, 33 countries of the Americas had agreements with the Strategic Fund, including 16 English speaking Caribbean countries - **Table 12**. However, since 2016 only 7 of the 16 country represents over 80% of all purchases done by the Caribbean through the Strategic Fund.

Table 12: Participation in OECS-PPS and Strategic Fund, July 2020

Country	OECS-PPS	PAHO Strategic Fund
Anguilla	Yes	
Antigua and Barbuda	Yes	
Bahamas		Yes
Barbados		Yes
Belize		Yes
Bermuda		Yes
British Virgin Islands	Yes	Yes
Dominica	Yes	
Grenada	Yes	Yes
Guyana		Yes
Haiti		Yes
Jamaica		Yes
Montserrat	Yes	Yes
St. Kitts and Nevis	Yes	Yes
St. Lucia	Yes	Yes
St. Vincent and the Grenadines	Yes	Yes
Suriname		Yes
Turks and Caicos		Yes
Trinidad and Tobago		Yes

The Fund initially focused on medicines for HIV, tuberculosis (TB), and malaria, but has theoretically expanded to include NCD medicines. In 2020, the product portfolio of the Strategic Fund had 410 pharmaceutical and non-pharmaceutical items, including products for COVID-19. Over USD\$235 million was spent to source essential medicines and diagnostic kits from gualified suppliers.⁷² When compared with the list of indicator medicines created for this study, the PAHO Strategic Fund List 2019 included 81 of the indicator medicines (45.5%).⁷³

Despite the availability of these mechanisms for pooled procurement, in the interviews with decision makers the "limited buying power of individual countries and local manufacturers" was noted as a challenge. Hence a study on their effective use could provide valuable information for decision making.

4.3.3 Application and management of intellectual property to contribute to innovation and promote public health

Research and development are needed to improve access to medicines. Intellectual property rights have been recognized as an important incentive for the research, development and diffusion of new and improved medicines and health technologies.⁷⁴

New products can meaningfully contribute to improve the health of people. For example, in 2013 a new class of oral medicines, known as direct-acting antivirals (DAAs), entered the market for the treatment of hepatitis C virus infection (HCV). This treatment revolutionized HCV treatment because DAAs proved to have a 95% cure rate and fewer side effects.⁷⁵

When a new medicine is introduced in the market, it is common that it is launched under a patent and that it has a high price until this patent expires. For example, when sofosbuvir, which is one of the new DAA treatment for HCV.

was introduced in the United States under the brand name Sovaldi™ it was done at a price of USD\$84,000 per person taking the standard 12-week treatment.⁶⁰ While the benefits of this treatment are undeniable, its cost puts it out of the reach of most people and health systems across the world.

Cancer treatment medicines are also an excellent example of this situation of elevated costs of new medicines. In 2013 a group of experts in chronic myeloid leukaemia (CML) pointed out that the three targeted therapies that the United States' Food & Drug Administration approved in 2012 for CML were priced above USD\$100,000 per year.⁷⁶ The 22nd WHO EML of 2021 also includes several high-cost medicines for cancer such as imatinib, rituximab and trastuzumab.

Tensions between the defenders of intellectual property rights of medicines (patents) and of a public health perspective that promotes access to affordable medicines has been one of the most debated topics in recent years. A middle ground in this debate supports the idea that if intellectual property rights are handled with a public health perspective, innovative medicines should be patented only under strict standards that account for their novelty, inventive step and industrial applicability to prevent the inappropriate granting or extension of market exclusivities.77,78

The patent versus access to affordable medicines exceeds the jurisdiction of national borders. With increasing international trade and interconnectedness. in the 1990s countries sought to harmonize the standards for protection of intellectual property rights, including patents, through the Agreement on Trade-Related aspects of Intellectual Property Rights (TRIPS). The negotiation of the TRIPS agreement was complex, especially regarding to medicines since many low- and middleincome countries feared that it could hamper Table 13: TRIPS flexibilities access to essential medicines.⁷⁹

In 2001 members of the World Tra Organization signed the DOHA Declarat on TRIPS and Public Health. This Declarat recognized the effects that patents have new medicine development and on prices a affirms that "the TRIPS Agreement does and should not prevent Members from tak measures to protect public health".80 -Declaration also outlines measures, known TRIPS flexibilities, that WTO members can u to ensure access to medicines.

Recognising the challenge of ensuring acce to affordable medicines, ministers of hea of CARICOM established in 2003 a Techni Advisory Group (TAG) on Trade-Relat Intellectual Property Rights (TRIPS). The T was mandated to assess the situation of d regulator and registration systems, and of patent and related issues.

the CARIFORUMEC Economic Partnership Agreement and others have bilateral trade In 2009 CARICOM published its regional agreements with the United States of America assessment of patent and related issues and that have some aspects that go beyond the access to medicines across 16 countries. One minimum required by TRIPS and could have an of the main conclusions of this study was that adverse impact on access to medicines. all the countries had patent acts but seven of them were considered obsolete and had to be The 2013 Caribbean Pharmaceutical Policy replaced.⁸¹ The 2009 study also stated that adopted by CARICOM member states established the inclusion of TRIPS flexibilities was uneven the development of a sub-regional mechanism across the region. This situation was also seen in to strengthen patent examination systems with 2012 in a PAHO report that showed that out of 11 a "pro-public health" approach and to support countries⁸² under study, none had incorporated the countries' efforts to promote public health the Bolar exception in their national legislation, and access to medicines, as one of its objectives 6 had included compulsory licencing, and three towards promoting access to medicines. considered parallel importing provisions.⁸³ This was done in order to take advantage of TRIPS flexibilities in conformity with the Doha Since TRIPS came into force and after the Doha declaration.³⁰ A study on the current state declaration, several bilateral and regional trade of the patent acts and the implementation of agreements have tended to set even higher TRIPS flexibilities in the region could be of use standards for IP protection.⁸⁴ For example, to confirm if legislation is now up to date. countries in the region adhered in 2008 to

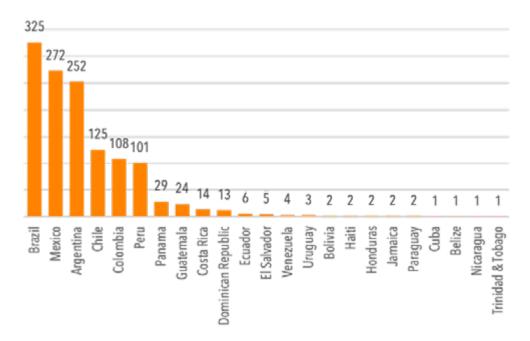
ade tion on and not King The as use	Parallel importation	Allows importation without the content of the patent holder of a product that is marked in another country			
	Bolar provision	Allows testing and regulatory approval of generics before a patent expires.			
ess alth nical ated TAG Irug	Compulsory Licensing	Is a license that allows the production and sale of medicines without the permission of the patent holder			

4.3.4 Research and development that meets public health needs and improves access to health products.

Research and development that meets public health needs and improves access to health products is another part of equitable access to medicines, including NCD medicines. This has several aspects to it, from the conduct of clinical trials, to local manufacturing and production, and the study of adverse events Caribbean out of all registered in the Americas in specific populations. There are challenges in 2018 – Figure 7. in the Caribbean on some of these fronts, but

promising developments on others. One such challenge is the scarcity of registered clinical trials with drug interventions conducted among Caribbean populations. Data from Clincaltrials. gov, a US government database of registered clinical trials, showed very few trials in the

Figure 7: Active registered clinical trials with drug interventions in Latin America in 2018



Source: ClinicalTrials.gov data and World Bank Population data for 2018.

Furthermore, there are challenges with those located in Barbados, Guyana, Jamaica, and regulatory oversight of clinical trials. According to PAHO data, 11 out of 35 countries (31%) in the Americas (mostly in the Caribbean), lack legal provisions for the regulation of clinical trials, which is recommended by WHO.

Another challenge is local manufacturing and production. There are few local manufacturers that produce products in the region, including

Haiti. Some information is available on the nature of these products primarily via procurement lists. These appear to be generics of lower complexity or simpler chemical structures and include some NCD medicines. However, due to the limited regulatory capacity in the Caribbean, the regulatory standards applied to local manufacturing are unclear. For example, it is unknown if the medicines produced are

required to demonstrate bioequivalence with reports from CARPHA Member States had a reference product, which is typically needed been shared with the CRS' VigiCarib network to be considered an effective generic medicine, since its inception in November 2017. Reports or if the information is derived from local were for suspected adverse drug reactions (280 - 69.3%), substandard / falsified medical populations. products (94 - 23.3%), and adverse events One positive development has been the following immunization (30 - 7.4%), from the introduction of the Caribbean sub-regional Bahamas, Belize, British Virgin Islands, Cayman network for pharmacovigilance and post-market Islands Dominica, Guvana, St. Lucia, St. Vincent surveillance, called VigiCarib, established by and the Grenadines, Suriname, and Trinidad the CARPHA-CRS described above. This system and Tobago.⁶¹

allows Caribbean countries to report adverse drug reactions from suspected medicines used Feedback from interviews of civil society in local populations to CARPHA for analysis, and indicated that there is a need for research to support vigilance by other Member States. among local populations to determine the Further. CARPHA-CRS reports these cases effectiveness and safety of various medicines, to WHO's Programme for International Drug instead of instant adoption of medicines based Monitoring in Uppsala, Sweden, where data on their use in more developed countries. In from around the world is pooled and analysed summary, population-specific reports on safety to better understand the safety of medicines and guality of medicines used by the populations, in different populations. Before VigiCarib and procedures to assess risk-benefit analyses network, there were fewer reports from the are needed to determine which medicines work Caribbean, predominantly from Barbados and best in local populations. Jamaica. Up to 15th September, 2021, 404 case

5. Discussion and Recommendations

This overview of the state of access to NCD medicines in CARICOM highlights existing frameworks, challenges faced and opportunities need to make the necessary legislative and/ available to Member States. The WHO Roadmap for Access to Medicines, Vaccines and Other Health Products remains a useful tool for framing the strategic areas and cross-cutting elements to be developed and/or strengthened in CARICOM to ensure reliable access to quality essential medicines for management of NCDs and the selected risk factors (tobacco use, harmful use of alcohol).

5.1 Ensuring the Quality, Safety and Efficacy of Health Products

Regulatory System Strengthening, Product Assessment. and Market Surveillance

National regulatory authorities in CARICOM vary in their capacity to regulate medicines in general, particularly to assess their quality, safety, and efficacy prior to market entry, and throughout its lifespan while on the local markets. The lack of regulatory frameworks and sustainable financing limit the ability of the national authorities to withdraw medicines that may be harmful to the population, or no longer have a favourable benefit-risk balance. Existing mechanisms to support regulatory functions, like the CARPHA Caribbean Regulatory System (CRS) and the WHO Pregualification programme present opportunities to Member States to make decisions about market access and retention, while they work towards strengthening internal capacity and infrastructure. Unlike the WHO Pregualification programme, the CRS reviews NCD medicines from all categories including biosimilars that have not been assessed by WHO for pregualification. In addition, Member States may work with the CRS and PAHO to develop collaborative approaches such as joint

reviews, thereby building internal capacity and procedures. However, national authorities or procedural changes to make use of these collaborative mechanisms to facilitate access to quality assured essential NCD medicines.

Systems for monitoring the guality, safety, efficacy, or performance of essential medicines used in Member States are key to regulatory decision-making. The market surveillance and control functions are not well documented, and the dearth of reporting mechanisms suggest that the systems of pharmacovigilance are underdeveloped among Member States. The lack of medicines quality laboratories, or the limitations of national laboratories that operate in Member States is concerning. Although pre-registration testing is not required where regulators use reliance, or where a riskbased approach to testing is applied, most Member States lack access to quality testing laboratories. The CARPHA Medicines Quality Control and Surveillance Department provides testing for some essential NCD medicines, but the inability to test injectable products means that several medicines for cancer or palliative care would not be eligible. The existing national and regional laboratories will need support to expand in scope, train personnel, and source equipment and reagents. In the short-term, national regulatory authorities may invest in field screening technologies to allow them to quickly identify substandard and/or falsified products that may be tested elsewhere.

5.2 Improving Equitable Access to **Health Products**

Although national strategic multisectoral NCD plans were found for the CARICOM countries reviewed, few had fully achieved the indicator for treatment guidelines, or for the provision of drug therapy and counselling in the WHO NCD essential medicines for national formularies, Progress Monitor 2020. None of the countries lists of essential medicines, and national fully achieved both indicators.²⁰ Given that procurement. However, standard treatment standard treatment guidelines and the provision quidelines (STGs) for other NCDs, tobacco of medicines with counselling are key to access cessation and harmful use of alcohol are still and appropriate use of essential NCD medicines, needed to support evidence-based decisionthis is a glaring shortcoming. making. The findings of regionally conducted clinical trials, drug utilization research, and National medicines policies, regulations, from pharmacovigilance systems will further standards and lists of essential medicines strengthen these guidelines and support in CARICOM need to be updated and made rational use of essential medicines. With STGs publicly available. This will allow regional and and rational use of NCD medicines, procurers international pharmaceutical companies with may more reliably forecast and quantify an interest in marketing to the region to identify pharmaceutical needs, enabling more efficient priority medicines for development, and inventory management, lower prices, and less standards for their market approval. In addition, wastage.

this will attract relevant applications of good guality to facilitate decision-making with less Additional collaborations or agreements delays (e.g. waiting for responses from market among Member States are needed to facilitate authorisation holders). It will also increase the additional pooled procurement mechanisms competition in the markets, thereby facilitating where Member States with large populations price negotiations. join with smaller states to attract lower prices, and medicines of agreed quality standards.

The inclusion of essential NCD medicines in reviewed lists varied among the Member States, Additional areas for strengthening include which may be due to variations in selection review of intellectual property legislation to procedures, procurement priorities, marketing facilitate faster access to generics, strengthened decisions by pharmaceutical companies (based policies for fair pricing, collaboration with on income status of the country, population private insurance companies to ensure essential size), frequency of revision of lists, and medicines are included and are affordable. pharmaceutical budget decisions.

All the recommended initiatives, mechanisms Agreements on research priorities and and strategies, including regulatory collaboration for research in the clinical strengthening, capacity building and efficacy, safety and real-world effectiveness information systems require sustainable of essential NCD medicines will support their financial structures for short-term and longcontinued use and/or clinical application, as term strategic planning and implementation. well as develop research capacity in the region. There are additional strategies identified in Collaborations with academic institutions, the WHO Roadmap, but the ones highlighted international organizations and donors are also here are identified as approaches that may be important strategies. prioritized for implementation based on the Regional standards for clinical treatment review conducted among CARICOM countries.

guidelines for diabetes and hypertension are available under CARPHA, which may be used by Member States to guide the selection

5.3 Key Recommendations

This report has identified several areas for strengthening to ensure equitable access to essential NCD medicines. However, the following key recommendations are presented as priorities improve equitable access to essential NCD medicines in CARICOM:

- 1. High-Level Commitments are needed to ensure equitable access to essential medicines. CARICOM countries should update the Caribbean Pharmaceutical so it identifies challenges and action lines related to access to NCD pharmaceuticals.
- 2. Enhance access to NCD Medicines through Affordable Prices and equitable financing. Affordable medicines can be promoted through various policies such as: generic promotion policies, improved public procurement, separating the prescribing and dispensing functions, among others. However, for the right policy to be selected we need to have information on current pharmaceutical spending. The widespread use of the System of Health Accounts methodology (SHA 2011) and ad hoc studies on NCD pharmaceutical spending should be adopted. Additionally, considering that the Caribbean is a net importer of pharmaceuticals, a study on the current state of the patent acts and the implementation of TRIPS flexibilities in the region should be undertaken to determine the relevance and timeliness of legislation.
- 3. Conduct in-depth studies on the effectiveness of the various NCD medicines programmes in facilitating equitable access to NCD medicines and reducing financial barriers in the Caribbean.
- 4. Determine the current pharmacist-population density and distribution in CARICOM, and identify strategies to promote more equitable distribution of pharmacists, and harmonization of pharmacy education.
- 5. Strengthen health information systems to routinely generate information products related to access to NCD essential medicines, such as publicly accessible quality standards, lists of essential medicines, lists of registered medicines, and procurement lists.
- 6. Strengthen regional regulation for marketing authorization approval of NCD medicines. All NCD medicines should undergo a process of evaluation to determine their safety, efficacy, and guality before being imported to the Caribbean. For this to happen in the short term, countries should require that all imported medicines are recommended by the CARPHA **Caribbean Regulatory System.**
- 7. Strong pharmacovigilance systems should be established, and pharmacovigilance activities should be incorporated as an integral part of NCD programmes that dispense medicines. Additionally, risk-based post-market surveillance activities that screen essential NCD medicines that may be high risk for falsification or illicit import should be developed.
- 8. Increase rational use of NCD medicines by updating national EMLs according to the latest WHO recommendations and by creating Standard Treatment Guidelines for priority NCDs.
- 9. Review and include appropriate essential medicines from the World Health Organization's Model List of Essential Medicine for Children to ensure that the priority health care needs of CARICOM children are also being considered.

6. Case Studies

"Recently, I spent 2 months without any medication because I skipped the follow-up visits. I didn't have any money to attend" - Haiti

6.1 Introduction out to its partners, network alliances and CSOs for suggestions and recommendations. The This section of the report captures the voices HCC also recruited through its newsletter to and experiences of people living with NCDs in identify volunteers to tell their stories. In order the Caribbean and their real, lived experiences to increase volunteer participation, anonymity in obtaining the essential medicines they need was assured to all and participants are not to manage their conditions. It is intended to identified by name. complement the overall technical report, by An interview script was developed and approved telling patient stories, through their own voices. by the HCC. The guide was intended to bring This approach resonates with the Global NCD consistency to the questions asked to case-Alliance's Our Views, Our Voices initiative which study participants. Interviews were conducted seeks to meaningfully involve people living in 2019. The majority of the volunteers were with NCDs in the NCD response. Our Views, Our interviewed by telephone. Three participants Voices seeks to put people front and centre in from Belize submitted responses in writing. The the NCD response. four volunteers from Haiti had help from the Fondation Haïtienne de Diabète et de Maladies 6.2 Methodology Cardio-vasculaires in completing the questions in writina.

In order to capture these voices, a small sample people living with NCDs in the region were interviewed and asked about their experiences 6.3 Participation in accessing their prescribed medications for These case studies should be viewed as a limited treatment and management of their conditions. sample of patients as the number of people The aim was to cover all 5 major NCDs who agreed to be contacted and interviewed cardiovascular diseases, diabetes, cancer, was unexpectedly small. No volunteers were chronic respiratory diseases, and mental health identified through the HCC newsletter and disorders and neurological conditions; and to getting referrals from partners organisations include experiences from at least 3 countries. was a challenge. It is possible that the following Interview participants were all volunteers who impacted participation: (1) over the months of graciously agreed to tell their stories. They were July and August many people were on leave or solicited with the help of the HCC, who reached travelling, and some offices were closed; (2) in

the region there is still a significant stigma attached to these NCDs and patients are reluctant to talk about them for fear of retribution or cancellation of benefits. This second point should not be underestimated as people living with NCDs in the region feel a stigma attached to their diseases, particularly cancer and mental health.

Case studies emerged from 7 countries and all 5 NCDs were covered. The majority of people willing to share live with Diabetes, while only one with mental health diagnosis volunteered. The following table summarizes the demography of the participants:

	Caribbean Country	#people	Se	ex	Age range	NCD covered
			М	F		
	Antigua and Barbuda	3	1	2	50-65yrs	Diabetes, hypertension, asthma
	Barbados	2	0	2	32-46 yrs	Diabetes, mental health (ADD)
	Belize	3	1	2	50-58 yrs	Cancer, hypertension
	Guyana	2	0	2	54-69 yrs	Diabetes, hypertension, arthritis
	Haiti	4	1	3	48-56 yrs	Diabetes, hypertension
	Jamaica	2	0	2	45-50 yrs	Cancer
	St. Lucia	2	1	1	28-35 yrs	Diabetes
Tot.	7	18	4	14		

Demography of Case Study Volunteers

"Cancer patients don't want people to know. They fear victimization"- Jamaica

NCDy Aldactone. Ar Hypertension Carvedilol, Co Isordi Gemcitabine Cancer Metformin, Gly Diabetes Asthma Attention deficit disorder

6.4 General Findings

Sources of medicine

For the majority of the case study participants, This helped to improve the likelihood that they their first point for sourcing their medications would get their medicine. was the government/public health service One interesting observation about the national health systems was that experiences with different drugs varied. There was a lack of consistency in experiences of patients in accessing medication on these schemes. Some drugs were readily available and in constant supply. Thus, the patient had no problem accessing their medicine. However, in the same country, another patient, even with the same condition/diagnosis but prescribed a different medication, found their medication perennially out of stock or unavailable and had to find money to purchase the medication privately. This was evident in Belize, Antigua and Barbuda and Guyana. This points to the need for better management of medication and some form of overarching surveillance on incidence, coordination of prescriptions and better supply chain management.

where they got most of their medications at no cost. Younger interviewees were able to take a more proactive approach to their care and discuss newer treatment options with their physicians. In cases in which their care physician had agreed on newer medication, these drugs were generally only available in private pharmacies. Availability of medicine In some countries, the government/public health service works relatively well. For example, in Antigua and Barbuda, The Medical Benefits Scheme (MBS) seems to always have medicine available for patients and it covers some percentage of tests and scans. On the other hand, the public health clinics in Guyana are usually out of stock when patients sought to get their medicines. This means that patients

Medications - The following medications being taken by patients were discussed during the interviews:

Medicine
mlodipine, Atenolol, Aspirin, Captopril, Carbimozole, o-diovan, Diclofenac, Enalapril, Hydrochlorothiazide, il, Lisinopril, Losartan, Metoprolol, Propanol
e (Gemzar), Tamoxifen, Doxorubicin Hydrochloride (Adriamycin) and Cyclophosphamide,
yburide, Daonil, 70:30 insulin, Novalin insulin, Lantus insulin pens, Apidra insulin pump.
Ventolin, Symbicort
Ritalin

had to pay for medication only when they could afford it. Patients also, often, rely on someone they knew (such as a nurse, a public official, a doctor) to help them source the medication.

Cost of medicine

This is singularly the greatest challenge facing interviewees. The cost of their medicines is too high. When the public health services were out of stock, patients had to buy their medication at local pharmacies. Most, especially the elderly, could not afford the private prices and either sacrificed essentials such as food or clothes and utility bills, in order to pay for their medication, or went without their medication. In addition, most testing, scans and lab work had to be paid for out of pocket. If a patient has Type 1 Diabetes and did not use insulin, they were not eligble for free blood testing strips. Even when they were eligble, patients get one box a month which usually only lasted for only 1-2 weeks. MRIs, CTs, blood work and other important diagnostic tools were not easily available publically. NGOs and civil society organisations were sometimes able to provide some support

for cost of medications or testing, e.g. the Jamaica Cancer Society and the Fondation Haïtienne de Diabète et de Maladies Cardio-Vasculaires (FHADIMAC) in Haiti. Patients depended on family and friends for financial support and some borrowed in order to get their medication. If they were not able to work, this increases their financial burden.

Quality of medicine

In general, interviewees were not concerned, nor did they question their medication. They did tend to feel that generic brands weree less effective than the specific prescribed medication. So many avoided the generics if they could help it. Usually they did not seek alternatives if their branded medication was unavailable. They just went without and try to manage by paying attention to lifestyle habits – such as sugar consumption, etc.

"I have a lot of difficulties to get the medicines I need. Oftentimes, I skip multiple doses because of lack of money"- Haiti

"In St. Lucia, the expense is totally prohibitive. You have to have personal contacts and connections to survive" - St. Lucia



6.5 Case Studies

Please note that the case studies capture the experiences of those specific individuals interviewed and may not be broadly reflective of the realities of accessing medicine in the identified countries. In addition, patients shared their experiences in 2019 and it is possible that these experiences may have changed since the interviews were conducted.



Antigua and Barbuda Case Study #1 - Diabetes and Hypertension

The Patient: Patient A is a 50-year-old woman with Type 2 Diabetes, (diagnosed in 2017), and Hypertension. The doctor recently took her off any hypertension medication.

Medication: She currently takes Metformin twice/day.

Availability and access: Patient A gets her medication from the Medical Benefits Scheme (MBS) at no cost to her. MBS usually has stock. However, a friend of A from her Church, works at the MBS and he usually helps her by getting her prescriptions filled and re-filled. This saves **Patient A** waiting in long lines, especially at the end of the month. Because she does not take insulin, **Patient A** does not qualify for blood testing machine or strips through the MBS. Instead, she bought her own machine (ECC \$125/ USD \$47) and she purchases her own testing strips at a cost of approximately EC \$125/box of 30 strips (USD \$47). This expense prevents her from using the testing strips every day. She only uses them when she suspects her blood sugar to be abnormal.

Quality and alternatives: Sometimes only 750mg Metformin tablets are available, instead of the 500mg tablets. If this happens, A has to adjust the dosages to suit and closely monitor her blood sugar levels.

Suggestions: "Make testing strips and machines more affordable"



Antigua and Barbuda Case Study #2 - Diabetes

The Patient: Patient B is a 60 year-old man with Type 2 Diabetes.

Medication: He is on Metformin to manage his condition.



Availability and access: He gets the medication from the Medical Benefit Scheme (MBS) at no cost. He does not qualify for a blood testing machine nor blood testing strips because he does not take insulin. The cost of these items is prohibitive, so he does not use them. Additionally, the MBS refunds a partial percentage of spend on laboratory tests, X-rays, surgery, ultra sounds, electrocardiographs or similar services, hospitalization. **Patient B** has to pay about EC\$100 every 3 months for tests prior to visiting his doctor.

Quality and alternatives: Patient B has no problems with quality of his medication and has not had to use any alternatives.

Suggestions: "Make blood testing supplies available to non-insulin dependent diabetics also"



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Antigua and Barbuda Case Study #3 - Asthma, Diabetes and Hypertension

The Patient: Patient C is a 64-year-old woman who has been living with asthma, hypertension and diabetes for over 10 years.

Medication: Patient C uses Ventolin and Symbicort (budesonide and formoterol) twice/day for asthma; one Co-diovan tablet per day for hypertension; and 70:30 insulin twice per day.

Availability and access: Patient C is able to get all her medications from the Medical Benefits Scheme in Antigua and Barbuda (MBS). This scheme offers financial assistance and pharmaceutical supplies to qualified residents. She is also eligible for one packet of 30 blood testing strips per month from the MBS.

Quality and alternatives: No alternatives are needed as the MBS is able to supply all the medications as prescribed. Patient C is never concerned about the quality of her medication and does believe it is working and helping her manage her conditions.



Barbados Case Study #1 - Mental Health

The Patient: Patient D is a 47-year-old woman who was diagnosed with Attention Deficit Disorder 15 years ago.

Medication: Patient D is prescribed Ritalin (10mg) twice daily or when needed.

Availability and access: Patient D buys her medication, privately, from a pharmacy with her prescription. One month's supply is approximately USD\$50. While **Patient D** trusts the quality of the Ritalin she buys, the pharmacy is often out of stock. The pharmacist explains that, "the Agent didn't bring it in" and she finds that it is only available about every 4 months. She resorts to drinking coffee when she does not have any medication.

Quality and alternatives: Patient D uses a generic brand when the Ritalin is not available. But she finds that it is not as effective and worries about the source and guality. She worries that a significant side effect of this medication is memory loss.

Suggestions: "Perhaps more than one agent on the island bringing it [Ritalin] in. They need to be available every month and waiting for me to pick up. My prescription is a repeat prescription so it's not a surprise I will be collecting every month".



Barbados Case Study #2 -Diabetes

The Patient: Patient E is a 32-year-old woman, diagnosed with Type 1 Diabetes at age 11. She is a patient advocate and coaches others living with Diabetes, so she hears many stories from others relating to their medication.

32 Medication: Patient E has been using insulin for the last 20 years. She currently uses the Apidra insulin pump to help to regulate her blood sugar. She did a lot of her own research and saw doctors in the USA (Miami). This was the stimulus for changing to the Apidra pump -amore cutting-edge way of treating her diagnosis. Her old medication regime was no longer working for her. The pump delivers doses of insulin every 5 mins or so throughout the day. She has been using the pump for the past 5 years.

Availability and access: The Apidra pump and insulin are not available within the public healthcare system in Barbados. It is prohibitively expensive and there are not many people using it. One pump cost USD \$100 and needs to be replaced every three days as the battery expires. A box of 10 (30 days) costs USD \$1000. The insulin costs about USD \$50 per vile and lasts approximately one week. So, a month supply costs about USD \$200. Her doctor in Barbados is able to prescribe the Apidra insulin and Patient E is able to source it at one local pharmacy where she has built a relationship. However, she has had to bring in the medication via FEDEX from Jamaica where there is no local stock. The Apidra pumps are not available regionally. So, Patient E travels to Miami every 3-6 months to check with her doctor there and to get a prescription for the pumps which she can source in the US and bring in to Barbados. She usually brings in 6 months' supply of pumps. When she cannot travel to Miami, she has to organise with her doctor there to write a prescription for a friend or relative to purchase and bring in for her. In addition, **Patient E** is eligible for one box of blood testing strips, with 30 strips, per month. She has to test her blood sugar levels on average 3 times per day. So, a box only lasts for 10 days, not the whole month, and she has to purchase her own.

Patient E has a close relative in a senior position at a local insurance company. As a child, she was covered under her parents' health insurance. After she finished her education, she could no longer be covered under their policy and the insurance company would not cover her due to her pre-existing diagnosis. The company had a window of time when you could sign up with pre-existing conditions and they would have to monitor you for 24 months before approving the policy. Patient E qualified under this and pays about USD \$300/month to the policy which then covers 80% of her expenses following her payment of the USD \$5,000 deductible. She depends on her parents and insurance to fund her treatment. She says without this financial support she would not be able to access her healthcare.

Quality and alternatives: Patient E says she does not worry about the quality of the insulin as she believes it works well with her body and she would know immediately if it was not working. She is sometimes sceptical about the pumps as she has heard that some of the pumps being sold are "rejects from Africa" so she wonders how much she should trust them. She has also spoken to people who have problems with the quality of their local Diabetes



Barbados Case Study #2 - Diabetes continued

medication, especially generics. **Patient E** is usually able to source her pump and insulin so she does not have to use alternatives. She does point out that in doing her extensive research, she has found that the treatment approaches and the medication being used in the Caribbean tend to be outdated, and some medicines are no longer used in the USA or Canada. These are still being used in the region, which she thinks is lagging behind in modern approaches, to the disadvantage of patients.

Suggestions: "Include patient voices into policy. Better patient education and autonomy in care management. We spend a lot of money treating complications from outdated drugs. If we start with newer, better medication from the start, we would not have so many side effects. We need to share procurement and costs of medication as a region. This will help to prevent spoilage, excess and shortages".



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Belize Case Study #1 - Hypertension

The Patient: Patient F is a 50 year-old male with heart disease and hypertension.

Medication: He has been taking Isordil, Aldactone, Carbonozole and Propanol for the past two years.

Availability and access: Patient F obtains all his medication through Belize's national health care system at the hospital. He pays approximately US\$10 per month for his drugs which he says are always available to him and easy to access. He says if there comes a time when he cannot afford his medicine, he would have to resort to begging for money.

Quality and alternatives: Patient F has not ever had to use alternative or generic brand medications. And while he believes his medications are helping him"100%", he indicated that there is always a worry about where the dugs come from.



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Belize Case Study #2 - Cancer and Hypertension

The Patient: Patient G is a 50 year-old woman who has had breast cancer and is currently diagnosed with hypertension.

Medication: She takes Enalapril and Losartan for her hypertensive condition.

Availability and access: Patient G usually gets her medication through the national health care system, either at a health centre or the hospital. She pays approximately US\$30 per month if the tablets are available through the system. However, when the medication is out of stock, she is told to buy the necessary medication at the pharmacy, with no subsidization. The cost in the pharmacy is usually prohibitive and she then may have to go without. She does save and sacrifice other essentials in order to purchase her medicines. Sometimes she can ask her adult children or her employer for financial assistance to help. She says it saddens her to think "health depends on money". **Patient G** always takes her medication as directed, once she has researched their side effects, which she says are often "worse than the cure".

Quality and alternatives: Patient G prefers not to take generic or substitution medication, as it usually does not agree with her. Instead, she visits "the herb man", (herbalist), to see if he has anything to help her condition or help with the side effects that afflict her.

Suggestions: "We need to find a way to make certain medication available especially when they are not under the NHI (national healthcare scheme)."



Belize Case Study #3 - Hypertension

The Patient: Patient H is a 58 year-old lady with hypertension.Medication: Patient H has been prescribed Carveilol at 6.25mg orally once per day.

Availability and access: In general, the medication is supposed to be available at the hospital or healthcare centre under the national health system. With this subsidization, medication costs **Patient H** about US\$16 per month. However, sometimes the medication is not available, and it is very costly at the pharmacy, and requires a doctor's prescription. Often times, she is unable to purchase it. While **Patient H** says many sacrifices are required to have the money for medication; she indicated that when funds are too low, she resorts to begging or to offering to wash a neighbour's clothes for cash.

Quality and alternatives: Patient H always uses her prescribed medication if she can afford it. She does not use alternatives or generics. But she does worry about the source of even the prescribed medication.

Suggestions: "no matter what we still have to get our medication".



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Guyana Case Study #1 - Diabetes and Hypertension

The Patient: Patient I is a 69-year-old woman who has been living with Type 2 Diabetes for 21 years. For the last 6 years she has been living with Hypertension and Arthritis related to her Diabetes. She has no living spouse and is unable to work because the arthritis has affected her knees to the extent that it is painful to walk, and the doctors advise that she needs both knees replaced. She lives with her daughter who also does not work as she provides homecare for her children.

Medication: Patient I takes Metformin and Daonil for her Diabetes and Captopril and Aspirin for Hypertension. She has been unable to schedule knee replacement surgery at the public hospital because she has been told there are currently no doctors available to perform the surgery.

Availability and access: Patient I gets all her medication from the free government clinic near her home. She goes to the clinic once a month to see her doctor and refill her prescriptions. Sometimes the clinic does not have Metformin for 2 or more months, and sometimes there isn't even any aspirin. If she has to purchase her own medications, she needs financial help from relatives. As an elderly person, her subvention from the government is GYD\$5,000/ month (USD\$24). 6 Metformin tablets (which is the dosage for two days) cost GYD \$600 so for a month Metformin alone would cost GYD \$9,000. The Daonil costs GYD \$100 for 10 which is a 3-day supply. So, one month would cost of this medicine is GYD \$1,000. In addition, if the local clinic does not have stock, **Patient I** has to take public transportation to Georgetown to try to get her medication. This costs GYD \$680, round trip and much more if she is not able to walk at all and must take a taxi. There are no machines available through the government clinic for helping her test her blood sugar levels. And there are many times when the clinic machines do not work.

Quality and alternatives: When the clinic has no stock, **Patient I** skips her regular medication dosages and instead of 3 Metformin/day, she takes only one. This results in headaches, high blood sugar levels and increased pain.

Suggestions: "Make better provisions for the elderly".



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Guyana Case Study #2 - Hypertension

The Patient: Patient J is a 54-year-old woman diagnosed with hypertension.

Medication: She takes aspirin, Amlodipine and Atenolol once per day.

Availability and access: While there are public health clinics/posts that supply her medication, **Patient J** usually finds that the clinics are out of stock. So, she ends up purchasing the required medication. It costs about GYD \$2,500 per month (USD \$13) and she uses her savings or relies on her children to help her buy her tablets. When she uses her own money, she sacrifices paying bills to run her home, including utility bills.

Quality and alternatives: Sometimes **Patient J** has to buy generic brands of her medication, either because of the expense or because the brands are out of stock. She has found that while the brand names work well, the generics do not help her to control her blood pressure in the same way.

Suggestions: "Health posts should have the medicines, so we don't have to purchase it. Also, the doctor should visit the health post/clinic at least once a month to see if any changes in medications are needed".

Haiti Case Study #1 - Diabetes

The Patient: Patient K is a 53-year-old woman with Type 1 Diabetes. She is married and not currently working. Her husband lost his job 2 years ago.

Medication: Patient K uses insulin twice per day and takes Vitamin B, which was also recommended by her doctor.

Availability and access: Patient K gets her insulin from the Fondation Haïtienne de Diabète et de Maladies Cardio-Vasculaires (FHADIMAC) at a reduced cost to the market price. While FHADIMAC always seems to have her medication in stock, it is still too expensive for **Patient K** and her husband. Therefore, she relies on her brother to help purchase her medication. The monthly cost is about USD\$30 and sometimes in order to make sure she has the medication she has to give up certain foods or other essential purchases.

Quality and alternatives: Patient K only uses the medications she gets from FHADIMAC. She trusts the pharmacy there and does not use generics or other alternatives. When she cannot afford insulin, she just doesn't use any. She did try to buy pain killers outside of the Foundation but found it too expensive so gave up on using them. She is not always able to take the Vitamin B consistently.

Suggestions: "I just need insulin at a lower price".

Haiti Case Study #2 - Diabetes

The Patient: Patient L is a 48-year-old male with Type 2 Diabetes, diagnosed 5 years ago. Medication: Patient L takes Metformin and Glyburide twice per day.

Availability and access: Patient L buys his medication at the pharmacy at the Fondation Haïtienne de Diabète et de Maladies Cardio-Vasculaires (FHADIMAC) and local pharmacies near his home. Both drugs are usually available, and he spends approximately USD\$35/ month which he pays for it out of the profits of his wife's small retail shop. If the pharmacies close by do not have stock, he takes public transportation to look for them elsewhere. The cost is a financial burden and if he cannot afford his prescriptions, he asks family or friends for help with money.

Quality and alternatives: Patient L does not use alternative medication to treat his diabetes. He does check everything before he leaves the pharmacy as he believes that they may not always meet rigorous standards. He does believe his treatment plan and his medication are helping him to manage his condition.

Suggestions: "If it's possible to give even samples of medicine to patients, it would be good".

Haiti Case Study #3 - Hypertension

The Patient: Patient M is a 56-year-old woman, diagnosed with hypertension nearly 30 years ago. She works as a nurse.

Medication: Patient M takes Amlodipine once/day (10 years), Aspirin one/day (20 years) and Hydrochlorothiazide once/day (29 years).

Availability and access: Getting medicines is not always easy. Patient M sometimes receives them at no cost at a national health clinic, but most of the time she has to purchase them herself from various pharmacies. The cost is an estimated USD\$30/month and she pays for them, using her monthly nursing salary. She says that because the economy is falling, it is increasingly more difficult to access good quality medicines at a lower cost. She stressed that prices are too high and salaries in Haiti are not suitable. Sometimes she gives up public transportation and clothes in order to save money for the medicine.

Quality and alternatives: On several occasions Patient M has had to purchase "equivalent" drugs because her prescribed medication was not available. She does not worry about the guality of these but prefers to take what her doctor has recommended. And when she is unable to afford the medication, she focuses on lifestyle changes.

Suggestions: 'It would be good to have partnerships with pharmaceutical companies to deliver high quality medicines at lower cost in Haiti".

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Haiti Case Study #4 - Hypertension

The Patient: Patient N is a 62-year-old woman recently diagnosed with hypertension. She is not working currently.

Medication: Patient N takes Amlodipine once/day (for 2 months), Enalapril once/day (for 1 year) and Diclofenac three times/day (just started)

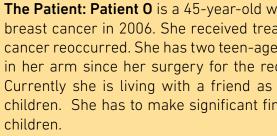
medication at all, she has to skip doses. This can last for two weeks at a time.

Quality and alternatives: While sometimes Patient N can't find the brands she wants, she does not take generic or other alternatives – she just does without the medication. She has been told that the quality of drugs in some pharmacies is not reliable, so she does not go there. When she does have her medications, she believes the drugs do a good job in helping her to manage her hypertension.

Suggestions: "It would be better to receive medicines freely".



Jamaica Case Study #1 - Cancer



Medication: Patient 0 is currently taking Gemzar (generic name: Gemcitabine) via IV. She has 6 cycles (each cycle is two treatments - so 12 in all) and she is on her 2nd cycle (3rd treatment). The Gemzar is available through the national drug service, DrugServ. These are dedicated government pharmacies. Continued.....

Availability and access: She, most often, gets her medication at reduced prices from the pharmacy at the Fondation Haïtienne de Diabète et de Maladies Cardio-Vasculaires (FHADIMAC). If they are not in stock, she goes to a private pharmacy down her street. She spends about USD\$35/month on medication. She depends on her adult three children to help pay for her medicine but sometimes she receives money as a gift from friends or family which she uses to pay for medication, among other things. When money is short, Patient N goes without meals or shoes to be able to buy her medicines. When she cannot afford her

The Patient: Patient O is a 45-year-old woman, diagnosed with oestrogen and Her2 positive breast cancer in 2006. She received treatment and went into remission. In 2016 the breast cancer reoccurred. She has two teen-aged children. She is suffering badly with lymphedema 4.5 in her arm since her surgery for the reoccurrence and as a result she is unable to work. Currently she is living with a friend as she is no longer able to support herself and her children. She has to make significant financial sacrifices as she fights to stay alive for her



Jamaica Case Study #1 - Cancer continued

Availability and access: Patient O started taking Tamoxifen tablets orally, these seemed to be working to contain the cancer reoccurrence. However, the Tamoxifen tablets were expensive. She was getting them at a reduced price of JAD \$33,000 or USD \$242 for a two-week supply at DrugServ, rather than JAD \$45,000 (USD \$330) from a private pharmacy. **Patient O** sometimes had to use her light bill money to pay for these tablets. Still unable to afford this medication, she switched to a different, less expensive hormone tablet. This new medication did not work well to contain the spread and, she believes, resulted in the recurrence. As **Patient O** could not afford to return to taking the original oral medication, her doctor changed her to the IV chemotherapy, Gemzar. This is available free at the national clinics.

No investigative testing (blood tests, MRIs, CTs, PET scans) is covered by the government, so **Patient 0** has to pay each time she needs any kind of examination requiring scans or lab tests. She says this is a heavy financial burden. The Cancer Society does provide some help.

Quality and alternatives: Taking a cytotoxic chemotherapy (Gemzar) is much harsher on the body, with many more side effects, than the oral oestrogen receptor modulator tablets (tamoxifen). **Patient O** would have stayed on the Tamoxifen if she could have afforded it, or even on the cheaper alternative if it worked well (it did not and she questioned its quality as well as effectiveness). **Patient O** now has challenges finding veins that will work for her IV, often resorting to her legs, which cause severe swelling. The doctor has recommended the insertion of a port-a-cath to help administer the IV. However, the port would cost JAD \$50,000, which **Patient O** cannot afford. She has at least 8 more treatments to get and is not sure where she will be able to insert the IV.

Suggestions: "A means-tested government fund to assist those who are not able to afford care."



Jamaica Case Study #2 - Cancer

The Patient: Patient P is a 50-year-old woman who was recently diagnosed with oestrogen positive breast cancer. Her daughter is her primary caregiver.

Medication: Patient P took Tamoxifen tablets prior to chemotherapy. She just completed 16 cycles of chemotherapy, including 4 with doxorubicin (Adriamycin) and cyclophosphamide.

Availability and access: Patient P received all her chemotherapy treatment free of charge at the National Cancer unit. She got the Tamoxifen at Drug Serv, the government-subsidized pharmacy. In addition, the Jamaica Cancer Society helps with the cost of scans and tests, so to date treatment has not been a significant financial burden.

Quality and alternatives: Patient P does not worry about the source or quality of her medication. She trusts the government supplies.

Suggestions: While **Patient P** has not faced financial challenges to date, she hears other patients often complain about the expensive cost of medication. *"Find a way to reduce costs"*

St. Lucia Case Study #1 – Diabetes

The Patient: Patient Q is a 28 -year-old woman who was diagnosed with Type 1 Diabetes in 2007 (age 11 years old).

Medication: She was using 70:30 Insulin but it stopped working well and she changed to a combination of Novalin R insulin (short acting) and Lantus pen insulin (long-acting) 8 years ago.

Patient Q has a very pro-active patient approach. When she realised that the 70:30 insulin was no longer helping to regulate her blood sugar levels, she spoke with a friend in the US with a similar diagnosis. She had to go to three doctors in St Lucia to find one that was willing to work with her to change her medication to one she regards as a more modern regime of Lantus and Novalin R. **Patient Q** explained that her former regime was old fashioned and modern methods and approaches were not being used in St. Lucia at the time. Her belief is that doctors are reluctant to change regimes because newer medication tends to cost more to the patient.

Availability and access: Patient Q obtains the Lantus insulin privately at her own expense of approximately USD\$73/month. She gets the Novalin R insulin from a national health centre at no cost to her. The Novalin R is rationed, however, which is a problem if a vial breaks or if a specific vial appears to be defective after a couple of uses. Neither the Lantus nor the Novalin R are always available. The cost of the Lantus is high for **Patient Q**, and she does make financial sacrifices to ensure she can purchase her medication. If she is unable to finance herself, she sometimes gets personal loans to help her.

Quality and alternatives: Patient Q believes the Lantus insulin she buys is good quality as her body responds well to it. She has questions about the Novalin R's quality. She continues to ask about newer regimes, but they are prohibitively expensive, so she and her doctor have settled on her current approach. When the Lantus and Novalin R are not available on island, she has to switch to Novalin N and the 70:30 insulin. Each time she has to switch, her body takes over a week to adjust to the change in medication and the regime is does not work well for her – it is neither effective, nor does it suit her lifestyle as a busy 28-year-old working woman.

Suggestions: "Find a way to decrease the cost of medication and also ensure it is always available".



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St. Lucia Case Study #2 - Diabetes and related illnesses

The Patient: Patient R is a 35-year-old male with Type 1 Diabetes, who was diagnosed at the age of 7 years old. He also suffers from Kidney disease, hypertension and diabetic retinopathy as a result of the diabetes.

In 2010, Patient R travelled to the USA to seek medical attention because his treatment plan in St. Lucia was not working. In the US, the newer approaches to diabetes management utilised insulin flex-pens. **Patient R** started using them and continues under the supervision of his physician in St. Lucia. The new insulin regime works better. He thinks that doctors in St. Lucia are aware of newer medications to manage diabetes, but that they do not prescribe these for their patients because they are too expensive and not affordable for the majority of people.

Medication: Patient R uses both Lantus insulin (long acting) and Nova-rapid insulin (short acting) to help manage diabetes. He treats his hypertension with Lisinopril and Metoprolol. In addition, he undergoes kidney dialysis three times per week and takes multivitamins and Erythropoietin (EPO) by injection to help bolster his red blood cells. He has had 10 laser surgeries and implants to try to help his vision.

Availability and access: While his old regime, the Novalin R and the 70:30 insulin, is available free from the national health clinics, **Patient R's** new medicationmmust be purchased privately from a pharmacy. One Latus pen costs USD\$40 (EC\$ 110) and a box of 5 Nova-rapid pens cost USD \$196 (EC\$530). These last about 1 month. He also pays privately for his Multivitamins and the EPO shots. Patient R has found his medication in Barbados and Trinidad at lower prices. There is a new pharmacy in St. Lucia, under a Trinidad and Tobago brand, where medication seems to be more cost accessible, (e.g. 1 Lantus pen is EC\$75). **Patient R**, however, gets all his diabetes medications through an close relative who lives in Barbados. She purchases it all for him and sends to St. Lucia via friends/family. This generous gift saves Patient R a significant monthly expense. Patient R lives with his parents, who help him financially. He uses blood sugar testing strips, which he is gualified to get at the national clinic. However, he says the supplies are limited and usually not available when needed. So, he orders a 5 month supply online through Amazon.com and has it shipped to St. Lucia. This is often cheaper than what he can get through the Diabetes Association in St. Lucia.

For the diabetes-related kidney disease, **Patient R** needs dialysis three times per week. There are two renal units in St. Lucia – one public and one private. These machines can treat about 90 people per week, while the waiting list is approximately 150 people. Patient R's mum is a retired nurse and helps him to get appointments at the public unit, when these are not available, he goes to the private unit, which allows patients to pay what they can at the time.

Quality and alternatives: Patient R feels that his regime is now working for the first time in 10 years. With his poor vision, the flax-pens reduce the mistakes in insulin dosage. He does not doubt the quality of the medication, but he does rely on family members bringing the insulin from Barbados to store it properly for travel (i.e. keep it at the right temperature). Also, he has to be in constant touch with a doctor in Barbados to write prescriptions.

Suggestions: "We need a regional approach to medication. We also need a regional body for donor storage and transplant services. Individually, we can't do it".

Appendices

7. Appendices

7.1 Appendix 1: HCC List of Essential NCD Medicines

To characterize the availability of NCDs in the region a review of national procurement lists or/ national essential medicines lists was undertaken to provide a snapshot of medicine availability. A list of indicator medicines was developed and used to compare with national procurement lists or national essential medicines lists, where available. Indicator medicines were included considering the following:

- Inclusion in the 22nd WHO List of Essential Medicines 2021²² and/or the WHO Package for Essential Noncommunicable (PEN) Diseases for primary health care 2020²³
- Used in the treatment of five of the major types of NCDs: diabetes, cardiovascular, respiratory, cancer (including medicines for palliative care), and mental conditions (including neurological disorders)
- Used in the treatment of smoking cessation, including nicotine replacement therapy
- Essential medicines for palliative care were assessed separately from cancer medicines. These products included analgesics, anti-emetics, laxatives, antibiotics (Access Group or WHO PEN), and electrolyte infusions
- In the absence of essential medicines in the WHO EML for the treatment of harmful use of alcohol, two medicines were noted in the treatment guidelines for harmful use of alcohol by the American Psychological Association.²⁴ There were not considered as essential medicines, but the lists were reviewed for their inclusion.

The final list was reviewed and approved by members of the board of the Healthy Caribbean Coalition prior to the assessment. The list comprised of a total of 178 medicines and can be found below. This list was compared with available public sector procurement lists of non-Latin Caribbean (NLC) countries, excluding Aruba and Puerto Rico. Where the procurement lists were not available, the most recent versions of national lists of essential medicines or national formularies were used. The WHO's repository of national essential medicines lists was used as a source, along with websites of ministries of health and/or procurement agencies, including the OECS' Pharmaceutical Procurement Service.²⁶

Pharmacologic Group	Medicine name (INN), route	List	Therapeutic Gr
MEDICINES	FOR PAIN AND PALLIATIVE CARE	including Infection	ons
	morphine (or hydromorphone, oxycodone) po./inj.	EML; PEN	Palliative
Opioid analgesics	fentanyl patch	EML	Palliative
	codeine po.	EML; PEN	Palliative
	methadone po.	EML	Palliative
NCAIDe (includes conirin)	ibuprofen po.	EML; PEN	Palliative
NSAIDs (includes aspirin)	paracetamol po.	EML; PEN	Palliative
	cyclizine po./inj.	EML	Palliative
	docusate sodium po.	EML	Palliative
	hyoscine butylbromide inj.	EML	Palliative
Medicines for other	hyoscine hydrobromide inj/patch	EML	Palliative
symptoms in palliative care	lactulose po.	EML	Palliative
	loperamide po.	EML	Palliative
	midazolam po/inj.	EML	Palliative / Neur
	senna po.	EML; PEN	Palliative
Anti-emetic medicines	metoclopramide po.	EML	Palliative
	ondansetron (or dolasetron, granisetron, palonosetron, tropisetron) po./inj.	EML	Palliative
	promethazine inj.	PEN	Palliative
	amikacin inj.	EML	Palliative / Infec
	amoxicillin (or amoxicillin/ clavulanate) po/inj.	EML; PEN	Palliative / Infec
	ampicillin inj.	EML	Palliative / Infec
Antibiotics	benzylpenicillin inj.	EML	Palliative / Infec
	benzathine benzylpenicillin inj.	EML; PEN	Palliative / Infec
	cephalexin po/inj.	EML	Palliative / Infec
	chloramphenicol po/inj.	EML	Palliative / Infec
	clindamycin po/inj.	EM	Palliative / Infec

Pharmacologic Group	Medicine name (INN), route	List	Therapeutic Group
	cefazolin inj.	EML	Palliative / Infect.
	cloxacillin po/inj.	EML	Palliative / Infect.
	erythromycin po.	PEN	Palliative / Infect.
	gentamicin inj.	EML	Palliative / Infect.
	nitrofurantoin po.	EML	Palliative / Infect.
Antibiotics (continued)	metronidazole po.	EML	Palliative / Infect.
, , , , , , , , , , , , , , , , , , , ,	phenoxymethylpenicillin po.	EML	Palliative / Infect.
	procaine benzylpenicillin inj.	EML	Palliative / Infect.
	spectinomycin inj.	EML	Palliative / Infect.
	sulfamethoxazole + trimethoprim po/inj.	EML	Palliative / Infect.
	trimethoprim po.	EML	Palliative / Infect.
Other	glucose injectable solution (or dextrose)	EML; PEN	Palliative
	sodium chloride infusion	EML; PEN	Palliative
	CARDIOVASCULAR MEDICINI	ES	
Antianginal medicines	isosorbide dinitrate po.	EML; PEN	CVD
Antianginat medicines	glyceryl trinitrate po.	EML; PEN	CVD
	digoxin po.	EML	CVD
Antiarrhythmia madiainas	lidocaine inj.	EML	CVD
Antiarrhythmic medicines	verapamil po.	EML	CVD
	amiodarone po.	EML	CVD
	amlodipine po.	EML; PEN	CVD
	bisoprolol (or atenolol, metopr-, carved-) po.	EML; PEN	CVD
Antihypertensive medicines	enalapril (or other long-acting ACEI) po.	EML; PEN	CVD
	hydralazine po.	EML	CVD
	hydrochlorothiazide (HCTZ) or other thiazide po.	EML; PEN	CVD

Pharmacologic Group	Medicine name (INN), route	List	Therapeutic Grou
	lisinopril (or long-acting ACEI) + HCTZ (or amlodipine) po.	EML	CVD
Antihypertensive medicines	losartan (or other ARB) po.	EML	CVD
(continued)	methyldopa po.	EML	CVD
	sodium nitroprusside inj.	EML	CVD
	furosemide po.	EML; PEN	CVD
Medicines used in heart failure	spironolactone po.	EML; PEN	CVD
	dopamine inj.	EML	CVD
Diuretics (includes HCTZ,	amiloride po.	EML	CVD
furosemide, spironolactone)	mannitol	EML	CVD
Ant: platalat	acetylsalicylic acid (aspirin) po.	EML; PEN	CVD
Anti-platelet	clopidogrel po.	EML	CVD
	heparin inj.	EML; PEN	CVD
Anti-coagulants	enoxaparin inj.	EML	CVD
	warfarin po.	EML	CVD
	phytomenadione inj.	EML	CVD
	tranexamic acid inj.	EML	CVD
	protamine sulfate inj.	EML	CVD
	desmopressin inj./nasal	EML	CVD
Anti-thrombotic Medicines	streptokinase inj.	EML	CVD
Anti-thrombolic Medicines	alteplase inj.	EML	CVD
Lipid-lowering agents	simvastatin or other statin po.	EML; PEN	CVD
	HORMONES, OTHER ENDOCRINE	MEDS	
	gliclazide (or glibenclamide) po.	EML; PEN	DM
	metformin po.	EML; PEN	DM
Insulins and other medicines	Insulin, soluble inj.	EML; PEN	DM
for diabetes	intermediate-acting insulin (NPH) inj.	EML; PEN	DM
	long-acting insulin analogues (degludec, determir, glargine)	EML	DM

Pharmacologic Group	Medicine name (INN), route List		Therapeutic Group	
Insulins and other medicines			DM	
for diabetes (continued)	diazoxide po.	EML	DM	
MEDICINES FOR MENTAL AND BEHAVIORAL DISORDERS				
	chlorpromazine po./inj.	EML	MBD	
	fluphenazine inj.	EML	MBD	
Medicines used in psychotic disorders	haloperidol po/inj.	EML	MBD	
	risperidone po.	EML	MBD	
	clozapine po.	EML	MBD	
Medicines used in mood disorders	amitriptyline po.	EML	MBD	
Medicines used in depression	fluoxetine po.	EML	MBD	
	carbamazepine po.	EML	MBD/Neuro	
Medicines used in bipolar	lithium carbonate po.	EML	MBD	
disorders	valproic acid (sodium valproate) po.	EML	MBD /Neuro	
Medicines for anxiety disorders	diazepam po.	EML; PEN	MBD/Neuro	
Medicines for obsessive- compulsive disorders	clomipramine po.	EML	MBD	
Medicines for disorders due	nicotine replacement therapy (NRT) po/patch	EML	TCN	
to psychoactive substances	buproprion po.	EML	TCN / MBD	
	varenicline po.	EML	TCN / MBD	
	ANTICONVULSANTS / ANTIEPILE	EPTICS		
	lamotrigine po.	EML	Neuro	
	lorazepam inj.	EML	Neuro	
Includes Carbamazepine, Valproic acid, diazepam,	magnesium sulfate (sulphate) inj.	EML; PEN	Neuro	
midazolam	phenobarbital po.	EML	MBD/Neuro	
	phenytoin po/inj.	EML	Neuro	
	ethosuximide po.	EML	Neuro	

Pharmacologic Group	Medicine name (INN), route	List	Therapeutic Group
	ANTI PARKINSONISM MEDICI	NES	
	biperiden po/inj.	EML	Neuro
	levodopa + carbidopa po.	EML	Neuro
М	EDICINES ACTING ON RESPIRATO	RY TRACT	
	beclometasone inh.	EML; PEN	Respiratory
	budesonide inh.	EML	Respiratory
	budesonide + formoterol inh.	EML	Respiratory
	epinephrine inj.	EML; PEN	Respiratory
Antiasthmatics, medicines for COPD	hydrocortisone po.	EML; PEN	Respiratory
	ipratroprium bromide inh.	EML	Respiratory
	prednisolone po.	EML; PEN	Respiratory
	salbutamol inh.	EML; PEN	Respiratory
	tiotropium inh.	EML	Respiratory
AN	TINEOPLASTICS & IMMUNOSUPPI	RESSANTS	
Immunomodulators for non-	adalimumab (or certolozumab pegol, etanercept, golimumab, inflixi-mab) inj.	EML	Cancer
malignant disease	azathioprine po/inj.	EML	Cancer
	ciclosporin po/inj.	EML	Cancer
	arsenic trioxide inj.		
	all-trans retinoic acid (ATRA) po.	EML	Cancer
	allopurinol po.	EML	Cancer
	asparaginase inj.	EML	Cancer
	bendamustine inj.	EML	Cancer
Cytotoxic and adjuvant medicines, including	bleomycin inj.	EML	Cancer
targeted therapies, supportive medicines	calcium folinate po/inj.	EML	Cancer
	capecitabine po.	EML	Cancer
	carboplatin inj.	EML	Cancer
	chlorambucil po.	EML	Cancer
	cisplatin inj.	EML	Cancer

Pharmacologic Group	Medicine name (INN), route	List	Therapeutic Group
	cyclophosphamide po/inj.	EML	Cancer
	cytarabine inj.	EML	Cancer
	dacarbazine inj.	EML	Cancer
	dactinomycin inj.	EML	Cancer
	dasatinib po.	EML	Cancer
	daunorubicin inj.	EML	Cancer
	docetaxel inj.	EML	Cancer
	doxorubicin inj	EML	Cancer
	erlotinib (or afatinib, gefitinib) inj.	EML	Cancer
	etoposide po.	EML	Cancer
	everolimus po.	EML	Cancer
	filgrastim inj.	EML	Cancer
	fludarabine po/inj.	EML	Cancer
Cytotoxic and adjuvant medicines, including	fluorouracil inj.	EML	Cancer
targeted therapies,	gemcitabine inj.	EML	Cancer
supportive medicines (Continued)	hydroxycarbamide po.	EML	Cancer
	ibrutinib po.	EML	Cancer
	ifosfamide inj.	EML	Cancer
	imatinib po.	EML	Cancer
	irinotecan inj.	EML	Cancer
	lenalidomide po/inj.	EML	Cancer
	mercaptopurine po.	EML	Cancer
	melphalan inj.	EML	Cancer
	mesna po.	EML	Cancer
	methotrexate po.	EML	Cancer
	nilotinib po.	EML	Cancer
	nivolumab (or pembrolizumab) po.	EML	Cancer
	oxalaplatin inj.	EML	Cancer
	paclitaxel inj.	EML	Cancer

Pharmacologic Group	Medicine name (INN), route	List	Therapeutic Grou
	pergaspargase inj.	EML	Cancer
	procarbazine po.	EML	Cancer
	rasburicase inj.	EML	Cancer
	realgar-Indigo naturalis formulation po.	EML	Cancer
Cytotoxic and adjuvant	rituximab inj.	EML	Cancer
medicines, including targeted therapies,	tioguanine po.	EML	Cancer
(Continued)	thalidomide po.	EML	Cancer
	trastuzumab inj.	EML	Cancer
	vinblastine inj.	EML	Cancer
	vincristine inj.	EML	Cancer
	vinorelbine inj.	EML	Cancer
	zoledronic acid inj.	EML	Cancer
	abiraterone (or enzalutamide) po.	EML	Cancer
	anastrazole po.	EML	Cancer
Hormones and anti- hormones	bicalutamide (or flutamide, nilutamide) po.	EML	Cancer
	dexamethasone po.	EML	Cancer
	Hydrocortisone inj.	EML	Cancer
	leuprorelin inj.	EML	Cancer
	methylprednisolone inj.	EML	Cancer
	tamoxifen po.	EML	Cancer

Key:

ACEI – Angiotensin Converting Enzyme Inhibitor, ARB – Angiotensin Receptor Blocker, CCP – Country Capacity Profile (PAHO), COPD – Chronic Obstructive Pulmonary Disease, EML – Essential Medicines List (22nd WHO List of Essential Medicines), HCTZ – hydrochlorothiazide, INN – International Non-proprietary nomenclature (generic name), MBD – mental / behavioral disorders, PEN – WHO Package of Essential Noncommunicable disease interventions for resource-limited settings, po – oral dosage form; inj – for injection or infusion; inh – for inhalation, TCN – tobacco cessation.

7.2 Appendix 2: Interviews

7.2.1 Methodology

Semi-structured interviews with public health professionals took place in June 2019 following the guide available in Appendix 2. Interviews with personnel from the Ministries of Health aimed to confirm the existence of pharmaceutical policies and elements for rational use of medicines, to clarify the supply systems applicable to the country, and to identify successes and challenges of the existing system regarding access to NCD medicines. Interviews with procurement agencies were structured to gain an understanding of insight the existing supply system and its related successes and challenges. A total of 6 professionals from the following government authorities or agencies were interviewed:

- Barbados Drug Service
- Drug Inspectorate, Ministry of Public Health, Guyana
- National NCD Focal Point, Ministry of Public Health, Guyana
- Senior Medical Officer, Hope Institute, Jamaica
- National Health Service. Jamaica and
- OECS Pharmaceutical Procurement Service (PPS).

The interview guide was sent to prospective interviewees in advance, and where needed, alternate persons were recommended to be interviewed. Interviews were conducted virtually using an online meeting platform, or via telephone, and lasted between 20 and 60 minutes. It was not possible to solicit views directly from the private sector due to the virtual nature of the assessment, but questions were included to identify the challenges to patients accessing medicines in the private sector in their country.

To capture the perspective of civil society, semi-structured interviews took place in June 2019 with five members and/or representatives of four non-governmental organizations (NGO). The goals of the interviews were: to determine the accessibility of NCD medicines in public and private sector, and to identify challenges faced by patients when accessing NCD medicines in public and private sector in the given country. In some instances, the interviewees provided a patient perspective as they themselves were people living with NCDs currently taking medication. The NGOs involved were:

- Antigua and Barbuda Diabetes Association
- Cancer Society of the Bahamas
- Heart and Stroke Foundation of Barbados
- T&T NCD Alliance, with input from the Diabetes Association of Trinidad and Tobago.

Interview guide was also sent in advance and the interviews were also conducted virtually.

7.2.2 Interview guides

For Civil Society / Patient Advocates / NGOs

Name:

Position / Organization:

Contacted via:

1. For the treatment of NCDs that affect your members, do members have difficulty accessing NCD medicines in public sector? 2. What are the challenges faced by members when they try to access medicines for NCDs in public sector? 3. Which types of medicines are difficult to source in public sector? 4. Are medicines in public sector dispensed free to patients? / How do patients afford medicines in public sector? 5. How do patients pay for medicines in private sector? 6. What are the challenges faced by members when they try to access medicines for NCDs in private sector? 7. What do patients do when they cannot get a reliable source of their medicines?

8. Are there any other issues or concerns about access to medicines for chronic diseases you would like to include?

9. Do you have any suggestions to address the challenges that limit access to medicines for chronic diseases?

Date / time:

Thank you for your time

For National Regulatory Authority (Ministry of Health) Personnel

Interviewee:

Position:

Organization:

Date:

Is there a national medicines policy or individual polices that govern the following:

- Selection of essential medicines
- Procurement of essential medicines
- Pricing of essential medicines

- Prescribing of EMs
- Distribution of Ems
- Dispensing of EMs

Where can I get a copy?

1. Is there a National Drug Formulary List or a List of essential medicines for your country that informs procurement of medicines in public sector?

- 2. How are medicines selected for the formulary list / removed from the list?
- 3. Who is responsible for updating the list?
- 4. In developing the Formulary, is the WHO Model List of Essential Medicines used?
- 5. What other policies guide or inform the content of the Formulary List?
- 6. Is there a national medicines policy or plan that addresses NCD medicines directly?
- 7. How are prices of medicines determined?
- 8. How do patients pay for medicines for NCDs?
- 9. Are essential NCD medicines available free of charge in public or private sector?
- 10. Is the supply of NCD medicines in public sector consistent?
- 11. What contributes to stock-outs?
- 12. Is the supply of NCD medicines in private sector consistent?
- 13. What contributes to shortages / stock-outs in private sector?
- 14. Does your country utilize the PAHO Strategic Fund to source
 - Essential NCD medicines?
 - For medicines for cancer?
 - For medicines for tobacco cessation?

15. Are there any other special funds or programmes that your country utilizes to source essential NCD medicines?

16. Are there treatment programmes for tobacco cessation in your country?

- Public sector
- Private sector

17. Are there treatment programmes for harmful use of alcohol in your country?

- Public sector
- Private sector

Why (or Why not)?

19. What are the major challenges patients face when trying to access NCD medicines

- In public sector?
- In private sector?

25. Do you have any recommendations to address these challenges? 26. What are successes that have facilitated access to essential NCD medicines by patients in

[country]?

Thank you for your time.

18. Would you consider access to essential NCD medicines to be equitable in your country?

7.2.3 Interview Schedule

Country	Name of Representative	Name of NGO / Organization	Date
Antigua and Barbuda	Mrs. Juanita James	Antigua and Barbuda Diabetes Association	20th June, 2019.
Bahamas	Dr Christine Chin	Cancer Society of the Bahamas	25th June, 2019
Barbados	Ms. Michelle Daniel	Heart and Stroke Foundation of Barbados	19th June, 2019
Bal Dauos	Ms. Delores Mascoll	Assistant Director Supply and Inventory Barbados Drug Service	25th July, 2019
Guyana	Dr. Kavita Singh	Coordinator, Chronic Disease Unit, Ministry of Public Health	25th July, 2019
Jamaica	Mr. Everton Anderson Ms. Erica McIntosh Ms. Keron Mais	Chief Executive Officer Procurement Manager Director of Operations National Health Fund	23rd July, 2019
Trinidad and Tobago	Dr Karen Sealy Mr. Andrew Dhanoo Dr. Asante LeBlanc	TT NCD Alliance Diabetes Association of T&T Victoria Clinic	24th June, 2019 Written feedback: 28th June, 2019
OECS	Mr. Francis Burnett	OECS Pharmaceutical Procurement Service	

7.3 Appendix 3: Country Profiles

7.3.1 Antigua and Barbuda

National Strategic Multisectoral Action Plan

In 2015, the government of Antigua and Barbuda published its National Strategic Plan for Health 2016-2020, which identified strategic goals, interventions and outcomes for the four-year period. As one of the strategic objectives, the ministry of health identified a 25% reduction in morbidity and mortality due to NCDs, along with the goal of strengthening health systems to achieve universal health care and community empowerment.⁸⁵ In 2015, the Cabinet approved the National Policy for the Prevention and Control of NCDs. The multi-sectoral action plan 2015-2019 sets the primary goal of reducing the relative risk of premature deaths due to NCDs by 25% by 2019. This includes strategies such as health systems strengthening, and maintenance of a list of essential NCD medicines, and ensuring that essential NCD medicines are available.³² The list of essential medicines for Antigua and Barbuda available via WHO's database was published in 2007.⁶⁷

Medicines Policies and Programmes

Medicines for public sector are procured via the OECS-PPS and distributed free of charge to patients at public health facilities. The government of Antigua and Barbuda implemented a Medical Benefits Scheme in 1978 to facilitate greater access to health care, including medicines at affordable prices. **The scheme enables patients with specific diseases to receive health care and medicines at no direct cost to them**, except at the public hospital, where a user fee is charged. The MBS provides medicines for the treatment of eleven diseases: asthma, cancer, cardiovascular diseases, "certified lunacy", diabetes, epilepsy, glaucoma, hypertension, leprosy, Parkinson's disease, and sickle cell anaemia.³⁵ The scheme is financed through contributions by employers, employees, and self-employed persons.⁸⁶ The medicines selected for distribution under the Scheme are determined by the Board. Non-formulary purchases may be made with the approval of the Board, but the distribution may be delayed. In the event that a medicine is not available in the public sector, patients may purchase them from private pharmacies.³⁰

Availability of Essential NCD Medicines

The availability of the essential NCD medicines for Antigua and Barbuda is discussed in the section for the OECS-PPS for 2019-2021.

7.3.2 Bahamas

National Strategic Multisectoral Action Plan

The Commonwealth of the Bahamas' Ministry of Health published its Multisectoral NCD Strategy and Plan of Action for the Bahamas 2017-2022 with the aim of achieving a 10% reduction in preventable premature deaths due to NCDs by 2022. In the plan, one of the key strategic lines of action includes the reorientation of health services towards prevention and care of NCDs. One indicator for success of this line of action is the provision and updating of a list of essential NCD medicines.87

Medicines Policies and Programmes

The public healthcare system consists of the Ministry of Health, the Department of Public Health (DPH) and the Public Hospitals Authority (PHA). The DPH and the PHA provide direct patient care including dispensing of medicines at public health facilities. The procurement of medicines and medical supplies is undertaken by the Supplies Management Agency of the Public Hospital Authority. Health services and dispensing is also available in the private sector. Healthcare is paid for by one of three primary sources: general government health expenditure, private health insurance and/or out-of-pocket payments at both public and private facilities.⁷⁸ The National Prescription Drug Plan of the National Insurance Board assists to make NCD medicines accessible to the persons living with NCDs in public and private sectors. It also aims to prevent NCDs and their complications through health promotion. The plan provides medicines free to eligible persons, specifically older adults, children, indigent persons, government workers, pensioners and persons with disabilities.⁸⁸

Availability of Medicines

The procurement list of medicines available under the National Prescription Drug Plan, supplied to primary care health facilities in the Bahamas reflected 28.7% of the listed essential NCD medicines. This list does not include medicines used in tertiary care institutions (e.g. injections), and therefore does not reflect overall availability in the country. As a result, the lowest proportions were found for cancer medicines and those for palliative care. All the categories of essential NCD medicines were included, except nicotine replacement therapy, from highest to lowest proportion: diabetes medicines, respiratory medicines, cardiovascular medicines, mental / neurological medicines, cancer, and palliative medicines – Figure 8.

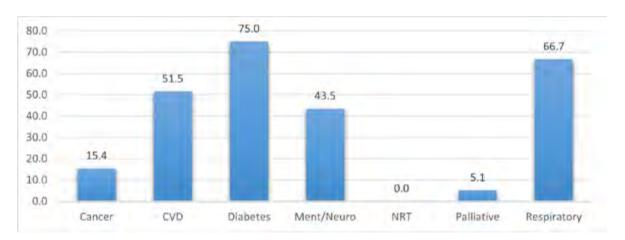


Figure 8: Percent of Essential NCD Medicines on Bahamas National Prescription Drug Plan List 2019

Key: CVD – cardiovascular, Ment/Neuro – mental health / neurological, NRT – nicotine replacement therapy

7.3.3 Barbados

National Strategic Multisectoral Action Plan

The Ministry of Health of Barbados has developed a national strategic plan of action for 2015-2019 to acquire a 25% reduction in premature deaths due to NCDs by 2025, and to reduce the preventable morbidity costs due to NCDs. In the plan's third strategic line of action, the government commits to support the strengthening of capacity and competencies of the health system, for the integrated management of NCDs. One of the key performance indicators related to medicines is the revision of the NCD formulary and completion of a national pharmaceutical plan.⁸⁹

Medicines Policies and Programmes

In Barbados, there is an essential medicines list that is incorporated into the National Drug Formulary. This list is developed by the National Drug Formulary Committee through the formulary development programme of the Barbados Drug Service (BDS). The National Formulary identifies medicines for use in public and private sectors of Barbados, and the BDS is responsible for procurement and distribution of the medicines nationwide. The BDS also provides a drug information service to prescribers and patients to support rational and appropriate use of medicines.⁹⁰ At the time of the assessment, the national standard treatment guidelines were under development. In the interim prescribers may refer to the regional standard treatment guidelines for NCDs (diabetes, hypertension, chronic respiratory diseases) developed by the Caribbean Public Health Agency (CARPHA).⁹¹

Financing of medicines in the public sector is through public funds, and some medicines are dispensed at no cost to patients seen in public health facilities. Medicines are classified into three categories that determine the price to be paid, if any. However, children, older adults and patients in need of financial assistance may access medicines from any of the categories free of charge. The National Drug Formulary classifies medicines into three categories that determine cost:

- Category A: Available to beneficiaries in both the public and private sector; Available at reduced price to non- beneficiaries through duty free and VAT zero-rated prices; Fully reimbursable to private pharmacies.
- Category B: Medicines that are not reimbursable in private sector but are available for public sector distribution via special authorization; reimbursable on special authorization.
- Category C: Branded medicines that are not available in public sector, but are available in private sector at reduced cost (tax-free) for purchase.⁹²

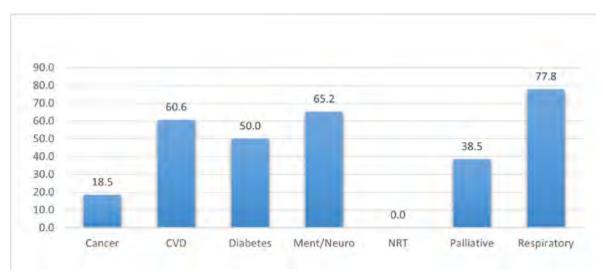
There is a special benefits service whereby participating private pharmacies provide free medicines at the cost of a dispensing fee, which is based on the price of the medicine. The pharmacy submits an invoice for reimbursement thereafter. In cases where patients have to purchase a medicine in the private sector, the payment is either out-of-pocket or via private health insurance.

Availability of Essential NCD Medicines

The price guide for procured medicines for 2018-2020 was used as a proxy for the comparison with the list of essential NCD medicines.⁹³ Overall, 41% of the essential NCD medicines were included. The list included essential NCD medicines from highest to lowest: respiratory medicines (78%).

mental / neurological medicines (65%), cardiovascular medicines (61%), diabetes medicines (50%), palliative medicines (39%), and cancer medicines (19%).

Figure 9: Percent Availability of Essential NCD Medicines in Barbados Price Guide List 2018-2020



Key: CVD – cardiovascular, Ment/Neuro – mental health / neurological, NRT – nicotine replacement therapy

7.3.4 Belize

In 2013, the Belize National Plan of Action for the Prevention and Control of Non communicable Diseases (NCDs) 2013-2023 was published with aims to reduce the premature mortality caused by the four major NCDs (cardiovascular diseases, cancer, diabetes and lung disease) by 25% by 2023. The plan was developed collaboratively with the Ministry of Health and relevant stakeholders involved in NCD prevention, control and management and with technical assistance from the PAHO Regional Office, Washington and the Instituto de Nutrición de Centroamérica y Panamá (INCAP).

The country has a multi-sectoral NCD commission chaired by the Director of Health Services of the Ministry of Health (MOH) with a stated goals to foster a multi-sectoral approach to addressing the epidemic of NCDs, to advocate and ensure appropriate policies and guidelines are put in place for NCD prevention and control, and to advise the Minister of Health on NCD policies and legislations. Planned actions in the strategy in the context of access to essential NCD medicines include:

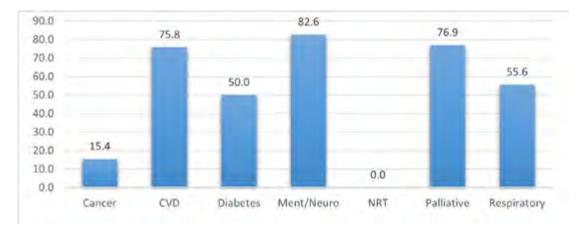
- Use of the PAHO Strategic Fund and Revolving Fund and/or other cost-saving mechanisms to procure essential medicines and health technologies relevant to prevention, control and palliation for the four leading NCDs including palliative care; and
- Expansion of social protection policies to provide universal health coverage and more equitable access to services, essential medicines, and technologies for NCD diagnosis, treatment, rehabilitation, and palliative care.

The following essential NCD medicines are available free in Belize: aspirin, insulin, metformin, thiazide diuretics, ACE inhibitors, calcium channel blockers, statins, morphine, steroid inhalers, and bronchodilators.

Availability of Essential NCD Medicines

The national formulary manual of Belize 2009-2011 included 52.2% of the listed essential NCD medicines. The formulary included essential medicines for mental / neurological conditions (83%), palliative care (77%), cardiovascular disease (76%), respiratory conditions (56%), diabetes (50%), and cancer (15%).

Figure 10: Percent Availability of Essential NCD Medicines in Belize National Formulary 2009-2011



Key: CVD – cardiovascular, Ment/Neuro – mental health / neurological, NRT – nicotine replacement therapy

7.3.5 Guyana

National Strategic Multisectoral Action Plan

The Ministry of Health of Guyana has published its National Strategic Plan for the Integrated Prevention and Control of NCDs and their Risk Factors 2013-2020. Consistent with the frameworks of WHO and the PAHO, the strategic plan of Guyana addresses the four major NCDs that cause premature death: cardiovascular disorders, cancer, diabetes and chronic respiratory diseases, and their risk factors. Among the lines of action identified, the plan includes strengthening health systems for the integrated management of chronic diseases, to reduce premature mortality due to NCDs by 14% by 2020. Under Priority Action 5, one of the activities to support the provision of essential medicines for NCDs and risk factors is the updating of the national formulary to include generic, essential medicines for NCDs and smoking cessation.⁹⁴

Medicines Policies and Programmes

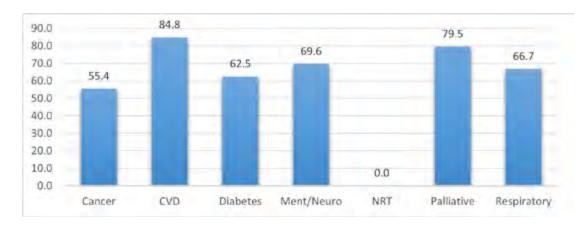
There is a national list of essential medicines, which was published in 2013, and being revised in 2019. The current list had not been published at time of this report. The national EML informs procurement of medicines for use in public health facilities, and is revised by the National Therapeutics Committee. Its content is guided by standard treatment guidelines (STGs), which are updated every five years, and is informed by the WHO Model List of Essential Medicines. Where needed, evidence-based guidelines, peer-reviewed literature, and guidelines of established societies (e.g. International Society of Paediatric Diabetes) may be considered in revision of the STGs and the EML. For the management of the four major NCDs in public health, the Ministry of Health has introduced STGs to guide prescribing, but there may be deviations in practice.⁹⁵

Medicines are dispensed free of charge to patients in the public sector. However, in the private sector patients pay for medicines out-of-pocket or via health insurance co-pays. There is a national social insurance scheme that subsidizes medicines up to 80% of the cost, but this only applies if the condition was developed before age 55. Once a patient claims for a condition, he or she is required to report all subsequent events to ensure the conditions and its complications are covered.⁹⁵

Availability of Essential NCD Medicines

Based on the essential medicines list of Guyana (2020-2022), 122 (68.5%) of the indicator medicines were included. The EML includes 85% of cardiovascular medicines, 80% of palliative care medicines, 70% of medicines for chronic mental / neurological conditions, 67% of respiratory medicines, 62.5% of medicines for diabetes, and 55% of cancer medicines – **Table 4, Figure 11**.

Figure 11: Percent Availability of Essential NCD Medicines in Guyana EML 2020-2022



Key: CVD – cardiovascular, Ment/Neuro – mental health / neurological, NRT – nicotine replacement therapy

7.3.6 Jamaica

National Strategic Multisectoral Action Plan

In 2013, the Ministry of Health of Jamaica published its national strategic plan for noncommunicable diseases 2013-2018, which identified goals, targets, indicators for the prevention and management of NCDs. The MAP refers to treatments for all five types of NCDs, smoking cessation and alcohol abuse. Strategies to support access and rational use of essential NCD medicines that are addressed include revision of the EML (known as the Vital-Essential-Necessary or VEN List), review of the supply chain or procurement processes, and the revision of standard treatment guidelines for prescribing.⁹⁶

Medicines Policies and Programmes

The list of essential medicines (VEN list) informs procurement of medicines. The selection of medicines on the VEN list is determined by the Central Therapeutics Committee (MOH) with consideration of input from therapeutics committees of public hospitals and expert groups. The VEN list is informed by the WHO Model List of Essential Medicines, and is reviewed every two to four years.^{97,98} Medicines for the treatment of NCDs are made available in public and private health facilities or pharmacies through the National Health Fund (NHF). The NHF is responsible for procurement, warehousing and distribution of medicines to public health facilities and to community pharmacies, called DrugServ pharmacies, where patients may access NCD medicines free of charge. The NHF is guided by the Government of Jamaica's public procurement policy and guidelines when undertaking procurement of medicines. Medicines must be registered under the Food and Drug Act through the Ministry of Health and must be of acceptable quality. At times, special arrangements can enable NHF to source unregistered products. The NHF uses an international competitive bidding process, which involves specific criteria (national registration of product, good quality, and lowest bid price). Other methods may be used for hard to source medicines, e.g. donors, PAHO Strategic Fund.⁹⁷ [Jamaica V.E.N. list 2015 at: https://moh.gov.jm/ wp-content/uploads/2015/12/Ven-List-2015.pdf.]

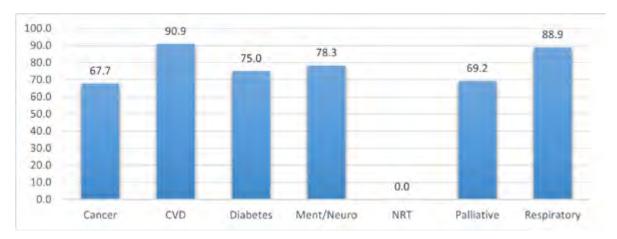
The NHF card allows citizens with any of 17 NCDs to get subsidized medicines through private **pharmacies**. The NHF pays fixed a portion and the patient pays a co-pay, based on the pharmacy's mark-up. The programme is governed by eligibility rules which determine who accesses the benefit, what is accessed, and frequency of access. Each patient is registered with the given conditions and can only access medicines approved for the treatment of the listed conditions. The plan's rules also govern quantity, with consideration of the physicians' input with respect to severity of the conditions (expected consumption / use). The list of items that may be accessed are not limited to VEN list, allowing patients access to a wider selection of medicines. This subsidized programme enables patients to access medicines at more affordable prices, improving equity.^{97,99}

The NHF also administers the Jamaica Drug for the Elderly Programme (JADEP) where patients over the age of 55 can access prescription medicines at no charge. The patient only pays a dispensing fee to the pharmacy.¹⁰⁰ Furthermore, patients may use their NHF card with the JADEP card to cover the cost of prescription medicines. In addition, the government has implemented a National Health Insurance Plan to enable more sustainable health financing and thereby facilitate equitable access to care including medicines.¹⁰¹

Availability of NCD Medicines

The procurement list of the national procurement agency (National Health Fund) of Jamaica included 74.7% of the essential NCD medicines. The availability of essential NCD medicines from highest to lowest was: cardiovascular medicines, respiratory medicines, mental / neurological medicines, diabetes, palliative medicines, and cancer medicines. Treatments for smoking cessation and harmful use of alcohol were not included. See Table 11 and Figure 12 for percent availability.

Figure 12: Percent Availability of Essential NCD Medicines on Jamaica Procurement List 2021-23



Key: CVD – cardiovascular, Ment/Neuro – mental health / neurological, NRT – nicotine replacement therapy

7.3.7 St. Vincent and the Grenadines

National Strategic Multisectoral Action Plan

The national strategic action plan for NCDs in St Vincent and the Grenadines encompasses the treatment of the four major NCDs. There are mental health services in the public sector that provide treatment for mental health conditions, smoking cessation and alcohol abuse, but the plan does not focus on these. The MAP includes strategies to support access to and rational use of essential NCD medicines, specifically improvement of supply, pharmaceutical legislation or governance, standard treatment guidelines, and drug use reviews.¹⁰² These strategies are implemented in the context of the existing pharmaceutical system.

Medicines Policies and Programmes

Like Antigua and Barbuda, St. Vincent and the Grenadines is a member of the Organization of Eastern Caribbean States (OECS), which uses the pooled procurement system through its Pharmaceutical Procurement Service (PPS). The OECS-PPS Formulary Manual is used as a guide for health professionals working in public health facilities. In the public sector, medicines are available free of charge to persons under the age of 17, those over the age of 60 years, and patients who receive public assistance (welfare). All other adults between 18 and 60 years of age pay a user fee for the service. In the private sector, medicines are available for purchase from pharmacies. The price of the needed medicine is subject to the cost of acquisition and a mark-up, which is determined by the pharmacy owner. However, the government regulates pricing in the private sector at a rate of 13% to control prices. Private health insurance schemes may enable lower payments for subscribers, but the medicines covered are limited by the company's formulary, and the ceiling amounts for deductions and co-payments are unknown. Otherwise, patients who do not have health insurance pay out-of-pocket. In addition, it actively conducts a medicines price monitoring system, and mandates the publication and broadcast of retail prices of medicines.94

Availability of Medicines

The availability of the essential NCD medicines for Antigua and Barbuda is discussed in the context of procurement by the OECS-PPS.

7.3.8 Suriname

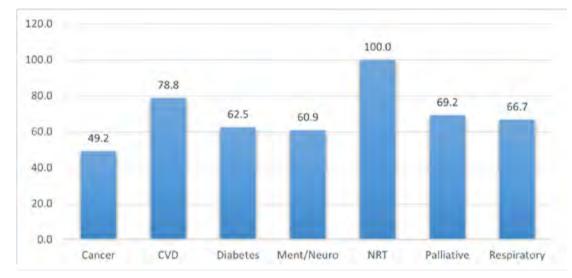
National Strategic Multisectoral Action Plan

This NCD Action Plan of Suriname was developed under the direction of the Ministry of Health (MOH), in collaboration with the Bureau of Public Health (BOG), the Regional Health Services (RGD), and Medical Mission (MM), with support from other partners, such as PAHO/WHO, the Caribbean Epidemiology Centre (CAREC), and the Centers of Disease Control (CDC). Workshops with various stakeholders and consultations were held in March 2010, from which participants identified component to include a plan of action, gaps and priorities for implementing an integrated approach for addressing NCDs.

Availability of Essential NCD Medicines

Based on the essential medicines list of Suriname (2020-2021), 111 (62.4%) of the indicator medicines were included. The EML includes nicotine replacement therapy (gum, patch), cardiovascular medicines (79%), palliative care medicines (69%), respiratory medicines (67%), medicines for chronic mental / neurological conditions (61%), medicines for diabetes (63%), and cancer medicines (49%) – Table 4, Figure 13.

Figure 13: Percent Availability of Essential NCD Medicines on National EML of Suriname 2020



Key: CVD – cardiovascular, Ment/Neuro – mental health / neurological, NRT – nicotine replacement therapy

7.3.9 Trinidad and Tobago

National Strategic Multisectoral Action Plan

The National Strategic Action Plan for the prevention and management of NCDs in Trinidad and Tobago was published in 2017 for the period 2017-2021.³⁰ Its focus is primarily on the treatment and prevention of the four major types of NCDs, as treatment for mental disorders may be captured under mental health services. Similarly, treatment for smoking cessation and harmful use of alcohol may be undertaken by mental health services in public sector. Approaches that support access and rational use of essential NCD medicines addressed by the MAP include the use of standard treatment guidelines (hypertension, diabetes, respiratory conditions). These approaches are implemented in the context of the health care system and the pharmaceutical situation of Trinidad and Tobago.

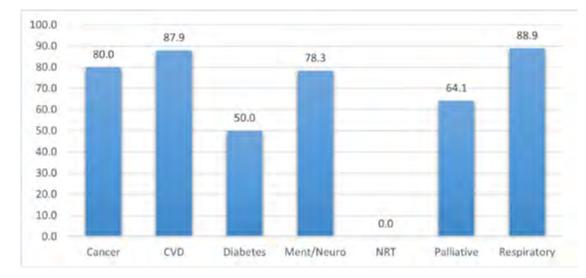
Medicines Policies and Programmes

The government provides universal access to health care and medicines free of charge to residents of Trinidad and Tobago via public health facilities. This is financed primarily through a Health Surcharge (or tax) paid by working persons. The medicines that are available for dispensing in public health facilities are determined by the National Formulary Manual and presented as a Vital-Essential-Necessary (VEN) List. There are regional and local standard treatment guidelines that may be used to guide prescribers in the public sector. The functions of procurement and distribution of medicines for the public sector are undertaken by the National Insurance and Property Development Company (NIPDEC). Through an information management system located at public health facilities, staff at NIPDEC can monitor stock levels of medicines and forecast needs of various public health facilities. In 2003, the government introduced the Chronic Disease Assistance Programme (CDAP), which expanded the distribution of medicines for four of the five major NCDs to private sector pharmacies for ambulatory patients. Members of the public may access CDAP medicines via a standard CDAP prescription issued by physicians in public and private sector. The programme does not include medicines for cancer, smoking cessation or alcohol abuse. Alternatively, patients may purchase medicines directly from private sector pharmacies. In these cases, payment may be out-of-pocket of via private health insurance. However there are no provisions for price monitoring for pharmaceuticals in the private sector.^{103,104}

Availability of Essential NCD Medicines

Overall 76.4% of essential NCD medicines were included on the public sector procurement list 2020-2021 for Trinidad and Tobago, from highest to lowest: respiratory medicines, cardiovascular medicines, cancer medicines, mental / neurological medicines, palliative care, and medicines for diabetes – Table 11, Figure 14.

Figure 14: Percent of Essential NCD Medicines in Trinidad and Tobago Procurement List 2020-2021

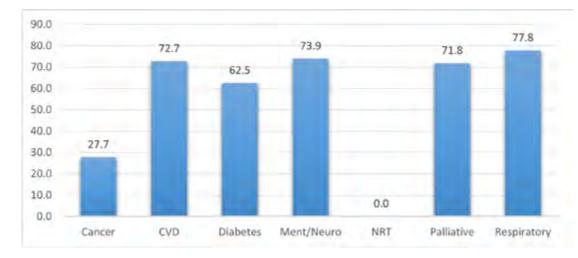


Key: CVD – cardiovascular, Ment/Neuro – mental health / neurological, NRT – nicotine replacement therapy

7.3.10 OECS Pooled Procurement

The pooled procurement of essential NCD medicines by a single agency (OECS Pharmaceutical Procurement Services) provided insight into availability across all 10 participating member states, including 6 CARICOM countries. Medicines are selected based on the regional formulary manual, and tenders are awarded by competitive bidding for two-year periods. The review of the tender awards for 2019-2021 found that 99 (55.6%) of the 178 selected indicator medicines were included for the procurement period. Inclusion in the list by the NCD medicine class, from highest to lowest were: respiratory medicines, mental / neurological medicines, cardiovascular medicines, palliative medicines, diabetes medicines and cancer medicines – Figure 15.

Figure 15: Percent of HCC Essential NCD Medicines in OECS-PPS Award List 2019-2021



Key: CVD – cardiovascular, Ment/Neuro – mental health / neurological, NRT – nicotine replacement therapy

7.4 Appendix 4: Case Study Interview Guide

Date:
Name:
Country:
Age:
Gender:
Noncommunicable disease (s):
Medications (how often do you take each and
What can you say about your overall experien
Where do you get your medicines (pharmacy,
Are your medicines always available when yo
What happens when they don't have your med
Do you ever try to get an alternative or simila
Do you always take the medication the way y not, why not? What happens if you don't?
How much does your medicine cost (per weel
How do you pay for your medicine? (who pays
What do you think about the cost of your medican pay for it?)
(What happens if you can't afford the medicir
Do you always use the brand name medicine
Do you ever worry about the quality of your m
Do you think your medicine is helping you? (qu
Do you ever tell your doctor if you think it is n
Do you have any side adverse side effects that the medicine advisory?)
Do you report these to your doctor or nurse?

Do you have any suggestions of how your access to medicines could be improved (made easier)

Id how long you have been taking each)? ence in getting the medicines you need? cy, healthcentre, doctor, hospital)? you need them? nedicine? What do you do then? lar medicine instead? your doctor has advised? Dosage and frequency? If eek/ per month)? iys?) edicines? (Do you have to sacrifice other things so you cines?) he that the doctor prescribes? (generics?) medicines or where it comes from? (quality) not working? that you didn't expect (either from the doctor or from

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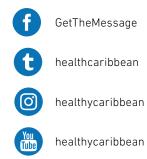
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Images: front cover: pg16: Falco/Pixabay| pg20 Sora Shimazaki/Pexels

Design and layout: Ian Pitts

ISBN: 978-976-8323-09-5

This report was developed with the support of the second phase of the NCD Alliance Civil Society Solidarity Fund on NCDs and COVID-19 in 2021, made possible thanks to the generous financial contributions of Access Accelerated, AstraZeneca, Ecobank Foundation, The Leona M. and Harry B. Helmsley Charitable Trust and Viatris.

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