Addressing the Gaps in Global Policy and Research for Non-Communicable Diseases

Policy Briefs from the NCD Working Group

Louis Galambos & Jeffrey L. Sturchio, Editors

Contents

Introduction

Non-communicable diseases (NCDs)—including cardiovascular disease, diabetes, asthma and chronic respiratory infections and cancers—are a leading cause of death worldwide; an estimated 36 million people die from such diseases each year, or roughly two out of three deaths globally; 80% of these fatalities occur in low- and middle-income countries.[1] These deaths are largely preventable, both through programs aimed at reducing high-risk behaviors and environments and also through improved treatment delivery for patients who need chronic care. Cost-effective interventions to reduce the burden of these diseases exist now and sustained action can prevent millions of premature deaths.

There has been growing awareness in the global health community of NCDs as primary threats to individuals, communities, health-system infrastructures and economic development. It is now acknowledged that NCDs contribute greatly to rising health care costs and the loss of economic productivity. A range of programs and interventions have been considered and some innovative efforts are underway, but positive outcomes have often been difficult to secure because of global inequities in healthcare access, the globalization of risk factors—many of which originate outside the health sector—and the costs of implementing interventions. In low- and middle-income countries, where the disease burden is transitioning from communicable to non-communicable diseases, many populations are currently suffering a double burden.

A global movement for action on NCDs has been gathering momentum in recent years. The UN General Assembly passed a resolution on the prevention and control of NCDs in 2010, followed in September 2011 by a High-Level Meeting that led to the adoption of a political declaration that laid out a clear plan for global surveillance, monitoring and health-system response to prevent and control NCDs. In May 2012, the WHO's 65th World Health Assembly set the first voluntary global targets for a 25% reduction in premature mortality from NCDs by 2025.

There are clear roles for the private sector as well as the public sector and civil society to work together in answering this call to action. Yet given the global fiscal crisis of recent years, it is unrealistic to expect large pools of new resources from traditional donors. Policy makers need to decide how best to incorporate NCD responses into existing funding streams and programs. We need recommendations for action that are sustainable in the current political and economic landscape.

This was the context in which the Johns Hopkins Institute for Applied Economics, Global Health and the Study of Business Enterprise convened an NCD Working Group of leading scholars to analyze gaps in NCD research, policy and practice, to make actionable recommendations to close the gaps.[2] Building on the 2011 RAND Report on "Improving access to medicines for non-communicable diseases in the developing world," they have focused on five areas where health systems need strengthening to address gaps in the provision of NCD care and treatment: structuring supply chains, accelerating regulatory harmonization, improving access to interventions, restructuring primary care, and promoting multisectoral action.[3] The policy briefs collected here distill the findings of Working Group members from a series of research papers that will be published in coming months. The policy papers and briefs emphasize how industry can bring its expertise to bear on preventing and controlling NCDs in developing countries and emerging markets. Together they develop a pragmatic agenda for reducing the burden of NCDs and provide an initial roadmap for policy development and progress in the fight against these chronic conditions.

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Notes

1 World Health Organization, *Global status report on non-communicable diseases, 2010.* Geneva: WHO, 2011.

2 The members of the NCD Working Group are: Sir George Alleyne (former director, PAHO), Robert Black (Bloomberg School of Public Health, Johns Hopkins University), Felicia Knaul (Harvard Global Equity Initiative), Margaret Kruk (Mailman School of Public Health, Columbia University), Louis Galambos (Johns Hopkins University), Richard Laing (WHO), Soeren Mattke (RAND Corporation), Sania Nishtar (Heartfile Pakistan), Tom Quinn (Center for Global Health, Johns Hopkins University), Kenji Shibuya (Tokyo University), Jeffrey L. Sturchio (Rabin Martin and Johns Hopkins University), Brian White-Guay (Université de Montreal), and Prashant Yadav (University of Michigan).

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Regulation of medicines in low and middle-income countries: current challenges and future prospects

Brian White-Guay

The central issue

The growing burden of non-communicable diseases (NCDs) in low- and middle-income countries has highlighted the urgent need to improve disease surveillance and access to essential drugs and technologies.[1,2,3]

While the majority of countries have established national medicines regulatory authorities (NMRAs) responsible to review and approve medicines at the national level, these agencies often have very limited levels of available expertise and capability to fulfill all the essential functions of a regulatory authority.[4] This has led to delayed initiation of clinical trials and approval of medicines, as well as increased circulation of sub-standard products. Furthermore, many national regulatory agencies have limited or no capabilities in the surveillance and control of products' post-marketing experience.

Several initiatives developed to promote regional cooperation between NMRAs have evolved in recent years to increase the sharing of assessment expertise, the adoption of common technical standards, and the conduct of inspection activities to ensure that the quality standards of approved products are maintained.

Improving access to medicines aimed at reducing the burden of NCDs will require greater efforts in support of such regional cooperation schemes and in support of capacity building in NMRAs, alongside the appropriate convergence or harmonization of technical standards across regions.

Following the path of convergence, some regions may choose to extend collaboration to full harmonization of regulatory systems and procedures, but this will be a decision mostly influenced by their broader economic interests. At a minimum however, convergence is needed, especially in response to the globalization of medicines development and supply.

NMRAs from low- and middle-income countries face significant challenges to building capacity and expertise, but they also need to develop science-based regulatory decisions that are aligned with the public health needs of their respective populations. Novel approaches will be required to ensure that the purported benefit-risk profiles of products initially assessed in more developed settings will be extended and examined within the setting of intended uses in less affluent nations to help effectively lower the burden of NCDs.

Advancing regulatory science in the more developed countries should come with a renewed policy agenda from all stakeholders to commit human and financial resources to advance the foundations of the regulation of medicines in less developed countries. The objectives of improving access to safe and effective medicines and enabling local manufacturing capabilities to produce quality supplies in these countries can be realized in a timely manner through a more concerted approach.

Background

Regulatory agencies worldwide share a common overall objective of protecting public health by ensuring the efficacy, safety and security of the human medicinal products placed on their respective markets, but the variety of activities necessary to secure that goal are often not widely understood. It is useful to review the current progress and ongoing challenges which NMRAs in low-and middle-income countries are experiencing as they seek to establish and strengthen the core elements of regulatory systems:

Licensing of medicines

- *What is being done?* Efforts have been applied in recent years to improve access to treatments for neglected diseases, and recommendations have been made in support of regulatory expertise and capacity building in particular to close these gaps, especially in the African region.[5]

- *What challenges remain?* The professional staffs of NMRAs in low- and middle-income countries are limited in number and often lack the range of skills to accomplish all regulatory functions. This has led to heavy workloads, long delays for approval of applications, and the perception of a significant burden of administrative requirements that are duplicative between regulators. A recent study conducted in the sub-Saharan region concluded that the existing regulatory resources did not form a coherent regulatory system and that, on the whole, countries did not have the capacity to control the quality, safety and efficacy of the medicines circulating on their markets.[6]

Access to essential medicines

- *What is being done?* The third WHO Medicines Strategy has identified the need for both continuity and change in increasing global access to essential medicines.[7] Despite the progress made through collaboration with various stakeholders, there is an urgent need to close the availability gap.[8] WHO Prequalification of Medicines Program has been coordinating a novel quality risk assessment mechanism with the establishment of an expert review panel. This process was well accepted by manufacturers and procurement agencies; numerous products became prequalified or approved by a stringent authority.[9] The WHO also established the Good Governance for Medicines program to reduce corruption in pharmaceutical systems through transparency and accountability in all administrative procedures.[10] Efforts in support of regulatory convergence or harmonization and capacity building must embody the program's objectives to reduce the risk of unethical behavior.
- *What challenges remain?* The availability of medicines for both acute and chronic conditions was found to be suboptimal across a recent survey in 40 developing countries, particularly in the public sector.[11] Availability of medicines for chronic conditions was lower than for acute conditions, suggesting that in efforts to improve management of NCDs, specific measures should be prioritized to improve access through NMRAs by low-and middle-income countries with the support of WHO and international regulatory agencies.

Multisource products

- *What is being done?* WHO has provided guidance toward the harmonization of requirements for NMRAs, expanded its scope to regional harmonization efforts[12] and recently updated it to reflect evolving knowledge.[13] These standards have been applied successfully within the WHO Prequalification of Medicines Program with a view to guaranteeing the quality of supplies in the procurement of antiretroviral drugs for HIV and other treatments for tuberculosis and malaria. Additionally, the WHO certification scheme is designed to provide assurance on the quality, safety and efficacy of pharmaceutical products imported by countries with limited regulatory capacity.[14] Its goal is to provide a standard format to facilitate exchange of information between NMRAs through a harmonized procedure and facilitate timely access to medicines by making greater use of data generated by other qualified reference NMRAs.
- *What challenges remain?* The WHO certification program encounters numerous problems in low- and middle-income countries, including lack of enforcement, counterfeit certificates, complex source routes that mask the real origin of products, administrative obstacles and the lack of a common global database for key information.[15] In the US, the FDA's new electronic drug registration and listing system might provide a useful model for adaptation, but the funding and management of such a trans-national system remain to be determined.

Inspections and quality control

- *What is being done?* The Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme (PIC/S) are international instruments between countries and pharmaceutical inspection authorities. Their primary mission is to lead the international development, implementation and maintenance of harmonized Good Manufacturing Practice (GMP) standards and quality systems of inspectorates. Industry representatives have called for greater use of mutual recognition agreements and/or memoranda of understanding to reduce the number of duplicative inspections by regulatory authorities around the world; greater focus on a risk-management approach for inspection; and increased acceptance of GMP certificates and certificates of pharmaceutical products prepared according to WHO recommendations and issued by competent regulatory authorities.
- *What challenges remain?* Few low- and middle-income countries currently participate in the PIC/S because of membership accession requirements. The presence of WHO as a partner organization to PIC/S does serve to ensure representation of their concerns and should be a basis for expanding and facilitating inspection harmonization efforts with low- and middle-income countries.

Clinical trials

- *What is being done?* The creation of the African Vaccine Regulatory Forum offers a new informal network of collaboration for the regulation of vaccine clinical trials and is increasingly recognized and supported by donors. The first Pan African Clinical Trials Registry[16] was established according to WHO's criteria. The recent creation of the Pan African Clinical Trial Alliance offers an opportunity to build harmonized procedures for review and ethical assessment of clinical trials, good clinical practice training, and support for joint inspections for vaccines and medicines in interventional clinical trials. PAHO in the Americas and the APEC Harmonization Center in the Asia-Pacific region are also working to establish common procedures and practices in the regulation of clinical trials.[17]
- *What challenges remain?* Continuing problems have been identified with respect to the conduct of clinical trials in low- and middle-income countries, especially regarding ethical considerations.[18] Other significant barriers include the lack of sufficient regulatory expertise and capacity in: application reviews, authorization of importation of clinical batches, infrastructure for the conduct of studies, certification of researchers and research centers, training in monitoring and good clinical practice

Regulatory constraints in low- and middle-income countries contribute to limiting access to essential medicines for treatment of both communicable and non-communicable diseases.

and funding mechanisms. Moreover, the need to conduct multi-country studies further compounds these challenges because requirements are not harmonized between countries. In a recent review the lack of regulatory capacity was identified as an important factor hindering trials and placing subjects at risk.[19] Strengthening regulatory capacity in the area of clinical trials review and oversight through international and regional cooperation should be a core objective.

Pharmacovigilance and risk management

- *What is being done?* Several barriers to the promotion of pharmacovigilance in low- and middle income NMRAs have been identified.[20] The importance of international collaboration in capacity building and training support in this field has been recognized and should benefit from the growing voluntary exchange agreements established between worldwide NMRAs, WHO and academic research centers. PAHO has sponsored the establishment of specific regional guidance in this area which represents a potential model for other regions.[21] There is growing support through the International Conference of Drug Regulatory Authorities. However, the number of low- and middle-income countries with national pharmacovigilance systems registered with the WHO remains quite limited, and increased access to medicines will not allow continuous monitoring of the risk-benefit profile in indigenous populations.[22]
- *What challenges remain?* The desirable goal of improving access through more efficient licensing procedures must be balanced by concerns about how these products will be used following their introduction to the market. Risks include unreliable supply chain systems for distribution, affecting quality and product performance, lack of trained health care workers that can advise on approved use and dosing information for patients, limited availability of treatment guidelines and information on risks for drug-drug interactions, and patients without the literacy level needed to follow safety warnings for their medicines. Finally, there are concerns over long-term adherence to chronic therapy, which has been identified as a global issue, with low- and middle-income countries rates even lower than the average of 50% reported for developed countries.[23]

Promoting regional cooperation of NMRAs

- *What is being done?* Two major regulatory harmonization efforts are ongoing in the Asia-Pacific region, one under the sponsorship of the Asia Pacific Economic Cooperation (APEC) and another under the Association of Southeast Asian Nations (ASEAN). The goal of putting in place an Asian Economic Community (AEC) with a single market is well underway, and this includes an initiative to achieve harmonization of technical standards and regulatory requirements under the pharmaceutical product working group (PPWG) in close cooperation with WHO, ICH, APEC and other partner organizations. In Latin America, PAHO[24] and the Pan American Network for Drug Regulatory Harmonization (PANDRH)[25] are major forces promoting the strengthening of national and regional regulatory authorities. In Africa, a more harmonized future is being promoted through the Southern African Development Community (SADC), the Pan-African Parliament,[26] and the World Bank. An innovative arrangement sees the World Bank acting as the fund holder for pooled funds going into the African Medicines Regulatory Harmonization (AMRH) initiative.[27] However, significant obstacles to the registration of medicines remain.[28]
- *What challenges remain?* There remains a wide resource gap between the NMRAs of low- and middle-income countries and those of high- or upper-income countries, and investments along a well-defined set of agreed priorities remain an important policy objective. Substantial differences in standards and policies persist among diverse nations. Furthermore, these examples from Africa, Latin America and the Asian Pacific illustrate that harmonization initiatives have been primarily built around existing frameworks of regional economic interests. The full realization of the benefits of harmonization demands greater support for inter-regional cooperation as well.

Promoting global cooperation of NMRAs

- *What is being done?* The International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) created the Global Cooperation Group. Regional Harmonization Initiative representatives can participate in ICH technical discussions in order to better understand and apply their guidelines. WHO has established many vital medicinal, clinical and technical standards and has promoted regulatory capacity building training for NMRA staff. WHO sponsors the bi-annual International Conference of Drug Regulatory Authorities with the goal of improving regulatory harmonization and promoting exchange of information between NMRAs. It has also been involved in the development of tools to assess the regulatory capacity of NMRAs and provide appropriate technical support and training to address the gaps identified.[29]
- *What challenges remain?* The ICH has primarily focused on new chemical and biological substances and dosage forms. The challenge of pursuing harmonization in areas that are more relevant to the needs of less developed regions remains to be fully realized. WHO leadership in coordinating training and building capacity in NMRAs to deal with the specific regulatory challenges of NCDs, and to fund research to identify existing problems, is needed.

Key findings

- Regulatory constraints in low- and middle-income countries contribute to limiting access to essential medicines for treatment

Expand support and global coordination from international health agencies, stringent regulatory agencies, academe, pharmaceutical industry, and NGOs for training efforts aimed at strengthening regulatory capacity (e.g. WHO's Prequalification of Medicines Program) and good governance.

of both communicable and non-communicable diseases.

- Few NMRAs from low- and middle-income countries can support and manage core regulatory functions on their own, and this has an effect on the timely conduct of clinical trials, pharmacovigilance and inspection activities.
- The major regulatory barriers are capacity, available expertise, information systems support, limited formal mutual recognition agreements with stringent regulatory agencies, duplicative and/or redundant administrative requirements, insufficient funding mechanisms and delayed implementation of good governance practices.
- Regulatory cooperation has progressed significantly over the last 10-15 years in non-ICH countries mainly around regional areas of economic interest with the continued support of WHO.
- There is a considerable range in the scope of declared regulatory goals and interests in certain regions, ranging from voluntary cooperation to the establishment of a single market.
- While the benefits of regulatory harmonization accomplishments under ICH can extend to other less developed regions, the specific needs of low- and middle-income countries need to be taken into further consideration.
- The current multiple sources of public/private/NGO support and assistance to regulatory capacity building in low- and middle-income countries remain fragmented, limited by institutional mandate, and would benefit from a more coherent global framework of execution.

Recommendations for action

Develop an end-stage vision for desired regulatory convergence efforts

- Develop a common end-stage vision for regulatory systems of NMRAs in each regional harmonization initiative based on the most urgent priorities to improve access to essential medicines and identify intermediate results indicators for the achievement of desired objectives.
- Review regulatory systems development proposals within each region of economic interest to gain Member States' full endorsement and support for execution over a defined time period.

Identify national and stakeholder funding model to support realization

- Expand innovative stakeholders' funding and execution to support mechanisms such as the one that was established with the World Bank in support of the African Medicines Regulatory Harmonization initiative.

Improve coordination of training and capacity building efforts

- Fund a research proposal to provide an updated comprehensive review and gap-analysis of core regulatory functions, capacity and systems in low- and middle-income countries under WHO sponsorship.
- Expand ICH/WHO support to facilitate adoption of existing guidelines and the development of guidelines for technical harmonization priorities in low- and middle-income countries.
- Expand clinical trial registration and scientific assessment support efforts in low- and middle-income countries for the assessment and monitoring of clinical trials through the regional harmonization initiative's plans, including access to a common searchable database for ongoing clinical trials.
- Expand support and global coordination from international health agencies, stringent regulatory agencies, academe, pharmaceutical industry, and NGOs for training efforts aimed at strengthening regulatory capacity (e.g. WHO's Prequalification of Medicines Program) and good governance.
- Improve overall NMRA transparency by improving access to assessment reports, inspection reports (e.g. WHO Public Assessment Reports, WHO Public Inspection Reports) and other important alerts and communications concerning the safe use of approved medicines.

Improve regional cooperation efforts and information exchange platforms

- Identify current best-practices for core regulatory functions across regional harmonization initiatives and facilitate their assessment and transfer through a process supported by the International Conference of Drug Regulatory Authorities.
- Identify management practices and efficient administrative procedures that can reduce inefficiency and waste of limited resources in NMRAs.
- Support the establishment of a fully operational and funded network of quality control laboratories to limit the circulation of substandard or counterfeit medicines.
- Establish a secure exchange e-platform to facilitate communications and knowledge transfer between NMRAs from low- and middle-income countries and stringent regulatory agencies.
- Using models from the US and the European Union, develop access to database systems on manufacturing licenses and import authorizations and GMP certificates adapted to product applications for NMRAs in low- and middle-income countries.

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Improving access to medicines for non-communicable diseases through better supply chains

Lisa Smith and Prashant Yadav

The central issue

Priority Non-Communicable Diseases (NCDs),[1] such as diabetes, cardiovascular disease, chronic respiratory disease and cancer, represent a large portion of the total global morbidity and mortality. To reach the global goals for an annual reduction in death rates attributable to the primary chronic diseases (heart disease, stroke, cancer, diabetes and chronic respiratory diseases), multisectoral policies aimed at decreasing risk factors for NCDs as well as effective and affordable delivery of health sector interventions are needed.[2]

Delivery and provision of care for these disease areas require ongoing access to a broad set of medicines, consistent/ongoing adherence to treatment regimes, and use of diagnostics and medical devices, which vary in complexity, for management of each disease. Insulin, an essential medicine used in the management of diabetes, requires cold chain specifications and utilizes supply chain configurations that are distinct from general NCD medicine supply chains.

As a result, NCD supply chains and distribution systems must be equipped to support a diverse set of treatment provisions. While the function and structural organization of supply chains is increasingly understood and is improving, the global medicines market and supply chains for NCDs are still far from optimal. NCDs require unique considerations, such as a greater number of required treatments and diagnostics/management tools; ongoing treatment and disease management; and an increased level of training and involvement of medical professionals. Improving access to NCD medicines requires a thorough understanding of the structural obstacles in medicine supply chains, along with a holistic examination of access from the top of the supply chain to the end-patient.

Background

There is a wide spectrum of medicines and diagnostics used to treat non-communicable diseases, with multiple treatments often required for certain disease areas.

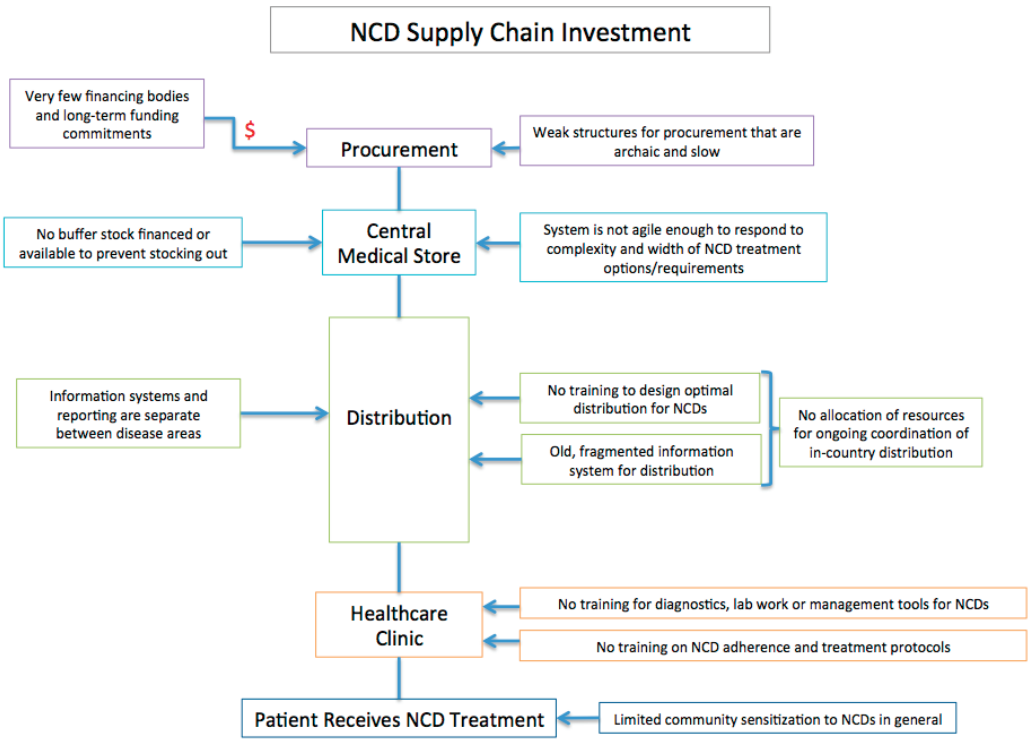
When physical architecture, information gathering and financial management are well aligned, supply chains can improve affordability, availability of diagnostics and medicines, and quality standards of treatments. Fewer divergent entities and tiers in the supply chain structure simplify the overall structure and improve the efficiency of information flows. Improved information transparency reduces stock-outs and supply imbalances. Less fragmentation in supply structures also improves pricing and overall affordability of products. Fewer intermediaries result in lower retail prices because of fewer distribution mark-ups at each tier. Decreased retail prices and higher availability lead to higher demand, which further decreases prices due to economies of scale achieved by manufacturers and distributors.[3] Overall, less fragmentation in the market enables better monitoring of quality along the supply chain and better adherence to standard treatment guidelines. It may also allow for improved tracking of the type of drugs procured and sold.

Key findings

In the current NCD medicines market, affordability remains a constraint for many individuals with non-communicable diseases. The long-term management of NCDs requires longer periods of purchasing treatments, which may mean larger financial burdens for patients over time. In addition, many individuals finance treatments for multiple chronic conditions, as NCDs are often caused by similar social determinants and exposure to related risk factors.[4]

Further, the shared risk factors and increasing connection between NCDs and communicable diseases means that management of comorbidities is increasingly common. As a result of these factors and the high percentage of out-of-pocket healthcare expenditures, non-functioning supply chains

Deficiencies in the current NCD supply chain



remain a key factor influencing the affordability of medicines.

The availability of diagnostics and medicines to treat non-communicable diseases also remains low. Without improved diagnosis, inappropriate treatment of individuals' symptoms and poor supply planning may continue to affect the global response to NCDs. Likewise, improved diagnosis without available treatments will deter individuals from seeking and potentially paying for diagnostic tools.

Many of the medicines included on the WHO essential list of medicines for NCDs are off patent; however, certain regulatory barriers continue to exist. Adoption and/or implementation of coordinated national strategies to prevent, treat and monitor non-communicable diseases have been limited.[5] The breadth of treatments and diagnostics required for the integrated management of NCDs presents new challenges for patients both in terms of affordability as well as diagnosis of conditions, familiarity with disease attributes and adherence to complicated treatment regimes.

With few NCD-specific national regulations and limited standard treatment guidelines, the quality of medicines is difficult to manage. Further strengthening of the regulation and management of drug quality is required.

In many developing countries, the focal points responsible for managing NCDs within the Ministry of Health have not yet been tasked with ensuring that there exists annual budget allocation for and program implementation of non-communicable diseases.

As a result, health system strengthening to support the distribution of NCD medicines and diagnostics along with treatments for prevalent communicable diseases has been limited.

The global response to the HIV/AIDS crisis provides a clear example of international community members and national stakeholders coordinating efforts to improve diagnosis and care of a specific disease. Efficient allocation of funds, coordination of partnerships and shared management of ongoing monitoring, and forecasting for matching supply and demand are elements currently lacking for NCDs at a global level. Though NCD working groups exist, few maintain a specific focus on the improvement and sustainability of supply chains for essential medicines and diagnostics across disease areas.

Recommendations for action

A well-functioning supply chain is critical to counter the rising burden of NCDs. For sustainable access to NCD medicines, changes need to be made to the architectures of both global and local supply chains. However, it is important to note that these modifications

Greater capacity for regulatory enforcement created with some limited funding through international financing mechanisms would improve access to high-quality medicines and lead to lowered risks of counterfeit products.

Efficient allocation of funds, coordination of partnerships and shared management of ongoing monitoring, and forecasting for matching supply and demand are elements currently lacking for NCDs at a global level.

can improve the effectiveness and efficiency of the supply chain only when there is a functioning ecosystem for NCDs. The prerequisites of such an ecosystem include:

- Healthcare workers trained and educated on NCDs
- Patient awareness of NCDs
- Availability of diagnostics
- Well-crafted healthcare financing policies that cover NCDs
- Better epidemiological data on NCDs to feed into planning and forecasting systems

Obtaining a full and clear picture of need and demand

Good demand forecasting is a prerequisite for building a well- functioning supply chain for NCDs and even more broadly to increase access to NCD medicines. Governments and international agencies need demand forecasts for budgeting and resource allocation for NCDs, while the supply system needs the forecasts to plan logistics for NCD medicines. Frequently updated information on epidemiological needs; availability of financing (public or private); information on standard treatment guidelines; and user preferences for NCD medicines are essential to knowing demand more clearly. In addition to knowing aggregate demand at a national level, it is also critical to better understand where people seek treatment for NCDs (public, private and NGO sectors), as this would vary significantly across therapeutic areas and regions. Industry associations such as the International Federation of Pharmaceutical Manufacturers and Associations and the Generic Pharmaceutical Association should commission studies to obtain a clear picture of need and demand for NCD medicines.

Innovative procurement for NCD medicines

Pooling the procurement of drugs enables small countries to obtain better prices and helps provide suppliers with a forecast of demand from a larger community of purchasers rather than relying on each individual tender. The Asthma Drug Facility is one such pooling arrangement targeted specifically at medicines for NCDs (i.e., asthma care). Many other innovative procurement initiatives exist, such as the Organization of the East Caribbean States.

Pooling arrangements for NCD medicines, diagnostics and other technologies should be considered based on the context and community of participants. Not all countries and products may be well suited to a pooling mechanism.

Differential pricing for NCD medicines

Pricing is seen as one of the key factors affecting access to NCD medicines in emerging markets. For newer NCD drugs—particularly those that have been patented—differential pricing is a sustainable way to provide access to NCD medicines to more people without compromising profits. The success of differential pricing requires cooperation from developing country governments, global agencies, NGOs, industry and academe. The NCD Alliance and other UN or multilateral agency task forces on NCDs should convene a platform that encourages continuing dialogue on issues that are preventing differential pricing from being used in a more scalable way.

Leveraging the private sector for supply chain services

Currently, in many low-income countries, the majority of medicines distribution is carried out by the government, through government-run Central Medical Stores and government-owned transport fleets. Long-term sustainable improvements in the supply chain for NCD medicines will require increases in effectiveness and efficiency to levels that can be guaranteed through increased competition in the supply chain. Private wholesalers or private logistics companies can work in tandem with the government to ensure consistent availability of a range of medicines in government health clinics at the lowest cost. This requires strengthening the capacity of the government to contract supply chain services. Global donor agencies should make this a high priority.

Strengthening pharmaceutical wholesalers

Pharmaceutical wholesalers provide a vital connection between the manufacturer and the retail pharmacy/drug store. In many low and middle-income countries the pharmaceutical wholesaling market is excessively fragmented, leading to poor scale economies, poor coverage and poor product traceability.

Pharmaceutical companies should work with three to four wholesalers/distributors in each country to enhance their distribution networks both in quality and reach. Pre-wholesaler models can facilitate this in each region. Wholesaler strengthening should be accompanied with complementary initiatives that will lead to smoother credit flows across different actors in the supply chain.

Accredited healthcare retail networks

In addition to improving access to medicines and diagnostics through coordination and quality improvements at the wholesaling level, ensuring access at the retail level is an equally important supply chain investment. One method for ensuring retail availability of quality medicines, appropriate prescribing practices and affordable pricing is through accredited healthcare retail networks. Accredited Drug Dispensing Outlets in Tanzania, CARE Shops in Ghana, and Child and Family Wellness Shops in Kenya represent three such models.

Standard treatment protocols for NCDs

Creation of national guidelines and treatment protocols for NCDs will facilitate better adherence to recommended treatment options, enable better supply chain planning and reduce irrational drug use. Poor adherence to guidelines makes demand for

particular drugs difficult to track and predict. This in turn inhibits effective supply planning and may lead to stock-outs, supply imbalances, and overall, lower availability and higher total costs. Standard guidelines will enable healthcare workers at different stages in the healthcare system to make decisions about appropriate treatments for specific NCD clinical conditions.

Select and implement a few targeted initiatives to improve supply chains

There are numerous challenges and needs for large-scale investment in the NCD supply chain. The work needed to improve the supply chains for all NCDs may appear overwhelming. The vast resources required and the necessity for concerted efforts from multiple actors could lead to inaction. While a well- functioning NCD supply chain is not feasible without a multi-disease focus, each NCD is different and may require a different set of tools, actions and interventions in the supply chain. Improving NCD supply chains will require a pragmatic, context-focused and adaptable approach. Selecting a few disease areas with the highest burden in poor countries can lead to concerted action and serve as an entry point to build robust supply chains for NCDs in consultation with local stakeholders.

Adapting NCD products for developing countries

Often, products must be adapted for the developing country context through modifications around packaging and appropriate dosage and administration forms. Manufacturers working with product development partnerships can play an important role in better adapting NCD medicines, diagnostics and preventive technologies where required.[6]

Better regulatory structures for NCD medicines

Both health and the economy in developing countries would benefit from investments in their drug regulatory systems. However, bilateral and multilateral donor agencies have not strongly incorporated this into their current investment strategies.[7] NCDs can provide a strong case for the value of investing in further strengthening of drug regulatory agencies' capacity in developing countries. Greater capacity for regulatory enforcement created with some limited funding through international financing mechanisms would improve access to high-quality medicines and lead to lowered risks of counterfeit products. In addition, these investments could help improve regulatory harmonization, along with reductions in the complexity of registration processes and specific labeling requirements, which sometimes prevent pharmaceutical manufacturers from registering certain NCD medicines in countries with small markets.

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Learning from the HIV/AIDS experience to improve NCD interventions

Soeren Mattke

The central issue

Reducing the burden of non-communicable diseases (NCDs) requires a balanced use of prevention and treatment of manifest disease, as has been done in the successful fight against the HIV/AIDS epidemic.[1] The focus of the public discourse to date, however, has largely been on prevention. This paper tries to bridge this gap by investigating how lessons learned in countering the HIV/AIDS epidemic can be applied to improving access to NCD treatment, and by outlining how the pharmaceutical industry can support such efforts.

Background

Making highly-active antiretroviral treatment available to HIV patients in developing countries was a key factor in containing the epidemic.[2] Theoretically, providing similarly broad access to treatment for NCDs should be achievable. NCDs are well-researched conditions for which drugs have long been available and an active drug development pipeline exists. Patent protection for first-line NCD medications has expired and drugs are widely available as low-cost generics.[3]

In practice, however, fundamental obstacles remain. The burden of NCDs exceeds that of HIV/AIDS by orders of magnitude, and the rapid increase in prevalence has left under-resourced healthcare systems to deal with a double burden of communicable and non-communicable disease.[4] Healthcare systems in developing countries are ill-prepared to handle NCDs, as they have historically focused on care for acute conditions, such as infectious diseases, injuries, and maternal and child health.

At the same time, it is unlikely that donor support can play a similar role as it had in the case of HIV/AIDS.[5] Thus, a robust response to the NCD threat in the developing world will require public-private partnerships that bring together local resources, donor funding and private sector contributions. This brief reviews how lessons learned from countering the HIV/AIDS epidemic can help to ensure timely diagnosis, referral to appropriate treatment, access to medicines and treatment adherence in NCD care, with a focus on sustainable models and public-private partnerships.

Key findings

Timely diagnosis

NCDs and HIV/AIDS share long latency-to-disease manifestation and the lack of specific symptoms at early stages. Educating patients and providers about risk factors and early symptoms is thus critical for diagnosis and referral to treatment. Countries such as Brazil, Senegal, Thailand and Uganda have been able to raise awareness for HIV/AIDS with political support; use of mass media; anti-stigma measures; and multi-stakeholder collaboration. Similar progress needs to be made in NCD detection.[6] For instance, two-thirds of diabetics in Kenya do not know they have the disease, but present with seemingly unrelated complaints.[7] Awareness of having hypertension ranges between 10% and 50% of patients.[8]

However, some progress is being made. Kenya's National Diabetes Strategy, for example, focuses on awareness and empowerment of patients.[7] Nokia and Arogya World, a US-based non-profit, collaborate on an SMS-based diabetes prevention program in India that hopes to reach 1 million consumers in rural and urban India over the next two years.[9]

Referral to appropriate treatment

Much like HIV/AIDS, NCDs are not curable and require lifelong treatment, implying a need for referral to appropriate treatment after diagnosis. The global response to the HIV/AIDS epidemic created a robust infrastructure for care delivery. WHO developed a public health approach to antiretroviral therapy that relies on a simplified decision algorithm so that lower-level health workers can deliver HIV care. The UNAIDS/ WHO Treatment 2.0

initiative aims at improving the efficiency and impact of HIV treatment programs and ensuring their long-term sustainability.[10]

Similar progress has yet to be made in NCD care. A recent study in 70 developing countries found that only about a third of respondents with a chronic condition had access to treatment.[11] Affordability of care remains a substantial obstacle, as many developing countries lack health insurance or access to subsidized care.[12] Providers are often unequipped to provide the continuity of care that NCD patients require, as medical records are organized by visit rather than by patients, and task shifting from treatment initiation to continuation of care does not occur.

Given the magnitude of the challenge of addressing gaps in infrastructure and insurance coverage, most efforts to date have focused on the near-term goal of provider education, as they were commonly less familiar with NCDs. The e-diabetes program, for instance, is a public private partnership supported by Sanofi. It trains providers in Francophone Africa through teleconferences on context-appropriate diabetes care.[13] A similar effort is the Changing Diabetes® in Children Program, a collaboration between the International Society for Pediatric and Adolescent Diabetes and Novo Nordisk.[14] More fundamental efforts exist as well. The Government of Jamaica has created the National Health Fund to subsidize NCD care, partly financed by a tax on tobacco products.[15] The Chinese Ministry of Health and the World Bank have jointly adopted a three-step approach with the aim of placing NCDs at the top of the government's agenda.[16]

Access to medicines

Access to medicines is a critical component for both HIV/AIDS and NCD treatment, and providing access to highly effective treatment is a remarkable success story in combating the HIV epidemic. Nearly half of eligible patients in low- and middle-income countries now receive antiretroviral treatment, which has averted an estimated 2.5 million deaths since 1995.[17] This success highlights the power of committed public-private partnerships. Its key components were large donor commitments, procurement support by the WHO's AIDS Medicines and Diagnostics Service and local government and non-governmental partners.[18]

Access to NCD medicines, however, remains limited in the developing world. A recent study, for instance, showed that medicines for NCDs are even less available than those for acute conditions, particularly in low- and lower-middle-income countries and in the public sector, because of factors such as regulatory burden, inadequate funding, poor planning, inefficient distribution and leakage.[19]

Resolving all of these obstacles will be challenging, as it would require fundamental changes in governance and funding of healthcare systems in the developing world —neither of which seems likely in the short run. But private-public partnerships have successfully expanded access. Novo Nordisk is currently piloting a model for insulin distribution in Kenya in partnership with local organizations and faith-based hospitals and clinics. Under this commercially sustainable model, the partners manage the entire supply chain and provide affordable access even in remote parts of the country.[20] A similar model has been introduced by Novartis in India—Arogya Parivar is a commercially viable venture that delivers nearly 80 pharmaceutical, generic and over-the-counter products as well as vaccines to poor and rural areas.[21]

Importance of adherence

In HIV/AIDS care, near-perfect adherence is a critical component to ensure reliable suppression of viral replication and decrease the risk of resistance formation. Recognizing this challenge, substantial efforts went into devising treatment protocols and tools to help patients adhere to complex regimens.

Adherence is also an important component of managing NCDs, but low adherence rates are a universal problem. As in the case of HIV/AIDS, low adherence can be caused by numerous interrelated factors, such as out-of-pocket costs, low levels of health literacy, the difficulty of treating asymptomatic diseases, depression, side effects of medications, and patients' lack of trust in their providers and treatments. However, there is more research available on how to overcome lack of adherence for antiretroviral treatment than there is for NCD drugs.[4]

Inspired by the success of fixed dose combinations for HIV/AIDS treatment, various "polypill" approaches have been proposed that combine multiple drugs like aspirin, statins, ACE-inhibitors and metformin into one pill.[22] The rationale behind the polypill is that diabetes and cardiovascular disease share common risk factors and that treating patients with a combination drug at low and safe doses will provide population-level benefits through risk reduction.[23] The safety and efficacy of this conceptually attractive approach is currently being studied in clinical trials. But it should be noted that polypills are mainly a risk reduction approach and that optimal disease management requires tailored treatment because of the complex etiology of NCDs. Such optimized treatment may not currently be feasible in resource-poor settings, but we should aspire to make it as accessible as possible.

Recommendations for action

Creativity and innovation will be required to mount a robust response and public-private partnerships will have to play a substantial role.[24] To successfully involve the pharmaceutical industry in such partnerships, two conditions have to be met. First, the initiatives have to leverage core industry capabilities. Second, while they may require initial private sector investment, solutions have to be viable in the long run under local resource constraints and governance, as industry alone cannot sustain efforts of the magnitude required to respond to the NCD challenge. This review has identified three areas in which industry should invest:

Improvement of care delivery systems

The pharmaceutical industry should bring its considerable expertise in treating NCDs to bear to help build NCD care capabilities and capacity. Developing countries commonly lack context-appropriate guidelines and training material for providers as well as patient education tools. Investing in such capabilities should also be in the interest of the pharmaceutical industry, as it will create the preconditions to have a sustainable market for medical products as countries grow wealthier.

Research on adherence solutions

Given the importance of long-term treatment adherence for NCD control, industry

should invest in research and development of innovations to improve adherence. This should encompass reminder systems and community support approaches, but also further research on polypills, if only as a bridge solution until tailored NCD treatment becomes more feasible.

Development of sustainable business models to improve access medicines

This review has pointed out several industry-supported concepts that offer safe, effective and affordable care in low-income countries. Successful models have also been developed locally, such as the Aravind Eye Care System in India.[25] Industry should help research and promulgate such innovative ideas that can concievably become models for the developed world, where healthcare systems and finances are increasingly strained by the growing prevalence of chronic disease.

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Reconfiguring primary care for the era of chronic and non-communicable diseases

Margaret Kruk, Felicia Marie Knaul and Gustavo Nigenda

The central issue

Non-communicable diseases (NCDs) are a rapidly growing contributor to death and disability worldwide. In fact, the vast majority of NCD deaths occur in low- and middle-income countries.[1] Yet the adverse effects of non-communicable diseases can be effectively mitigated through a combination of population- and individual-level actions.

Indeed, much of the opportunity in reducing the health and economic impacts of NCDs lies in prevention, early diagnosis and treatment—the domain of primary care.[2]

Primary care—defined here as first-contact care that promotes ease of access, care for a broad range of health needs, continuity, and the involvement of family and community—is perfectly positioned to be the main platform for the health system response to NCDs.[3,4]

However, health systems in low- and middle-income countries are fundamentally unprepared for tackling the NCD challenge because of their historic orientation toward infectious disease and maternal/child conditions, as well as persistently low funding levels.

The diagnosis and care of NCDs require a fundamentally different clinical approach because of the asymptomatic nature of early diseases, their chronicity and frequent co-morbidities.

Background

Conditions such as cardiovascular disease, diabetes, cancer and chronic respiratory disease are projected to cause 44 million deaths by 2010—80% of which will occur in low- and middle-income countries. This is due to a number of factors including aging populations, urbanization, changes in diet and activity levels, smoking and substantially higher mortality in poor countries. NCDs also tend to strike relatively younger people in low- and middle-income countries, with one in three NCD-related deaths happening in people under the age of 60.[5]

Primary care can address primary prevention as well as serve as the main platform for clinical management of existing disease and the prevention of sequelae. It is also a vehicle for providing palliation.[6] A great number of highly effective clinical interventions for NCDs can be provided by generalist health workers in a primary care setting.[7]

However in many low- and middle-income countries, primary care providers are untrained and unequipped to screen asymptomatic patients, much less provide long-term care to patients with NCDs.

Most health clinics are not equipped to promote continuity of care. In low-income countries, healthcare funding is barely adequate to treat infectious disease and much of the donor funding targets specific infectious and maternal/child conditions —explicitly limiting the use of funds for non-targeted conditions or general health system strengthening.[8]

Non-communicable diseases share several features that have important implications for the organization of care. One, they are interlinked and caused by many of the same risk factors. A high fat diet, smoking, and being overweight, for example, are risks for heart disease, stroke, cancer, and type II diabetes. Two, comorbidity or the occurrence of multiple diseases at the same time is common. Three, some NCDs are risk factors for others: diabetes increases the likelihood of heart disease and stroke, for example.

Four, they are chronic, lasting for many years and often decades. Fifth, while treatment can greatly reduce functional impairment, there is no cure for most NCDs. The goals of care are thus not to cure but to enhance functional status, minimize symptoms, and prolong and enhance the quality of life.[9] The chronicity of NCDs requires continuous monitoring and care as well as adherence to lifelong treatment. In this way, many of the non-communicable diseases resemble chronic communicable diseases, such as HIV.[10]

As these examples make clear, the patient, not the disease, needs to be the focus of diagnosis, care, and treatment and integration of

care needs to move from the rhetoric of Alma Ata to reality.[11]

This paper explores four levers to improve the functioning of primary care in the NCD era: integration of services, innovation in service delivery, inclusion of communities, and information and communication for better care.

Key findings

Integration and continuity of care

While in high-income countries integration of care implies removing boundaries between community, primary level, and specialist care, in low-income countries integration of care must begin with the reorganization of care delivery in primary care clinics where today's services are provided in silos.[12] As noted above, NCDs are characterized by shared risk factors, multi-morbidity and chronicity. Continuity of care with monitoring of risk factors, medication adherence and screening for complications is essential to forestall the progression of disease. This requires patient-centered, not disease-centered care, which is the current model in most low- and middle-income countries. For example, in most rural African clinics, patient records are organized by visit and not by patient, making follow-up and monitoring impossible.

In sub-Saharan Africa, the massive expansion of HIV treatment—which has many similarities to NCDs—has produced important lessons for NCD programming. These include: establishing multi-disciplinary care teams, introduction of patient-level medical records and appointment systems, and data systems that permit tracking of patient retention in treatment as models that can be used in managing NCDs.[13] Several clinics in Cambodia explicitly adapted an HIV chronic care model to the management of diabetes and hypertension.[14] While implemented in a referral hospital, most elements of this model can be replicated in a primary care setting.

Team-based care, by teams comprising professionals such as physicians, nurses, social workers and health educators, has been particularly effective at promoting ease of access, integration of services and continuity in countries like Brazil, Mexico and Costa Rica. Primary care in any setting also needs to be integrated with secondary, specialist care, which requires coherent referral systems.

Case Study: Adapting the HIV/AIDS chronic care model to diabetes and hypertension in Cambodia[14]

In 2002, two chronic disease clinics were established at provincial referral hospitals in Cambodia through a collaboration of the Cambodian Ministry of Health and Médecins Sans Frontières. These clinics sought to apply lessons learned in the management of HIV/AIDS as a chronic disease to diabetes and hypertension management.

Medical personnel were trained in current treatment guidelines and patients had individual records that were readily shared between services. Further, as per standard practice in the HIV clinic, financial barriers to access were assessed for each patient entering treatment.

All new patients followed an intake protocol adapted from established HIV/AIDS procedures. New patients were diagnosed and given a treatment plan in accordance with standard international protocols. Patient education and counseling were central with substantial time spent from the first visit onward on adherence to drug regimens, healthy lifestyle improvements, and patient empowerment and responsibility. Psychosocial support in the form of peer groups was implemented to improve adherence and retention.

Two years after the clinics were established, 71% of diabetes patients were in active follow-up as were 90% of diabetes patients from the initial 3-month cohort. Participating patients reported high levels of satisfaction.

The adoption of successful HIV/AIDS program components, especially psychosocial peer support groups and early patient education and counseling, in Cambodia led to high adherence rates after two years.

Innovations in service delivery

Shortages of physicians and nurses are pervasive in both low- and many middle-income countries, and are particularly severe in rural areas.[15] While 45% of the world's population lives in rural areas, only 25% of doctors practice there.[16] This limits the potential of the traditional physician-centered care model in addressing NCDs. Task-shifting, or the devolution of care from physicians to nurses and other health workers, is a promising approach to expanding access to NCD services. In Africa, non-physicians have achieved good results in treating HIV and other infectious diseases, as well as providing surgery and maternal health services.[17,18] One striking example of the potential of this strategy comes from Mozambique where 90% of rural Caesarian sections are performed by non-physician surgeons.[19] HIV programs have further extended the use of non-physicians to the care of communicable chronic disease with good results at low cost.[20,21,22] Non-physicians have further shown promise in caring for patients with cardiovascular disease in several low- and middle-income settings.[23]

There are comparatively fewer experiences in task-shifting for NCDs in Africa, although several countries are embarking on nurse-led approaches.[24,25] However, task-shifting is not an easy fix for weak health systems. It should be complemented by training more primary care doctors and reforming training to promote team-based care.[26] Scaling up task-shifting while ensuring quality care will also require supportive national policies, stable financing, functioning supervision systems, and regulatory reforms.[27]

Decision aids and protocols are invaluable in ensuring high quality care. Although NCD management guidelines exist in most countries, they are universally underused. Decision aids cannot be imposed top-down but need to be integrated into existing practices and supported by the broader health system to be used by providers.

Point-of-care testing that generates a diagnosis in real time without the need for a laboratory is a particularly exciting approach in detecting asymptomatic diseases early and monitoring for complications. Point-of-care tests now exist for cervical cancer, diabetes and hypertension, and their use is growing.[28] One example of a cheap and relatively simple test that can save lives is visual inspection with acetic acid for cervical cancer and pre-cancerous lesions. This test replaces the more complex Pap smear, which required pathological examination in a laboratory; even a single test in a woman's health history reduces the population risk of cervical cancer.[29] It has been shown to be highly

sensitive in identifying disease and feasible to implement primary care clinics in Sudan, Mozambique, Botswana, China and Peru.[30,31,32]

Inclusion of communities and patients in care

To scale-up diagnosis and care seeking, NCDs should be included in guaranteed benefit packages, and diagnosis and care of NCDs should be provided for free at the point of care.[33] In Costa Rica, this approach has resulted in 98% of the population having coverage for primary care treatment of diabetes and hypertension.[34] Health systems need to treat patients as legitimate stakeholders—not just beneficiaries—of healthcare. This requires reinforcing the concept of citizenship in healthcare, including the right to be treated competently and with respect by health providers.

Community health workers, non-health professionals who receive training in various aspects of NCD management, can improve outcomes by assisting individuals and communities with prevention and lifestyle management, case finding of asymptomatic disease and disease management.[35,36] Information and communication technologies for better care.

Mobile phone use has exploded in low- and middle-income countries. Mobile phone technology is thus increasingly being harnessed in healthcare for health promotion, medication adherence, appointment reminders and patient communication. Although there are few good evaluations of mHealth, this approach has shown promise for smoking cessation, and medication adherence for patients with chronic diseases.[37,38]

Recommendations for action

Primary care, as the level of care provision closest to the patient and the community and focused on the whole patient rather than a single organ or disease, has a starring role in the fight against NCDs. We suggest four universal elements that are essential to effective functioning of primary care in the NCD era:

Case study: "See and treat" mobile cervical cancer screening in Peru[30]

The Peruvian League to Fight Against Cancer is a private non-profit institution that has been using an innovative approach for early and effective diagnosis of cervical cancer among low-income women in Lima. Cervical cancer ranks as the most common cancer among women in Peru and 7.5% of the general population of women are infected with human papilloma virus—the cause of cervical cancer. However, given the strained Peruvian health system, many women fail to get diagnosed or treated for this highly preventable and curable cancer.

The organization uses a "See and Treat" approach that dispenses with the need for a return visit. Each woman receives a visual inspection of the cervix with acetic acid (VIA), which allows healthcare providers to make onsite assessments and provide immediate recommendations to patients. Patients are all also offered breast, thyroid and lymph node exams. All patients with a positive screen are referred to specialized care. Online medical records databases within the mobile detection unit track each patient.

The mobile units target remote and poor areas. To prepare a community for the screening, a social assistant spends time in the community to sensitize women about the importance of early diagnosis. The mobile units visit four communities each month and serve more than 5000 women each year. Between 2009 and 2010, the league screened 37,774 women for cervical cancer.

The innovative experience of the Peruvian League exemplifies that innovative technologies, in concert with strong outreach, can dramatically scale up screening for cervical cancer in underserved areas.

- **Integration of care:** Shifting from episodic care for discrete symptoms to continuous care for monitoring chronic illness and preventing complications.
- **Innovations in service delivery:** Task shifting of some primary care services to non-physicians; active use of treatment guidelines; and adoption of point-of-care diagnostic technologies.
- **Inclusion of communities and the voice of the patient:** Including NCDs as essential services and reducing financial barriers to access; understanding and incorporating patient preferences in the care delivery; and leveraging community and peers to support self-care.

Information and communication technologies

Exploiting the high penetration of mobile phones in low- and middle-income countries to promote information sharing and communicating health data in real time.

These innovations must be evaluated rigorously to ensure effectiveness and permit course corrections. Evaluation designs should use comparison groups, consider the effects of local context, and include assessment of implementation challenges. Thoughtful evaluation will not only provide important policy direction but can also help to build a platform for stronger health information systems.[39]

We have proposed a refocusing of primary care to promote high-quality, integrated and continuous services that are universally accessible. This reset offers an opportunity to fulfill and expand the vision of Alma Ata in a way that responds to today's health needs and builds a resilient base for tomorrow's health challenges.

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Sectoral cooperation for the prevention and control of non-communicable diseases

Sir George Alleyne and Sania Nishtar

The central issue

The major social problems of our time are by definition complex and—certainly in democratic societies—the only hope of addressing them is through the involvement of many parts of society. Difficult though collaboration may be, there is no other option. Health is one such complex social field.

In recent years, the threat that non-communicable diseases (NCDs) pose to public health has become better understood and more urgent. The compelling nature of the challenge of NCDs was clear from the September 2011 Political Declaration of the United Nations High-Level Meeting on the Prevention and Control of Non-communicable Diseases, which emphasized the critical need for a multisectoral response.[1] The term "multisectoral" was mentioned 15 times in the document, often in different contexts. The opening paragraph, under the heading of "Responding to the challenge: a whole-of-government and a whole-of-society approach," establishes the framework for a multisectoral approach. The document continues to state:

> "Recognize that the rising prevalence, morbidity and mortality of non-communicable disease worldwide, can be largely prevented and controlled through collective and multisectoral action by all Member States and other relevant stakeholders at local, national, regional and global levels, and by raising the priority accorded to non-communicable disease in development cooperation by enhancing such cooperation in this regard."

Thus there is a call for cooperation at the government level, with subsequent language naming possible sectors outside of health—education, energy, agriculture, sports, transport, communications, urban planning, environment, labor, employment, industry and trade, finance, and social and economic development.

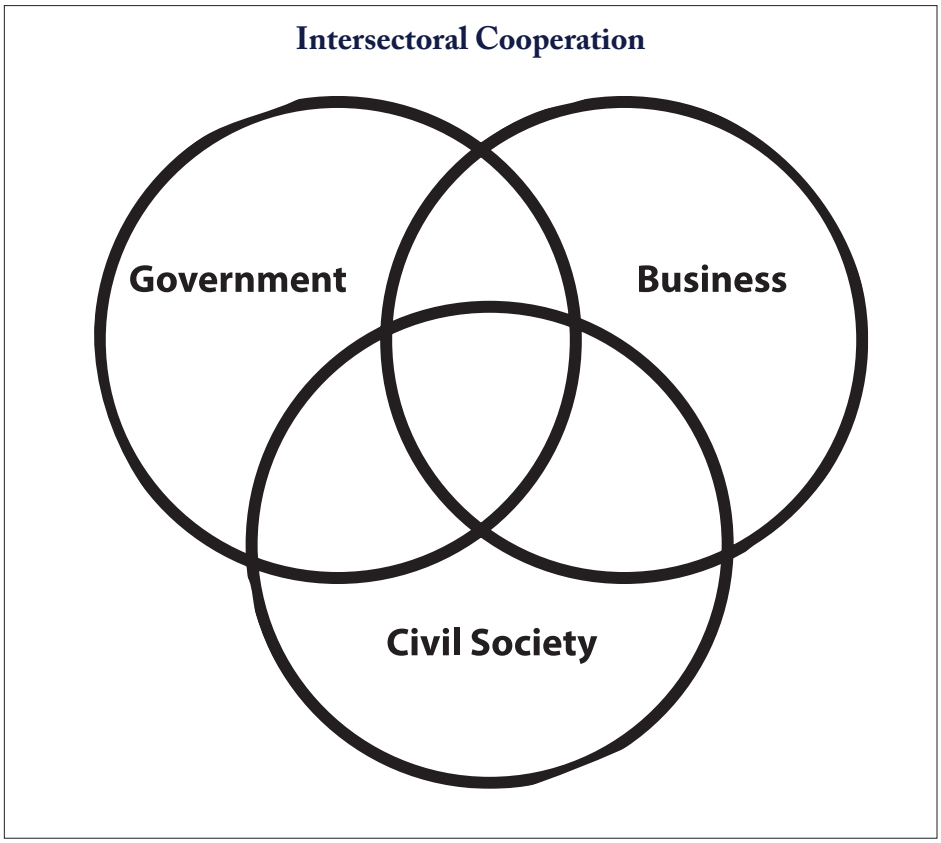
This policy brief explicates the nature and possibilities of the sectoral cooperation that is necessary in health and of particular relevance to the NCDs. It also reviews some of the historical and theoretical background as a basis for explaining the approaches that need to be considered in operationalizing the mandates of the declaration.

Background

Non-communicable diseases are now the leading causes of death globally. The World Health Organization estimates that 80% of deaths in low- and middle-income countries are due to NCDs. In 2008, nearly two-thirds of the 57 million deaths in the world were attributed to NCDs, with one-quarter of NCD-related deaths occurring in adults younger than 60-years-old.[2] In the next two decades, NCDs are estimated to cost society more than US$ 30 trillion.[3] It is not surprising that high-level political discussions to address NCDs emphasize the critical need for a multisectoral response.

The 2011 Political Declaration on NCDs stressed the importance of multisectoral action and sketched a framework for the collaboration of many different actors. The declaration also refers to the many arrangements to be made under this rubric —engagement, efforts, actions, approaches and interventions—noting the relation to national and public policies and emphasizing that effective responses to NCDs must be multisectoral as well. The Political Declaration also calls for the UN Secretary General to present "options for strengthening and facilitating multisectoral action for the prevention and control of NCDs through effective partnership." The World Health Organization has been engaged in an active process of consultation on the form and function of such multisectoral action.[4]

The Political Declaration emphasized the importance of multisectoral action for governments in a number of ways. Foremost among these was its advocacy for the "whole



of government" principle, and the notion of "health in all polices," directly, but also by calling for multisectoral national policies and national plans for NCDs; the integration of NCDs in national development agendas; and by consistently referring to a level of leadership in its language that placed responsibility at a level much higher than the Ministries of Health.

The declaration was not the first international normative instrument to emphasize the notion of multisectorality. This was evident in many of the fora leading up to the UN High-Level Meeting. The Caribbean Heads of Government, in their historic 2007 Summit in the Port of Spain on the Prevention and Control of NCDs, issued a 15-point declaration that emphasized multisectoral action:

> "The burdens of NCDs can be reduced by comprehensive and integrated preventive and control strategies at the individual, family, community, national and regional levels and through collaborative programs, partnerships and policies supported by governments, private sectors, NGOs and our other social, regional and international partners."

It also called for establishing National Commissions, which should be multisectoral.[5] The 54 Commonwealth Heads of Government, in calling for a UN Summit on NCDs in 2009, stressed the importance of sectoral cooperation in similar language, as did at least 20 other international instruments that referred to and emphasized the notion of multisectoral action in the years preceding the 2011 Political Declaration. But these documents left a certain ambiguity in the definition of what precisely was meant by multisectoral or intersectoral action, how such actions should be governed, and how to optimize their benefits.

Key findings

Multisectoral and intersectoral approaches

The term "sector" in this policy brief is understood in the social sense as a distinct subset of a market, society, industry or economy where components share similar characteristics. We assume that the term "multisectoral" was used in the Political Declaration on NCDs deliberately, but some of the contexts in which it was used would indicate that the concept of *intersectorality* was more appropriate. The terms multisectoral and intersectoral are often used interchangeably, but in our view there are fundamental differences in the two approaches—indeed, some of the approaches recommended in the document do not fall into a single category of being multisectoral. Thus, it is useful to examine more closely their specific definitions as they relate to health. The possible differences are not merely epistemological niceties, but represent fundamentally different approaches to structuring the possible solutions to health problems in general and NCDs in particular.

Multisectorality essentially refers to the interaction among the administrative agencies of the government, while *intersectorality* applies to the interaction among the three main actors of the State—the public sector, the private sector and civil society. Both approaches can be described as a form of partnership. Bryson et al. give a useful characterization of such partnerships. They describe a continuum, at one end of which we find organizations or sectors existing almost in isolation with hardly any contact between or among them. At the other end, they fuse so intimately as to result in the near formation of a completely new entity that takes on a character in which authorities and capabilities are merged.[6] Most arrangements occur somewhere along this continuum. A multisectoral arrangement would tend toward the isolation end of the continuum, while an intersectoral one would find itself toward the merged end of the continuum.

Defining multisectoral cooperation

It is possible to define multisectoral cooperation as one in which each party maintains its identity and approaches the problem from the perspective of its respective agency and with the use of its own resources. This is the more common situation within government in which sectors are usually within the administrative and political responsibility of a ministry or other government institution.

Intersectoral cooperation as currently interpreted

One can trace the interest in intersectoral cooperation back to the Declaration of Alma Ata, which, in defining primary healthcare, specified that it:

The private sector has accepted a corporate social responsibility and the theory that business, in general, does well by doing good. More recently the concept of shared value has been put forward, which proposes that the competitiveness of a company and the well-being of its community are mutually dependent and that there is an intimate connection between societal and economic progress.

> "...Involves, in addition to the health sector, all related sectors and aspects of national and community development, in particular agriculture, animal husbandry, food, industry, education, housing, public works, communications and other sectors; and demands the coordinated efforts of all those sectors."[7]

Note that the reference was uniquely to the institutions of government, and the standard requisites for effective primary healthcare were set out as intersectoral cooperation, appropriate technology and community participation.

More recently, this form of cooperation has been restricted to cooperation among the sectors of the State – the government, the private sector (or the market) and civil society. This is referred to in the Political Declaration within the context of the whole-of-society approach. However, some of the actors mentioned in the document who are critical to the prevention and control of NCDs—such as individuals, families and communities—do not usually contribute directly in sectoral approaches. Whereas in the case of multisectoral cooperation there is the assumption that there is uniformly a liberal interest in health matters, this cannot be assumed to exist in the sectors of the state. They have essentially different interests, but the assumption is that their peculiar skills and assets can be combined to improve health.[8] The government and its institutions should be concerned with public order and producing public goods. It has, at its disposal, the instruments of legislation, regulation and taxation, through which it can establish conditions for human development and pursue it, given that it is one of the highest societal goals. The market or the private sector is concerned with the efficient production of goods and services and has profit as its fundamental raison d'être. However, the private sector has accepted a corporate social responsibility and the theory that business, in general, does well by doing good. More recently the concept of shared value has been put forward, which proposes that the competitiveness of a company and the well-being of its community are mutually dependent and that there is an intimate connection between societal and economic progress.[9]

Civil society is not a monolithic entity. It comprises multiple groups, of which non-governmental organizations are but one. Its strengths as a sector lie in its ability to respond to different issues of societal importance and mobilize public opinion. The weaknesses intrinsic to its diversity are well known, as is its power to articulate and promote value-driven propositions and be a watchdog to prevent individual abuse by the government. In many instances it serves as an honest broker between government and the private sector.[10]

One view is that sectors of society collaborate only when they absolutely have to do so, and in other instances the collaboration is driven by external agents.[11] The success of possible intersectoral collaboration has been attributed to the following: forging initial agreements, building leadership, building legitimacy, building trust, managing conflict and planning.

They are all important, but perhaps priority might be given to building leadership, building trust and planning. The leadership usually comes from the government and one of the difficulties that must be overcome in the initial planning stage is the almost instinctive distrust of the private sector by civil society. This has to be overcome by clearly defining the rules of engagement and establishing the parameters of conflict of interest. It is critical that in matters of public policy, while there may be cooperation in providing the data on which policy can be formed, the actual formation of public policy is the particular and sole responsibility of the government. Other sectors may collaborate in the execution of the policy but never in its formulation.

Benefits of sectoral cooperation

Cooperation, whether intersectoral or multisectoral, should produce public value. In general it should produce economies of scale and there should be productivity gains, especially through reducing duplication. In the case of health, such cooperation should result in improved health, particularly at the population level, and it is critical for the prevention and control of NCDs as indicated in the Political Declaration. Cooperation is not without costs and there is inherent conflict, which must be managed.

Recommendations for action

Stimulating multisectoral cooperation

Multisectoral cooperation will usually arise when the solution of the particular problem is a matter of national interest to such an extent that it becomes national rather than sectoral policy and the interests of all possible contributing sectors is catalyzed by higher-level directives. For example, the Head of State or Prime Minister, either through the cabinet process or directly, indicates that there must be cooperation among or between sectors.

Multisectoral cooperation is also stimulated by pressure from civil society emphasizing the relevance of the relevant issue that affects achievements of the sector in question. There is also the view that multisectoral cooperation becomes progressively easier as one travels through the political hierarchy or down the levels of a governmental organization. The internal politics in the higher echelons of any entity may make cooperation difficult. Thus, multisectoral cooperation becomes easier at the local or community levels and it is also claimed that collaboration between sections or departments of sectors is intrinsically easier than through whole-of-sector arrangements.[12] In the context of NCDs, multisectoral action has largely been confined to concomitant action

Healthy public policy is only possible when the health consequences of different policy options can be identified and there is some clear mechanism for influencing the development of policy such that health consequences are considered and health promoted and protected. It can in essence be regarded as one of the tools of healthy public policy.

by different levels of government, mandated and driven by a level above the leaders of each group. The private sector can play a critical role by supporting civil society groups which stimulate the administrative agencies of government to address the problems which can only be dealt with in a multisectoral manner and in addition facilitating the dialogue between them, especially at the local level. This has been one of the lessons learned in relation to HIV/AIDS.

Facilitating multisectoral cooperation through health impact assessment

Health impact assessment represents the most widely accepted approach to ensuring effective multisectoral cooperation. The 1999 Gothenburg consensus statement defines it as "a combination of procedures, methods and tools by which a policy, program or project may be judged as to its potential effects on the health of a population, and the distribution of those effects within the population."[13] It is considered to be the best way of ensuring that health concerns are considered in projects or activities that are thought to be outside the health sector.[14] It brings public health considerations to the attention of persons and sectors whose main orientation is not health.

It had its conceptual origins in the notion of healthy public policy, which is one of the five key health promotion actions identified in the Ottawa Charter.[15] Healthy public policy is only possible when the health consequences of different policy options can be identified and there is some clear mechanism for influencing the development of policy such that health consequences are considered and health promoted and protected. It can in essence be regarded as one of the tools of healthy public policy.[16] It has also been influenced by the logic of environmental impact assessment.[17] To the extent that policy formulation in health is quintessentially the function of government, it is obvious that this tool has its most useful application in multisectoral cooperation.[18] The private sector can contribute by providing inputs and by helping to ensure that up-to-date scientific categories are employed in such assessments.

Modes of intersectoral collaboration

Intersectoral cooperation may involve all three sectors, but more frequently it only involves two groups:

Government-NGO relationships are common, especially in situations in which government engages a non-profit organization to carry out activities that might normally be the responsibility of government. The relationship between the government and the nonprofit may take the form of a principal/agent relationship or be in the nature of a stewardship agreement. In the standard principal/agent relationship the principal seeks to maximize welfare and the agent seeks to maximize utility. In the stewardship relationship there is goal convergence. The two forms are perhaps extremes, and many government-NGO relationships fall somewhere along a continuum between the principal/agent mode and the stewardship arrangement.[19, 20]

Public-private partnerships have emerged as significant mechanisms for achieving global health objectives. They have been described as "relatively institutionalized initiatives, established to address global health problems, in which public and private-for-profit sector organizations have a voice in collective decision making."[21] Their emergence has been attributed to the complexity of the global health challenges; the recognition that the production of global public goods may be beyond the capacity of the public sector and the need for the speed and agility which characterize the private sector; and the "availability of unprecedented resources, largely precipitated by the Bill & Melinda Gates Foundation."[22] Public-private partnerships are diverse arrangements, which bring together actors with varying goals and motivations in the pursuit of objectives that have a similar outlook. The nature of public health action in NCDs inherently warrants an intersectoral response with partnerships as its key feature. However, it is important to note that of more than a hundred global partnerships on health, not even one is explicitly focused on NCDs.[23, 24, 25] There are country examples of public-private frameworks, both for policy as well as implementation of NCD policies, of which Heartfile in Pakistan is a salient example.[26]

Burgeoning new technologies and transformative tools such as those used in mHealth programs are rapidly changing the inventory of potential collaborators toward multisectoral action. A new emphasis on bottom of the pyramid technologies, outreach tools, telecommunication connectivity and innovative means of resource generation is rapidly altering the landscape of actors and potential partners relevant in multisectoral action toward achieving NCD prevention and management goals. The private sector can be, of course, an important source of advanced technology and new tools if a multisectoral approach is implemented.

Governance

Governance presents challenges in all sectoral cooperation. In the case of health, the lead is usually taken by the health sector, which has the capacity to outline the nature of the problem to be addressed with more precision. The best results are obtained when another sector addresses the non-health area that has an impact on health as part of its regular activities and does not have to devote specific resources diverted from the basic work and concern of the sector. The success of this approach has been clear in the case of HIV/AIDS. There is less need for formal joint agreement in many instances of multisectoral cooperation. For instance, the financial

A new emphasis on bottom of the pyramid technologies, outreach tools, telecommunication connectivity and innovative means of resource generation is rapidly altering the landscape of actors and potential partners relevant in multisectoral action toward achieving NCD prevention and management goals.

sector or the Minister of Finance may make the decision to raise tobacco taxes not only because smoking contributes to disease, but also for fiscal reasons.

Intersectoral cooperation may be different as there is usually a need for a more formal agreement describing the roles and responsibilities of the relevant partners. In the case of the government-NGO collaboration to implement a project, this is based on a formal contract. This is also true with public-private partnerships.

The Political Declaration refers to multisectoral action at the global level, which presents a special challenge. Some of the vectors responsible for NCDs cross national borders. The propaganda that promotes smoking and behaviors inimical to health permeates national borders and the businesses responsible for them are global. In the case of tobacco, there is clearly no cooperation, but a formal treaty—the Global Framework Convention for Tobacco Control. It may be useful to think of a similar mechanism for some of the other products that are known to be risk factors for NCDs such as salt. The best possibility for establishing any form of global governance to effect sectoral cooperation with regard to NCDs is through the World Health Organization, which has the constitutional responsibility "to act as the directing and co-coordinating authority on international health work."

Notes

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- Screening (identifying plans, projects or policies for which an HIA would be useful),
- Scoping (identifying which health effects to consider),
- Assessing risks and benefits (identifying which people may be affected and how they may be affected),
- Developing recommendations (suggesting changes to proposals to promote positive health effects or to minimize adverse health effects),
- Reporting (presenting the results to decision-makers), and
- Monitoring and evaluating (determining the effect of the HIA on the decision).

See Centers for Disease Control and Prevention. Health Impact Assessment. 2012. http://www.cdc.gov/healthyplaces/hia.htm and http://www.cdc.gov/healthyplaces/hiaresources.htm#factsheet. Accessed June 18, 2012 and October 14, 2012.

The WHO also provides extensive material on the methodologies and examples of how it has been applied in non-health sectors such as agriculture, housing, and tourism, among others. World Health Organization. Health impact assessment. 2012. http://www.who.int/hia/en/. Accessed June 18, 2012. Indeed, there is no limit to the possible number of sectors in government that might be involved in determining the health impact assessment of a particular project. It is possible, however, that this powerful tool is more applicable to a discrete program or project than to ongoing cooperation over a broad field, such as is the case when the whole of another sector's basic functions and remit affect health.

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Sir George Alleyne, a native of Barbados, became Director of the Pan American Sanitary Bureau (PASB), Regional Office of the World Health Organization (WHO) on 1 February 1995 and completed a second four-year term on 31 January 2003. In 2003 he was elected Director Emeritus of the PASB. From February 2003 until December 2010 he was the UN Secretary General's Special Envoy for HIV/AIDS in the Caribbean. In October 2003 he was appointed Chancellor of the University of the West Indies. He currently holds an Adjunct professorship in the Bloomberg School of Public Health, Johns Hopkins University. Dr. Alleyne has received numerous awards in recognition of his work, including prestigious decorations and national honors from many countries of the Americas. In 1990, he was made Knight Bachelor by Her Majesty Queen Elizabeth II for his services to Medicine. In 2001, he was awarded the Order of the Caribbean Community, the highest honor that can be conferred on a Caribbean national.

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