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Framework legislation for noncommunicable diseases: and for the Sustainable Development Goals?

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ABSTRACT

'Framework legislation' refers to legislation that sets out structures for governance and accountability or other processes for guiding the decisions and actions taken by government or the executive. Framework legislation for non-communicable diseases (NCDs) provides the opportunity for countries to focus their political commitment, to set national targets, and a time-frame for achieving them, and to create cross-sectoral governance structures for the development and implementation of innovative policies. Although they extend well beyond NCDs, the health-related Sustainable Development Goals (SDGs) create similar demands for effective national governance. A similar case might, therefore, be made for framework legislation for the health-related SDGs or for legislation to govern particular aspects, such as managing commercial relationships with the private sector or managing conflicts of interest. This article considers the possible benefits of framework legislation, including what issues might be appropriate for inclusion in a framework law. The absence of framework legislation should neither be seen as an excuse for inaction, nor is framework legislation a substitute for detailed regulation of areas such as sanitation and water quality, tobacco and alcohol control, food safety, essential medicines or poisons. The ultimate test for framework legislation will be its capacity to provide a catalyst for action and to accelerate progress towards national and global health goals.

INTRODUCTION

'Framework legislation' is an important yet neglected tool for improving health governance at the country level. Although there is no simple definition of the term, 'framework legislation' refers to legislation that sets out processes for government actions or executive deliberations or that creates structures, processes, constraints or other parameters to guide decision-making.1 Framework legislation seeks to create an enabling environment for decision-making, in contrast to legislation that prescribes particular requirements or solutions that are a substantive product of the decision-making process. Substantive legislation on tobacco, for example, might include comprehensive bans on tobacco advertising,

Key questions

What is already known about this topic?

- ► Heads of state made a number of time-bound commitments at the high-level meeting of the United Nations (UN) General Assembly on non-communicable diseases in 2014. These included commitments to set national targets and process indicators for 2025 and to consider strengthening national multisectoral plans and policies.
- ► In 2014, members of the UN General Assembly adopted the Sustainable Development Goals. The health-related goals and targets represent an ambitious plan for advancing global health for the period 2015–2030.

What are the new findings?

- ▶ 'Framework legislation' refers to legislation that establishes structures or processes to guide future actions and decisions by governments or the executive.
- ▶ Framework legislation for non-communicable diseases (NCDs) provides the opportunity for countries to focus their political commitment, to set national targets and to create cross-sectoral governance structures for the development and implementation of innovative policies. Although they are broader than NCDs, the health-related Sustainable Development Goals impose similar demands on countries for effective national governance.

Recommendations for policy

- ► While the absence of legislation is not an excuse for inaction, framework legislation may contribute to the effective coordination of national responses to non-communicable diseases (NCDs) and to the health-related Sustainable Development Goals and targets.
- ► Framework legislation is not a substitute for detailed legislation governing tobacco, alcohol, food, poisons, essential medicines and other areas. Nevertheless, framework legislation has the potential to accelerate national progress by raising the political profile of NCDs, clarifying who is accountable for taking action and coordinating a cross-sectoral response.
- Alternatively, government may consider more limited legislation; for example, to manage commercial relationships with the private sector or to manage conflicts of interest.



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Table 1 Global targets for reductions in risk factors for NCDs

Comprehensive global monitoring framework, including nine voluntary global targets for prevention and control of NCDs (WHO)

Overall target

▶ By 2025, a 25% relative reduction in mortality from cardiovascular disease, cancer, diabetes and chronic respiratory diseases in persons aged 30–70 years.

Eight supporting targets

- ▶ 10% relative reduction in the harmful use of alcohol;
- ▶ 10% relative reduction in the prevalence of physical inactivity;
- ▶ 30% relative reduction in mean average population salt intake;
- ▶ 30% relative reduction in the prevalence of tobacco use (persons 15+ years);
- ▶ 25% relative reduction in raised blood pressure;
- ▶ 0% increase in diabetes and obesity;
- ▶ 50% coverage for drug therapy and counselling for those at risk of cardiovascular disease:
- 80% coverage of affordable technologies and essential medicines for treating NCDs in both public and private facilities.

Sustainable Development Goals: target 3.4 (United Nations General Assembly)

By 2030, reduce by one-third premature mortality from NCDs through prevention and treatment and promote mental health and well-being.

NCD, non-communicable diseases.

the imposition of a tobacco excise tax and even the establishment of a tobacco and nicotine authority with regulatory functions. Framework legislation, on the other hand, might include a national target and formal commitment to become a smoke-free country by 2025^2 or a process for documenting and ensuring the transparency of communications with the tobacco industry. Within the health sector, framework legislation may serve a variety of functions. These include symbolism (signalling government's commitment to a programme of action) and assurance that policy deliberations or decision-making processes embody particular characteristics, such as a coordinated, multisectoral approach or the avoidance of conflicts of interest.

Some countries are beginning to develop framework legislation in order to strengthen national governance for non-communicable diseases (NCDs) and to implement the commitments made at the high-level meeting of the United Nations (UN) General Assembly in 2014.³ Heads of state agreed, by 2015, to consider setting national targets and process indicators for 2025 and to consider strengthening national multisectoral plans and policies in order to achieve them.³ These commitments seek to advance the set of global targets for reductions in risk factors for NCDs adopted by the World Health Assembly in 2013 (table 1).⁴

Heads of state also agreed, by 2016, to reduce NCD risk factors and underlying social determinants and to strengthen primary healthcare, building on the menu of policy options contained in the WHO global action plan for NCDs.^{3 4} An updated menu of policy options was adopted by the World Health Assembly in May 2017. It contains a set of highly cost-effective 'best buys' addressing tobacco, alcohol, unhealthy food, cancer and cardiovascular disease.⁵

This article briefly reviews some of the issues countries might consider when developing framework legislation for NCDs. In addition to NCDs, the UN General Assembly has undertaken an ambitious governance role in global health through the adoption, in 2015, of the Sustainable Development Goals (SDGs). The SDGs provide a blueprint for economic, social and environmental development for the period 2015–2030 for all countries, irrespective of income level. Health is the focus of SDG3 ('ensure healthy lives and promote well-being for all ages') but is also a determinant of other goals and targets and/or a beneficiary of their achievement (box 1). Although they extend well beyond NCDs, the health-related SDGs create similar demands for effective national governance. A similar case might, therefore, be made for framework legislation or for legislation to govern particular aspects, such as public–private partnerships to accelerate progress towards the SDGs.

Countries vary widely in terms of their historical and legal traditions and constitutional structures. In some countries, legislative powers are devolved to provincial or regional governments. Provincial, as well as local and city administrations, may consider legislation to support the implementation of strategies for reducing health risks and to contribute to the achievement of national health goals. In many countries, governments will already have the legislative or executive authority they need to take decisive action to protect the health of the population. The absence of framework legislation is not, therefore, an excuse for inaction in addressing substantive challenges such as tobacco, alcohol and unhealthy foods and drinks. Where legislatures do enact framework legislation, its ultimate value will depend on it being a catalyst, rather than a substitute for action.

WHAT SHOULD A FRAMEWORK LAW SEEK TO DO?

The core assumption that underlies both the SDGs and the UN General Assembly's involvement in NCDs is that periodic measurement of the collective progress of the

Box 1 Selected health-related goals and targets in the Sustainable Development Goals

Goal 2. End hunger, achieve food security, improve nutrition and promote sustainable agriculture

- 2.1 By 2030, end hunger and ensure access by all people, in particular the poor and people in vulnerable situations, including infants, to safe, nutritious and sufficient food all year round
- 2.2 By 2030, end all forms of malnutrition, including achieving, by 2025, the internationally agreed targets on stunting and wasting in children under aged 5 years and address the nutritional needs of adolescent girls, pregnant and lactating women and older persons

Goal 3. Ensure healthy lives and promote well-being for all at all ages

- 3.1 By 2030, reduce the global maternal mortality ratio to less than 70 per 100 000 live births
- 3.2 By 2030, end preventable deaths of newborns and children under aged 5 years
- 3.3 By 2030, end the epidemics of AIDS, tuberculosis, malaria and neglected tropical diseases and combat hepatitis, waterborne diseases and other communicable diseases
- 3.4 By 2030, reduce by one-third premature mortality from non-communicable diseases through prevention and treatment and promote mental health and well-being
- 3.5 Strengthen the prevention and treatment of substance abuse, including narcotic drugs and harmful use of alcohol
- 3.6 By 2020, halve the number of global deaths and injuries from road traffic accidents.
- 3.7 By 2030, ensure universal access to sexual and reproductive healthcare services, including for family planning, information and education...
- 3.8 Achieve universal health coverage, including financial risk protection, access to quality essential healthcare services and access to safe, effective, quality and affordable essential medicines and vaccines for all
- 3.a Strengthen the implementation of the Framework Convention on Tobacco Control in all countries, as appropriate

Goal 6. Ensure availability and sustainable management of water and sanitation for all

- 6.1 By 2030, achieve universal and equitable access to safe and affordable drinking water for all
- 6.2 By 2030, achieve access to adequate and equitable sanitation and hygiene for all and end open defecation...

Goal 11. Make cities and human settlements inclusive, safe, resilient and sustainable

11.7 By 2030, provide universal access to safe, inclusive and accessible, green and public spaces, in particular for women and children, older persons and persons with disabilities

Goal 16. Promote peaceful and inclusive societies... and build effective, accountable and inclusive institutions

- 16.5 Substantially reduce corruption and bribery in all its forms
- 16.6 Develop effective, accountable and transparent institutions at all levels
- 16.b Promote and enforce non-discriminatory laws and policies for sustainable development

international community towards global targets will be a catalyst for action by all stakeholders, including governments, civil society and the private sector. Countries can adopt a similar strategy at the national level by establishing a process for setting national targets that are ambitious, time-sensitive and adapted to national circumstances and by requiring regular evaluations of progress. In some countries, national governments may not need an additional legislative mandate to engage in national surveillance of NCD risk factors or to collect indicators of progress towards national goals. For example, countries may simply adapt existing legislation requiring the reporting of communicable diseases to the context of NCD risk factors or other health indicators. Nevertheless, in countries that have state or provincial governments (ie, federal systems), it may be helpful to formally set out the functions and responsibilities of different levels of government-whether in legislation or by means of an intergovernmental agreement—in order to ensure national coverage and timely provision of data.

National surveillance systems enable countries to monitor their burden of disease and to identify national priorities. In countries with significant resource constraints, it may be wiser for governments to adopt a stepwise approach to risk management, directing scarce resources to proven, highly cost-effective interventions that will have the greatest impact on disease burden, monitoring progress and expanding the scope of interventions as resources permit. While legislation has been widely used and is a vital component of tobacco control, legislative approaches to controlling other NCD risks, such as high levels of salt intake, are also emerging. 10 11

The integrated, indivisible nature of the SDGs⁶ means that governments will need to coordinate actions by all ministries in a coherent, interconnected set of national policies. The need for multisectoral action is also the most fundamental strategic feature of the WHO's global action plan for NCDs.⁴ Framework legislation should therefore create or designate a national multisectoral mechanism, with high-level political or executive leadership (such as a national prevention committee or NCD task force) and set out its functions and responsibilities. The roles of any regional, advisory and technical committees could also be defined. Countries may consider establishing an explicit mandate to evaluate progress and a formal reporting process to ensure that Parliament remains accountable for national progress.

An important goal for a national multisectoral mechanism is policy coherence. For example, countries may undermine their own capacity to expand access to essential medicines at affordable prices if they adopt legislation that fails to adequately balance the protection of intellectual property rights with public interest safeguards. ^{12–15} Similarly,

the trade agreements a country enters into may potentially constrain its capacity to pass legislation or implement policies addressing dietary and other NCD risk factors. ^{16–18}

In some countries, such as the United States¹⁹ ²⁰ and Mexico,²¹ the national government has already established a national prevention committee comprising heads of executive government agencies. Other countries have experimented with health promotion foundations and health portfolio agencies whose role may extend to proposing policies or making recommendations to government for the development of regulations or decrees, managing regional prevention committees or bodies, developing national codes and standards in response to risk factors and collating information and publishing periodic reports about risk factors.

For example, in 2007, in response to its NCD crisis, Tonga established an independent Health Promotion Foundation.²² Known as Tonga Health, the Foundation has a mandate to promote healthy lifestyle changes throughout the Kingdom, to serve as a catalyst for the development of new policies, programmes and environments, to conduct social marketing campaigns and to administer a competitive research grants scheme that funds research, programmes and facilities to promote health and reduce NCD risk factors.²² The existence of an independent statutory agency may help to ensure that health promotion receives the budgetary resources it needs within the overall health portfolio. In the Australian State of Queensland, proposed legislation would create a Healthy Futures Commission, whose functions would be to 'support the capacity of children and families to adopt a healthy lifestyle' and contribute to the reduction of health inequalities for children and families.²³ The legislation would require the Commission to spend 55% of its budget on grants to community and industry organisations, universities, businesses and local governments in order to support the Commission's functions.

A useful distinction can be drawn between cross-sectoral coordinating mechanisms within government or, in federal systems, between different levels of government, and formal mechanisms for encouraging engagement between government, civil society and the private sector. For example, an important role of Australia's National Preventive Health Agency was to encourage prevention through partnerships with industry, non-government organisations and the community sector. ²⁴ In some countries, such as Brazil ²⁵ and Thailand, ²⁶ community input into national health plans is formalised through consultative assemblies that provide a platform for community participation by civil society, businesses and universities.

FRAMEWORK LEGISLATION, PUBLIC-PRIVATE PARTNERSHIPS AND CONFLICTS OF INTEREST

The scale of the investments that will be needed to achieve the SDG health targets means that government funding will likely be grossly inadequate. Private sector engagement, including private sector financing, is vital. ^{27 28} For this reason, legislation plays a vital role in establishing ground rules for engagement, requiring transparency and eliminating—if at all possible—conflicts of interest.

Although focused on infrastructure rather than health projects, Uganda's Public Private Partnership Act (2015) provides a helpful case study of a legislative framework for managing government's commercial relationships with the private sector.²⁹First, the Act sets out principles that shall govern the implementation of public-private partnerships: these need to be institutionalised and woven into the fabric of relationships with the private sector. In the context of health projects, the governing principles could also include the requirement that the projected partnership results shall make a substantial contribution to national health goals and, wherever possible, reduce health inequalities; the requirement for transparency in the roles of partners and in the processes leading to the award of any contracts and the requirement for there to be clear mechanisms for identifying and mitigating any conflicts of interest.

Second, the Act establishes a cross-sectoral Public Private Partnerships Committee with representatives from six ministries, as well as from the private sector, academia and the judiciary. The Partnerships Committee formulates policy on public-private partnerships, scrutinises and approves projects and formulates standards for the award of contracts. It also oversees the monitoring and evaluation of each partnership by the contracting authorities and is responsible for ensuring fiscal accountability.²⁹ In the health context, governments might consider even broader participation on such a committee, including representatives from civil society and the health professions. However, the functions of such a committee should be clearly defined; in particular, policy should be made by governments, and this function should not be delegated to a multisectoral committee.

The Act establishes the Public Private Partnerships Unit within the Ministry of Finance. This ensures that the Partnership Committee is fully supported by technical, financial and legal expertise. The functions of the Partnerships Unit include compiling an inventory of highly rated prospective projects that are likely to attract private sector investment and developing an 'open, transparent, efficient and equitable process' for managing projects across their life cycle. Beginning with a cost–benefit analysis and feasibility study, the Act sets out a process for procuring public–private partnerships and includes an offence for interfering with or exerting undue influence over an official during the course of their duties.

Although the rewards of private sector collaboration and financing may be significant, substantial risks may also arise. Opportunities for partnerships with the private sector cover a spectrum from genuine opportunities for shared value creation, to projects where engagement with the private sector is likely to harm public health, to enhance the reputation of a health-harming industry or to create significant opportunity costs. Opportunity costs may arise for the simple fact that governments are more likely to forego the use of regulatory powers to regulate harmful products or to otherwise mitigate health risks

when the industry has voluntarily joined with government in the pursuit of 'shared goals'. Not surprisingly, encouraging the development of partnerships with government is highly desirable for industries that produce or sell harmful products. For example, the most significant theme emerging from a series of interviews carried out by the author with global tobacco executives was the desire of the industry to gain access to policy-makers and to partner with government in pursuing shared goals. As the Director of Corporate and Regulatory Affairs at British American Tobacco said, 'I'd like to see us pass through the polemical phase into a pragmatic one because I think that *together* we could... produce a far greater net benefit to public health than the sort of loggerheads approach [that we have currently]'. ³⁰

Article 5.3 of the WHO Framework Convention on Tobacco Control (WHO FCTC) requires Parties, in setting and implementing their public health policies with respect to tobacco control, to protect these policies from 'commercial and other vested interests of the tobacco industry in accordance with national law'.31 Guidelines adopted by the Conference of the Parties to the WHO FCTC point to the irreconcilable conflict between the tobacco industry's interests and public health interests.³² They recommend that Parties reject partnerships with the tobacco industry, denormalise the corporate social responsibility activities of the tobacco industry, establish measures to limit interactions with the tobacco industry and ensure that any interactions that do occur are transparent.³² A growing body of evidence also supports the view that partnerships between governments and manufacturers of armaments, alcohol, 33-35 breast-milk substitutes³⁶ and sugary drinks^{37–39} should be avoided due to the record of these industries in undermining or distorting research, weakening health policies and resisting regulatory efforts to reduce the harm caused by these products.

In circumstances where government has chosen to enter into a public–private partnership, great care should be taken to ensure that it does not subtly undermine the government's capacity to pursue national health goals. For example, the willingness of pharmaceutical manufacturers to issue a voluntary licence⁴⁰ to assist a country in achieving greater access to an expensive drug may come with the expectation that government will exercise restraint in issuing compulsory licences or making use of the flexibilities contained in the TRIPS Agreement (Trade-Related Aspects of Intellectual Property Protection), ⁴¹ even when doing so is consistent with that country's World Trade Organization obligations. ^{14 42}

Similarly, the participation of food manufacturers in public–private partnerships that are intended to reduce levels of salt, added sugars and saturated fats in processed foods may be based on the assumption that participation is optional, that all food reformulation targets are voluntary, and that government will rule out consideration of mandatory, maximum levels for salt, ^{11 43 44} a tax on sugary drinks, ^{38 45 46} and other regulatory policies. In both cases,

the willingness of government to consider regulatory approaches as a back-up strategy is precisely what is necessary if public–private partnerships are to achieve their potential. ⁴⁷ ⁴⁸ For example, crucial to the achievement of substantial reductions in salt levels in processed food in the UK were clear targets and time frames, independent monitoring, media pressure and sustained political pressure on industry from public health ministers. ⁴⁹

DESIGN ISSUES IN FRAMEWORK LEGISLATION

Enabling provisions in framework legislation may authorise ministers, statutory agencies or public health officials to act unilaterally and to take specific kinds of actions in future. Agencies may be given delegated authority to issue codes of conduct or regulations within specified areas, and public officials may be granted power to take actions that are incidental or conducive to the performance of their statutory functions.

For example, public health legislation in the Canadian province of British Columbia creates a flexible process for imposing requirements on a person whose activities constitute a risk factor for chronic disease. The legislation provides a process for prescribing, and thereafter issuing regulations with respect to a 'condition, thing or activity' that causes or is associated with a health impediment. For A 'health impediment' includes a prescribed condition, thing or activity that causes significant chronic disease in the population, or whose cumulative effect, over time, is likely to adversely affect public health. British Columbia has used this mechanism to set limits for trans fats in foods served or sold in food service establishments.

Similarly, public health legislation in the State of South Australia empowers the health minister to declare that a disease or medical condition is a non-communicable condition, and thereafter to issue a code to prevent or reduce the incidence of the declared NCD.⁵² A code may apply to an industry or sector, including goods or services that are manufactured, advertised, marketed or sold, to buildings and to sections of the public. Ministerial Codes are not intended to regulate aspects of individual lifestyle or clinical practice but to address the 'causal factors that underpin many lifestyles issues'. 53 In the Republic of Korea, legislation on children's diets empowers the head of each self-governing city or local government to designate areas within 200 m of schools as 'green food zones'. 54 Local food businesses that comply with minimum nutrition standards that apply to a range of children's preferred foods may apply for designation as exemplary stores. The minister may also prohibit the sale of high-calorie, low-nutrient foods within green food zones.⁵⁴

It will be a question of judgement for legislators in each jurisdiction whether it is more appropriate for regulatory standards or controls to be included in principal legislation, or alternatively, developed and issued by ministries, statutory agencies and officials according to processes set out in the legislation. Legislation that is perceived as giving the health ministry or another part of the executive a mandate to impose standards that may substantially impact on business interests or the economy, without first being subjected to parliamentary scrutiny may, for that reason, fail to win support. On the other hand, it is important to ensure that government agencies are given an unambiguous mandate to act in areas where the evidence supports prompt action. Public officials should not be held captive to unrealistic conditions or standards of proof that prevent them from taking action in areas where the scientific consensus supports action.

REGIONAL LEGISLATIVE FRAMEWORKS

In addition to serving as a tool for national governments, countries may also consider the potential benefits of a regional legislative framework as a way of harnessing the collective power of participating countries to address regional health challenges. A regionally agreed legislative framework for action on NCDs, or for the health SDGs, could bring many benefits, especially for countries with a history of cooperation in health matters, and for small island states, such as those in the Caribbean, and Pacific and Indian oceans. A regional legislative framework might focus on national structures for governance and accountability, as discussed in this paper, such as setting national targets, formalising monitoring and evaluation and creating a cross-sectoral mechanism for addressing the multiple determinants of NCDs. More ambitiously, it might extend to regionally agreed standards on aspects of tobacco control, alcohol control, risk factor surveillance or other matters. A regional approach could enable countries with limited resources to rapidly adopt regional best practices or to become early adapters of promising new measures, such as a tax on sugary drinks⁵⁵ or a higher minimum purchasing age for tobacco products.⁵⁶ By acting collectively, countries might also manage any risks that trade and investment agreements might pose for national legislation in a proactive and efficient manner.

Whether focused on governance and accountability or extending more broadly to the substantive regulation of risk factors, a regional legislative framework could bring region-wide benefits. These include strengthening political commitment and facilitating constructive competition and shared learning between participating countries, enhanced further by transparent processes for monitoring and reporting at the regional level. A common, regional approach to dealing with the tobacco industry, for example, could reduce participating countries' vulnerability to 'divide and conquer' tactics by the industry. It might also lead to the development of new governance structures at the regional level, such as a regional commission on the health SDGs, further strengthening political commitment within each country.

A regional legislative framework would not need to be complex, nor would it necessarily need to be embodied in a formal, intergovernmental agreement. Rather, a common approach might be approved by heads of government at meetings hosted by an appropriate regional forum, with governments adopting all or parts of the framework in accordance with their national circumstances.

CONCLUSION

There is no magic in the term 'framework legislation'; its underlying purpose is to create an enabling legal environment to address risk factors and treatment priorities in a powerful way. In many countries, governments already have a legislative mandate to take action to protect the health of the population. The absence of a framework law for NCDs or, more broadly, for the health-related SDGs should not be seen as an excuse for inaction. Nevertheless, framework legislation has the potential to accelerate national progress by raising the political profile of NCDs and the SDGs, clarifying who is accountable for taking action and coordinating a cross-sectoral response. Framework legislation may also advance health by setting time-sensitive, national targets for achieving reductions in risk factors, authorising national surveillance of key risk factors, defining the powers and accountabilities of frontline agencies and creating a mechanism for engagement with the private sector that insists on transparency and the avoidance of conflicts of interest. The form that a framework law takes will vary between countries; in some, it may take the form of a separate Act of Parliament or executive decree, whereas in others there may simply be incremental changes to a number of existing laws. As with public health laws generally, it is important to monitor the performance of countries that enact framework legislation in order to test its capacity to accelerate progress towards national and global health goals.

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