



World Health
Organization

REGIONAL OFFICE FOR Europe



Public health policy and legislation instruments and tools: an updated review and proposal for further research



ABSTRACT

This document reviews the current policy and legislation instruments and tools in place for delivering public health operations in the WHO European Region. It aims to underpin and complement the European Action Plan for Strengthening Public Health Capacities and Services (EAP). It provides initial findings on the wide spectrum of legal and policy frameworks at regional and global levels discovered by mapping the available public health instruments and tools across 10 essential public health operations (EPHOs). The main findings are that at the global level legally binding instruments and tools are mainly concentrated in EPHO 3 (health protection) with 306 tools, EPHO 4 (health promotion) with 31 and EPHO 6 (governance) with 41. This corresponds to more than 90% of the total number of public health tools. However, there were only 2 tools for EPHO 5 (disease prevention), 3 for EPHO 7 (workforce) and 1 for EPHO 8 (organizational structures and financing). No legally binding tools were found for EPHO 9 (communication) and EPHO 10 (research). For EPHO 1 (surveillance) and EPHO 2 (response to health hazards and emergencies), there is a more balanced use of both legally and non-legally binding tools. More evidence is needed on the cost-effectiveness of such instruments and tools. In addition, there is a need for greater advocacy, with a balance of regulation and persuasion, on what already exists – such as “best buy” interventions for noncommunicable diseases (NCDs) and the WHO Framework Convention on Tobacco Control (FCTC) – as well as a need to strengthen approaches to intersectoral governance.

Keywords

FINANCING, HEALTH
HEALTH MANAGEMENT AND PLANNING
HEALTH POLICY
PUBLIC HEALTH – LEGISLATION AND JURISPRUDENCE – TRENDS
PUBLIC HEALTH ADMINISTRATION

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Contents

	page
Acknowledgements	iii
Abbreviations	iii
Executive summary	1
Introduction	7
Methods	9
Findings	14
Conclusions	27
References	33

Acknowledgements

This report was written by Carlos Dias and Rita Marques from the National Institute of Public Health, Portugal, and Maria Ruseva, Jo Nurse and Casimiro Dias from the WHO Regional Office for Europe. Other major contributions came from Snezhana Chichevalieva from the South-eastern Europe Health Network, Jose Pereira Miguel from the National Institute of Public Health, Portugal, and Jose Martin-Moreno and Hans Kluge from WHO Regional Office for Europe.



Instituto **Nacional de Saúde**
Doutor Ricardo Jorge

Abbreviations

CIS – Commonwealth of Independent States

EAP – European Action Plan for Strengthening Public Health Capacities and Services

EPHOs – Essential public health operations

EU – European Union

FCTC – Framework Convention on Tobacco Control

GLC – Green Light Committee

HiAP – Health in All Policies

IHR – International Health Regulations

LMICs – Low- and middle-income countries

NCDs – Noncommunicable diseases

SARS – Severe acute respiratory syndrome

SEEHN – South-eastern Europe Health Network

TB – Tuberculosis

Executive summary

1. Through resolution EUR/RC61/R2 on strengthening public health capacities and services in Europe (1), the WHO Regional Committee for Europe endorsed the development of an action plan, to be led by the WHO Regional Office for Europe and submitted to the Regional Committee for consideration at its sixty-second session in September 2012. This plan would be centred on actions that are strategic and reflect modern public health practice (including a focus on both structural determinants and individual actions) and would form a key pillar of the new European health policy framework, Health 2020. The purpose of the plan is to ensure that public health services are strengthened to respond to the current and emerging public health challenges facing the WHO European Region. The overall vision is to support the delivery of the Health 2020 policy framework by promoting population health and well-being in a sustainable way.

2. The European Action Plan for Strengthening Public Health Capacities and Services (EAP) aims to support the 53 Member States of the WHO European Region in improving health and tackling inequalities by securing delivery of 10 essential public health operations (EPHOs) (see Box 1) and a core set of accessible, high-quality, efficient and effective individual, community and population-based public health services, and thus to strengthen public health capacities. This report aims to underpin and complement the EAP by reviewing the range of available public health instruments in order to develop evidence-based policies and tools for future programmes.

Box 1. The 10 EPHOs

1. Surveillance of population health and well-being
2. Monitoring and response to health hazards and emergencies
3. Health protection, including environmental, occupational, food safety and others
4. Health promotion, including action to address social determinants and health inequity
5. Disease prevention, including early detection of illness
6. Assuring governance for health and well-being
7. Assuring a sufficient and competent public health workforce
8. Assuring sustainable organizational structures and financing
9. Advocacy, communication and social mobilization for health
10. Advancing public health research to inform policy and practice

Note: following resolution EUR/RC61/R2 on strengthening public health capacities and services in Europe (1), the 10 EPHOs which form the basis of the EAP were revised to the above in 2012.

3. The purpose of this review is to provide the Regional Office, Member States and other partners with direction in addressing, among others, the questions below.

- What are the relative advantages of the different types of public health instruments and tools available?
- How can the effectiveness of public health instruments and tools be enhanced at Member State level?
- How can gaps in the toolkit of available instruments and strategies be addressed?

- How can evaluation and monitoring of these instruments and tools be made more effective?

4. It was not possible to answer these questions in full, but this study advances our understanding of the effective use of public health instruments and tools across the European Region. The following summarizes the responses to these questions.

What are the relative advantages of the different types of public health instruments and tools available?

5. A recent report from the WHO Regional Office for Europe highlights four major roles for the law in advancing public health. These are: defining the objectives of public health and influencing its policy agenda; authorizing and limiting public health action with respect to protection of individual rights, as appropriate; serving as a tool for prevention; and facilitating the planning and coordination of governmental and nongovernmental health activities (2).

6. While for some areas (such as health protection) legally binding tools can reflect higher potential gains, for other areas (such as health promotion) the use of influence mechanisms can be more effective. Furthermore, both definition and enforcement of legally binding public health tools need to be considered when assessing the cost-effectiveness of these tools. It is particularly important to achieve a balanced approach with the different tools. While legislation is enforced through legal systems, national governments try to ensure implementation of national health strategies and policies through a range of monitoring, audit and performance management arrangements often associated with meeting standards.

7. This report concludes that an array of instruments and tools for policy and legislation is available to support the delivery of EPHOs in a wide variety of settings. The number and complexity of tools developed at the global and European levels has increased in recent years, as illustrated by the WHO Framework Convention on Tobacco Control (FCTC) and the International Health Regulations (IHR). While international regulations are non-negotiable, the degree and nature of governance arrangements, including regulation and legal enforcement, will vary across Member States. However, evaluation of these instruments and tools is not widely available; it is therefore difficult to compare the relative advantage of public health instruments and tools in different countries or at a regional level, or to recommend one tool over another.

8. The findings point out that the wide range of instruments available to WHO (including conventions, regulations, recommendations and standards) reflects the variations in deployment of specific instruments by different countries, and note changes in national regulatory frameworks arising from a growth in pluralism and democratization. There is a need to familiarize government and public health agencies with a range of current public health instruments and tools, and to provide guidance on how to deploy them in tackling the major challenges of population health.

How can the effectiveness of public health instruments and tools be enhanced at Member State level?

9. Evidence on the effectiveness of different public health policy and legal instruments and tools is currently limited. This section summarizes examples of data in the main areas where evaluations were found. Overall, further evaluation is needed to inform the future effectiveness of different instruments and tools, including analysis of cost-effectiveness and feasibility of implementation.

10. WHO has identified a set of evidence-based “best buy” interventions that are not only highly cost-effective but also feasible and appropriate to implement within the constraints of health systems. The report on “best buy” interventions for noncommunicable diseases (NCDs) concludes that there is a set of interventions that have significant public health impact and are highly cost-effective, inexpensive and feasible to implement (3). The primary benefit is a reduction in premature mortality from NCDs. Studies have found that implementing a specific set of “best buy” interventions for NCDs in 23 large low- and middle-income countries (LMICs) could prevent 30 million premature deaths between 2006 and 2015, or an average of 3 million per year. Population-based measures for reducing tobacco and harmful alcohol use, as well as unhealthy diet and physical inactivity, are estimated to cost US\$ 2 billion per year for all LMICs; less than US\$ 0.40 per person.

11. Approximately 3.8 billion people (55% of the world’s population) are covered by at least one tobacco control measure at the highest level of policy achievement, according to the latest WHO report on the global tobacco epidemic (4), including 1.1 billion covered by a new policy since 2008. In the WHO European Region, over 244 million people (27% of the population in the Region) became newly covered by at least one tobacco control measure at the highest level of achievement between 2008 and 2010. This has great potential to make remarkable improvements in health. For example:

- just three months after the comprehensive smoke-free legislation was enacted in Scotland, bar workers reported a 26% decrease in respiratory symptoms and asthmatic bar workers showed reduced airway inflammation (5);
- within the first year of the introduction of the tobacco control law in Turkey there was a substantial decrease of 24.2% in the number of patients with smoking-related diseases (6).

How can gaps in the toolkit of available instruments and strategies be addressed?

12. The EAP sets out the 10 EPHOs which should be incorporated into public health practice and into current strategies to measure and improve public health performance (see Box 1). These EPHOs were used as a structure to map different instruments and tools and identify major strengths and weaknesses.

13. The extensive mapping exercise undertaken for this review indicates the EPHOs for which public health instruments and tools are available, as well as critical gaps, and highlights six major points.

- There are 396 different tools for EPHO 3 (health protection) and 300 for EPHO 6 (governance). These two areas reflect more than 75% of the total number of public health tools available, and are particularly developed in European Union (EU) countries.
- There are 58 instruments and tools for EPHO 1 (surveillance), 37 for EPHO 2 (response to health hazards and emergencies), 70 for EPHO 4 (health promotion), 17 for EPHO 5 (disease prevention), 14 for EPHO 7 (workforce) and 6 for EPHO 8 (organizational structures and financing).
- EPHOs 9 (communication) and 10 (research) have only non-legally binding tools and instruments.
- While countries of the Commonwealth of Independent States (CIS) and South-eastern Europe Health Network (SEEHN) have historically strong services in EPHOs 1–3, capacity and laboratory equipment have often become outdated, and legislation and policy also need updating.

- At the global level, legally binding instruments and tools are mainly concentrated in EPHO 3 (health protection) with 306 tools, EPHO 4 (health promotion) with 31 and EPHO 6 (governance) with 41 tools. This corresponds to more than 90% of the total number of tools.
- The WHO European Region has a particularly strong record of adopting legal public health measures compared to the global picture. Legally binding public health tools represent one-third of the total number of available tools in the Region: this proportion is more than double the global average.

How can evaluation and monitoring of these instruments and tools be made more effective?

14. The review's conclusion outlines further possible research for evaluation, including analysis of the processes, outcomes and cost-effectiveness of a wider range of instruments and tools. The main gaps identified in the survey of public health policy instruments and tools include a lack of explicit monitoring and impact assessment mechanisms. The population health outcomes and effectiveness of legal interventions might be compared directly with other options. Such an approach should be broad enough to include comparative effectiveness both for different laws and policies and for other types of intervention.

15. Adding a cost component to the assessment of the impact of public health laws and policies allows the identification of a set of strategies with the greatest value for money. A focus on improving both the processes and the health outcomes would allow a dynamic system of accountability. In line with this, standards for the delivery of public health services should be made explicit and their quality ensured through regular scrutiny, inspection or assessment arrangements and accreditation.

Key message

Advocate for effective tools – for example, good evidence exists to support “best buy” interventions for NCDs and the WHO FCTC. Legal approaches are best balanced with intersectoral policies that create environments for healthy living. Strengthening governance is important to ensure effective implementation of laws and accountability arrangements of cross-sectoral working.

Recommendations

16. Besides tackling the major gaps in public health tools by EPHO, there is also a need to reach a balance between regulation and persuasion. The effectiveness of traditional public health instruments and tools – including legislation, sanctions, regulations and taxes – may be limited without additional tools more focused on citizen engagement in behavioural changes. As the WHO report on governance states, “smart governance” is mainly evaluated in terms of the effective use of a specific tool within the context of a diversity of tools and modes of application

(7). With this in mind, the information collected in this review makes it possible to offer the following recommendations to Member States of the WHO European Region.

Advocate for effective tools and apply evidence to different settings

- Advocate for tools with good evidence of effectiveness, such as “best buy” interventions for NCDs, the WHO FCTC and IHR.
- Advocate for tobacco control, including tax increases, smoke-free indoor workplaces and public places, health information and warnings, and bans on tobacco advertising, promotion and sponsorship.
- Advocate for control of harmful alcohol use, including tax increases, restricted access to retailed alcohol, and bans on alcohol advertising.
- Advocate for promotion of healthy diet and physical activity, including reduced salt intake in food, replacement of trans fats with polyunsaturated fats, and raising public awareness of diet and physical activity through mass media.

Strike a balance between regulation and persuasion

- Balance different instruments and tools, such as Health in All Policies (HiAP), governance, and both legally and non-legally binding tools; for example, toolkits, guidelines, approaches to citizen engagement, advocacy and communication.

Strengthen intersectoral responses and governance

- Develop and employ an HiAP approach to consider the health effects of major legislation, regulations, and other policies that could potentially have a meaningful impact on public health.
- Make use of health impact assessment tools to strengthen health gains in an HiAP approach.
- Strengthen the governance and accountability arrangements of cross-sectoral policy.

Address gaps in instruments and tools

- Consider appropriate instruments and tools, and respond to the relative gaps in the toolkit to support the delivery of the 10 EPHOs.
- Specifically, consider the development of tools for EPHOs 5, 7, 8, 9 and 10 (disease prevention, workforce, organizational structures and financing, communication and research).
- Focus on enhancing the integration of health promotion, health protection and disease prevention by strengthening primary health care.

Strengthen tools for monitoring performance and accountability

- Enhance effective use of time-bound targets and tools for monitoring and evaluating health trends and policy implementation at national, regional and global levels.
- Develop standards for the delivery of public health services and ensure their quality through regular scrutiny, inspection or assessment arrangements and accreditation.

Strengthen evidence

- Create a resource map and gap analysis of a wider range of instruments and tools, including toolkits and guidelines at the national level.

- Based on findings from the systematic review on legal and policy tools, summarize the main types of evaluation report and the key findings on the effectiveness of tools.
- Evaluate the population health outcomes and costs of major legislation, regulations and policies: such evaluation should occur before and after enactment.
- Evaluate the process and feasibility of developing and enforcing legislation and policy.
- Develop research on the cost–effectiveness of public health tools to inform policy-makers of the interventions with higher value for money.
- Enhance methodologies to evaluate the relative effectiveness on health of a range of different instruments and tools.

Introduction

Public health challenges

17. Health and well-being are vital components of social development; they have become critical macroeconomic and political factors throughout society (7), whose role has been reinforced as a result of the Millennium Development Goals initiative (8). The current financial crisis has tipped several countries into recession and forced governments to adopt restrictive policies, with consequences and impacts on investment, health spending, and the scope and quality of health care services (9). The new public health challenges in the WHO European Region, the re-emergence of “old challenges”, the need for a global response and concerns with the sustainability of health systems have an impact across all sectors.

18. Demographic changes continuing over the coming decades – including longer life expectancy and falling birth rates, which have led to an increase in the mean age of the population in Europe – will produce a major challenge for many areas of public policy. Alongside these demographic changes there has been an epidemiological shift; as a result, the large majority of the burden of disease across the Region is now accounted for by chronic NCDs (10) and mental health disorders, including Alzheimer’s and dementia among older people. NCDs have the greatest effect on public health across the European Region and account for most of the years of life lost, as well as the years of life lived with disability.

19. Communicable diseases also present new challenges for policy-makers and public health institutions and professionals. For example, the need to prepare for different strains of influenza, potential new pathogens such as severe acute respiratory syndrome (SARS), new drug-resistant strains of tuberculosis (TB) and rising HIV and AIDS infections in many countries of the Region are well documented. Communicable disease surveillance and response consequently remain a core occupation for public health services.

20. The large, avoidable and unfair differences in health outcomes between and within countries in the European Region persist and are growing in many countries, as structural determinants and conditions of daily life are affected. These have an impact on the distribution of power, income, goods and services, as well as on the circumstances of people’s lives, such as access to good quality health care and education, good working conditions and proper housing and environment (11).

21. Integration of the knowledge base – including tracing health disparities to their social determinants and to differences in access to services, financial coverage and deficits in patient empowerment in public policy instruments – is one of the critical benefits modern policy instruments and tools are expected to bring to public health efforts. Moreover, there is evidence that suggests that people at risk of social exclusion and those with special needs more generally – particularly migrants and people with mental health problems – continue to call for more attention in the further development of policy strategies and public health instruments.

22. Population health is also strongly dependent on the stability, productivity and resilience of the natural environment (12). The findings of several assessments, research projects and national health impact assessments have made it clear that climate change-related exposures will increase health effects from extreme weather events among other impacts of importance to human health in the next decades in the European Region (13; 14).

23. Globalization has given rise to particular challenges and opportunities for public health. Communicable diseases have never respected borders, but as the SARS outbreak and more recently pandemic (H1N1) 2009 have demonstrated, the global spread of disease occurs in a very short time scale and requires ever-improving surveillance, communication and action (15).

Public health instruments and tools

24. The number and complexity of health policy statements, strategies and other policy instruments developed by WHO has increased in recent years at the regional and global levels. There was a breakthrough with the advent of more legally binding types of instrument, such as the WHO FCTC and the IHR. At the same time the number of actors continues to increase, not least with the broader public health agenda of the EU (16).

25. Increasing pluralism and decentralization in Europe renders the task of seeking and building consensus and implementing various policy instruments more complex. This heterogeneity determines a multiplicity of specific instruments, varying by the nature of the actors involved (whether political, public or social), the sector of society upon which it intends to act (such as health, economy, education and so on) (17), and the aim that the government intends to pursue: “governments can act through different instruments to achieve particular goals” (18). Lascoumes and Le Galès, on the other hand, refer to the political and technical approach to the instruments within policies, which have a more pragmatic character (19).

26. For authors such as Perrels, the nature of the instruments also varies according to the level of government (global, central or local) (20) or, as referred in the EU White Paper on Governance: “the choice of the level at which action is taken (from EU to local) and the selection of the instruments used must be in proportion to the objectives pursued” (21).

27. The governance role of ministries of health increasingly entails activities outside the health system itself (22). It is a vital part of public health that the ministry of health and other actors responsible for health take or oversee selected intersectoral actions, where they take responsibility for advocating for improvements in areas outside their direct control. This may include actions in schools (education), road safety (transport), the workplace (labour and various regulatory bodies) or pollution (energy and environment). The intersectoral, multisetting dimension to public health services delivery is an essential component of health promotion and disease prevention.

28. These concerns should be reflected in whole-of-government policies at all levels – international, regional, national and local – which thus require action from the whole of society (7), involving an increasing number of stakeholders and actors. For this, governments have new and different ways to implement and achieve their objectives, and to bridge the gap between governance and society as a whole (15). The majority of recent authors call these forms of government action in the context of public policies “tools” and “instruments”.

Impact and effectiveness of instruments and tools

29. Over the past 10 to 20 years, there has been a substantial increase in the number of public health policy statements, strategies and other policy instruments developed by WHO at both the global and the European Regional levels. The trend has been towards using more legally binding instruments; in particular at the global level. However, evaluation and monitoring of these instruments has been limited.

30. It seems timely to undertake a review of possible gaps in the instruments and tools available in response to the public health challenges for the WHO European Region in the 21st century. Three major questions on public health tools remain partially unanswered: to what extent are existing public health policy instruments able to address the full range of challenges that have been identified as priority areas of attention; how can the mix of instruments be improved; and what are some of the remaining challenges of monitoring and evaluation? While this review does not present a full and detailed answer to all these questions, it provides initial findings that might be the subject of further research in the near future.

31. The review aims to address questions on the types of policy process and public health process that have worked well in terms of their impact on health and health systems; to what extent they were taken up by national governments and integrated in policy-making at national or subnational levels; and the results in terms of improved outcomes and processes (23).

32. The substantial growth of public health policy instruments – combined with the lack of evaluation and monitoring – justifies the effort to map the global and regional instruments of public policies. This first exercise and the classification of instruments by EPHO may assist with identification of the main areas of action for the EAP.

33. Simultaneously, the mapping exercise contributes to identification of those instruments that are already being evaluated, as well as those whose implementation has built-in monitoring mechanisms. This information is essential when considering the need to identify real and potential gains from public health instruments and tools and the best ways to enhance their effectiveness. In addition, evaluation of successful assessment and monitoring methods allows identification of the strengths and weaknesses of the models adopted, facilitating the search through benchmarking of the impact assessment models that best fit the specifics of governmental action on health (24).

Methods

34. The many public health challenges identified above justify a renewed European health policy, as well as policy instruments and tools capable of strengthening the capacity of health systems to achieve better health for the Region. Adoption of the Health 2020 policy calls for the identification and analysis of “governance mechanisms and instruments that can improve health policy and deliver health outcomes in an equitable and sustainable manner and to consider how priorities are set and strategic goals are implemented” (25).

35. The increasing complexity of global and European governance in health, with a wide variety of actors and stakeholders (at international, regional and national levels), combined with an increasing differentiation and specialization of responses and implementation responsibilities and expectations (26), has been described and analysed in great depth by WHO. The current paper was grounded in this knowledge and the vast body of work already undertaken (2; 5; 27; 28; 29).

36. A new classification matrix based on a conceptual definition of public health policy instruments and tools was developed for this mapping exercise. The matrix aims to contribute to the new focus of Health 2020 on strengthening regulatory frameworks for protecting and improving health. It could be developed into an active “roadmap” of documents related to instruments and tools for public health, based on the identification of available data sources and the preliminary literature review and classification tables produced thus far.

37. The work for this review was undertaken in four phases:

- definition of concepts
- definition of the classification matrix
- identification of available data sources
- literature review.

Definition of concepts

38. The definition of concepts consisted of an initial literature review on the basic concepts of “policy instrument” and “policy tool”. This was conducted using legal and public health databases to search for work including firstly descriptors of a legal nature (“legal”, “juridical”) and secondly descriptors of proximity to “public health policy”. During this phase search categories were also elicited and emerged when comparing the findings with previous reviews from WHO, including treaties, conventions, resolutions, codes, agreements, resolutions, strategies, recommendations and reports.

39. On the basis of the intended scope and purpose of the study, which is situated within subject of health governance and public health governance in particular, the instruments and tools specific to public health activities found during this search phase – such as epidemiological surveillance tools, monitoring tools for services, health surveys and user questionnaires, among others – were excluded. Only regulatory or normative instruments were considered for their importance for public health policy at global, national and subnational levels (30).

40. Thus, the search in this first phase focused on global and regional (European Region) governance. At this level, instruments with a normative nature – such as treaties, conventions and regulations – appeared to be the most important instruments and tools of governance. However, protocols, agreements and declarations emanating from international organizations are also important instruments. Policy instruments for public health differ in the degree to which they are legally binding and in the ways they are negotiated and implemented, where the role of WHO may focus on an advisory, normative, collaborative or operational role, including mixed strategies, as illustrated by Tables 1 and 2.

Table 1. The broad range of policy instruments for public health

	More legally binding		
Advisory	Technical Advisory Group	Expert Advisory Panel Expert Committee Study and Scientific Group	Commission
Normative	Resolution	Code	Regulation
			Convention; agreement
Collaborative	Network or alliance	Independent governance, borrowed legal identity	Independent legal identity
Operative	WHO Secretariat strategy	World Health Assembly, Regional Committee noted or endorsed strategy	Negotiated strategy

Source: WHO Regional Office for Europe (31).

Table 2. Policy instruments according to the WHO Constitution

Type of instrument	Example at the global level
Conventions and agreements (Article 2 (k))	FCTC
Regulations (Article 2 (k))	IHR
Recommendations (Article 2 (k))	Global strategy and plan of action on public health, innovation and intellectual property
Nomenclatures (Article 2 (s))	International Nonproprietary Names for pharmaceutical substances
Standards (Article 2 (u))	Codex Alimentarius Commission on food safety

Source: WHO Regional Office for Europe (31).

41. At the European level there is also a variety of EU documents with different natures and purposes, such as conventions, directives, regulations and the “Green and White Papers, Communications, advisory committees, business test panels and ad hoc consultations” (19).

42. For the purpose of this review the concept of “instrument” will include the treaties, conventions, regulations, agreements, declarations, norms, nomenclatures and standards, strategies and frameworks – with different scopes and implementation levels – through which Member States, supranational organizations, national and local governments and other entities with competence govern and regulate areas of action and coordinate international, national and local initiatives to protect and promote public health, and ensure health in all policies and sectors of society.

Definition of the classification matrix

43. Having identified the appropriate documents, it was necessary to build the mapping model. On the basis of the conceptual policy framework of Health 2020 and the EAP, a matrix was developed, showing seven key categories of the review findings:

1. EPHOs as thematic categories
2. EPHO subdivisions as thematic subcategories
3. title of instrument or tool and web link
4. lead organization
5. level of implementation
6. legal status
7. evaluation notes.

44. The success of the new strategy for public health in the European Region, Health 2020, and the EAP depends on their effective implementation and on a better understanding of the reality observed in each of the different Member States. In order to achieve these objectives, the 10 EPHOs (see Box 1) are set out as a detailed checklist for assessing public health capacities and services, alongside the actions required to strengthen them. The categories of the mapping document allow organization of the main documents chosen for the review in the light of the 10 EPHOs (category 1) and their operational aspects (category 2).

45. Category 3 displays the official title of the document and a link to the official latest updated version; the next category identifies its lead organization. Clear identification of the lead organization is a fundamental requirement, since the instruments of international law (conventions, treaties, protocols and agreements) are negotiated under the auspices of a transnational entity (or entities) with competence; this entity leads the negotiation process to its signature and entry into force, and – in the majority of the situations – becomes the entity with responsibility for monitoring the process of adoption and implementation of the instruments.

46. Category 5 identifies whether (at this first phase of the study) the document has global, regional or national and local implementation. At the end of the phase two, it should be possible to establish the relationship between the global and regional initiatives and local initiatives and strategies for action. The legal status of the instruments arises from the nature of the entity involved or from ratification by Member States, and for most of them it is the act of ratification that makes the text legally binding.

47. On the basis of the scope of the study, it was also considered important to include information on the process of assessing and monitoring implementation of the instruments and tools referenced. In this context, the last category contains information concerning the existence or lack of assessment and monitoring procedures, the competent authority and the existence and frequency of related reports.

Identification of available data sources

48. The work to identify available data sources was then undertaken in the following stages:

- an initial review and analysis of available WHO documents on the subject of public health policy, including available reviews of public health policy instruments and tools;
- a search of available repositories of legal documents in the WHO Regional Office for Europe;
- a web-based search of policy instruments and tools not included in previous sources;
- a search in the libraries of the Portuguese National Republic Assembly, the National School of Public Health of the New University of Lisbon, the Higher Institute of Social Sciences and Policies and the Law Faculty of the University of Lisbon.

49. The results then determined the following steps:

- identification of supranational organizations that produce documents with global and regional consequences for health and public health (conventions, treaties, protocols and agreements);
- identification of the main texts produced (including the WHO FCTC, IHR, Convention on the Rights of the Child, Convention on the Rights of Persons with Disabilities, United Nations conventions, ILO conventions and others);
- identification of the nature and juridical binding of the documents.

50. To comply with these procedures the authors researched the web pages of the international organizations involved, including the pages of the WHO international digest of health legislation; WHO tobacco control database; WHO IHR; United Nations Treaty Collection; United Nations Rule of Law; Office of the United Nations High Commissioner for Human Rights; UNECE conventions; ILOLEX; WTO documents and resources; EUR-Lex; ECOLEX; and others with institutional information.

51. At this stage other documents were considered, including declarations such as the Universal Declaration of Human Rights, the Berlin Declaration on Tuberculosis, World Health

Assembly resolutions, WHO Regional Committee for Europe resolutions and International Law Association rules, as well as charters such as the European Charter on Counteracting Obesity. Inclusion of these non-legally binding documents is justified by the importance they assume in health and public health promotion and protection, as in the case of the International Code of Marketing of Breast-milk Substitutes, which was adopted into national legislation by many of its signatory countries.

Literature review

52. The literature review was conducted in English. Review of policy and legal documents was conducted in English and Portuguese, as all global instruments and tools have been adopted into national law. A detailed collection of global and regional documents and policy documents already compiled by WHO was used as the primary source for this review. The results of a consultation exercise by WHO also provided relevant material, particularly for some eastern European countries. A recent collection of European legislation by the National Portuguese Assembly was available and also used to update this information.

53. The literature search was undertaken using Boolean logic, was unrestricted concerning time frame and included indexed journals and books. It was performed in bibliographic databases searched through a national platform called B-on, provided by the Ministry of Science of Portugal. The following databases are covered by this platform and were included in the literature search: Academic Search Complete, American Chemical Society, American Institute of Physics, Annual Reviews, Elsevier, ACM Digital Library BioMed Central, BioOne, Bioline International, Blackwell, Cambridge University Press, Cinahl, DOAJ, Elite, Emerald, Future Science Group, Health Business, IEEE, IOP Publishing, MedLine, MedicLatina, Nature Publishing Group, Nursing Reference Center, Psychology and Behavioral Science, PubMed Central, Public Library of Science (PLOS), RCAAP, Royal Society of Chemistry, Sage Publication, Scielo Global, SIAM, SportDiscus. SpringerLink, Taylor & Francis, Web of Knowledge, Web of Science, Wiley.

54. The search terms used were “public health instruments”, “public health tools” and “public health instruments and tools” (as exact phrases). In a second stage the terms “policy”, and “legislation” were also included in the search algorithm.

55. The literature search included the following exact search phrases in the subject field:

- “public health instruments”, which retrieved 9055 documents
- “public health tools”, which retrieved 12533 documents
- “public health instruments and tools”, which retrieved 3014 documents.

56. Including the word “policy” in the above search terms resulted in:

- “public health policy instruments”, which retrieved 3055 documents
- “public health policy tools”, which retrieved 5084 documents
- “public health policy instruments and tools”, which retrieved 1305 documents.

57. Including the word “legislation” in the above search terms resulted in:

- “public health legislation instruments”, which retrieved 1824 documents
- “public health legislation tools”, which retrieved 958 documents
- “public health legislation instruments and tools”, which retrieved 57 documents.

58. A first step in the classification of documents into the EPHO subdivisions consisted of reading the texts of the documents in question. When a clear identification with the EPHOs was not possible, the authors sought the area of closest proximity; this approach may have led to a loss of information and bias on further analysis of the documents in light of the goals pursued by the study (32).

Findings

59. This review provides a refined map of the main global and regional policy and legal instruments of the range and type set out in the WHO Constitution of 1948. The information is categorised in line with the revised version of the 10 EPHOs forming the basis of the EAP following resolution EUR/RC61/R2 on strengthening public health capacities and services in Europe (1; 32) (see Box 1).

60. Analysis of available public health policy instruments and tools reveals several major gaps. In particular, a great majority are related to EU initiatives and apply only to EU countries, whereas fewer instruments and tools are identifiable among CIS and SEEHN countries.

61. A clear concentration of public health policy instruments and tools is linked to the first EPHOs in the list. EPHO 1 (surveillance), for example, is associated with 58 policy instruments, while EPHO 3 (health protection) is associated with 396 instruments. On the other hand, instruments and tools are relatively scarce in relation to EPHOs 7 and 9 (workforce and communication).

62. Evidence of monitoring and evaluation of public health instruments and tools is relatively scarce, although some instruments – including some non-legally binding ones – have produced a series of evaluation mechanisms to facilitate this. Among the 58 policy instruments and tools classified within EPHO 1 (surveillance) only 29 provided evidence of any type of evaluation, such as monitoring and assessment reports, activity reports, expected outputs, country implementation or transparency. A total of 37 policy instruments were found for EPHO 2 (response to health hazards and emergencies), among which evidence of any type of evaluation was found for only 18. Of the 396 policy instruments and tools classified under EPHO 3 (health protection) evidence of evaluation was found for 214; of the 70 instruments for EPHO 4 (health promotion) evidence of evaluation was found for 36; and of the 17 instruments for EPHO 5 (disease prevention) evidence of evaluation was found for only 6.

The range of legally and non-legally binding public health instruments at global and regional levels

63. There has been significant progress over the past two decades in developing global and regional public health instruments that seek to address specific areas of public health. Overall, the range of policy instruments for public health has expanded considerably over time. They have also tended to become more complex, taking into account the growing complexity of health governance in Europe, but they now also apply more fully the range of legal instruments set out in the WHO Constitution (see Box 2).

Box 2. Nosocomial infections – Norwegian regulations

The nationwide occurrence of nosocomial infections in Norway was first estimated in three prevalence studies of 1979, 1985 and 1991. In 1996, the Norwegian Ministry of Health issued regulations on the prevention of nosocomial infections. These regulations were revised in 2005. As part of the infection control programme, hospitals and long-term care facilities are obliged to have a nosocomial infection surveillance system in place and to report the results to the Norwegian Institute of Public Health, which coordinates the surveillance activities and publishes annual statistics. This surveillance system is compatible with the recommendations of the Hospitals in Europe Link for Infection Control through Surveillance (HELICS) cooperation project of the EU.

Norway. Regulations No. 610 of 17 June 2005 on protection against infection in the health service.

Made in pursuance of, inter alia, Law No. 55 of 5 August 1994 on protection against communicable diseases (see IDHL, 1995, 46, 27, Norw. 95.5), these Regulations repeal Regulations No. 699 of 5 July 1996 on protection against infection in health institutions – nosocomial infections (see *ibid.*, 1997, 48, 164, Norw. 97.3). They impose the requirement of an infection control programme on a wider range of establishments than that covered by the repealed Regulations.

They comprise the following Chapters: 1. Purpose, scope, and definitions (Sec. 1-1 to 1-3); 2. Infection control programme, organization and supervision (Secs. 2-1 to 2-5); 3. Responsibility and tasks (Sec. 3-1 to 3-6); and 4. Final provisions (Secs. 4-1 to 4-3).

Source: WHO (33).

64. One useful issue arising from the current exercise relates to the intersection of global and regional initiatives with national and local ones, as well as valuation models. The inclusion of information on all these aspects in a single study matrix may contribute to a better understanding of how implementation of global initiatives filters down to the local level, and the gains (or lack thereof) that these juridical initiatives bring to the lives of individuals and populations.

65. Policy instruments for public health differ in the degree to which they are legally binding and in the ways they are negotiated and implemented, where the role of WHO may focus on an advisory, normative, collaborative or operational role, including mixed strategies. Among the normative instruments, regulations, conventions and agreements are usually regarded as legally binding instruments in a strict sense. Since 2000, legally binding instruments have become increasingly common, in particular at the global level.

66. The WHO European Region has a particularly strong record of adopting legal public health measures compared to the global picture. Legally binding public health tools represent one-third of the total number of available tools in the Region: this proportion is more than double the global average.

67. Although an extensive literature search was completed, the current report faces some limitations. Full identification of the broad range of instruments cannot be regarded as complete. Additional protocols to conventions and treaties have not been included in this review, and other documents may also be missing. Although it is possible to find a greater number of documents than those identified and classified here (see Table 3), some of those documents may need monitoring because they are in the process of ratification, and thus additional protocols may also arise during the negotiation process.

Table 3. Public health instruments and tools at global and regional levels

	Total	Legally binding	Non-legally binding
Global	253	39	214
Regional	664	378	299

68. The increasing use of legally binding instruments is illustrated by the fact that since 2000 three out of eight WHO commissions and seven of the sixteen strategies adopted by the World Health Assembly have been of a more legally binding nature. Most notably, this is the case for the two new instruments (of the five new global regulations and conventions since 2000) the WHO FCTC and the IHR (see Box 3).

69. Examples of other important policy framework developments relevant for public health in the European Region are:

- the Millennium Development Goals
- the Global Strategy on Diet, Physical Activity and Health
- national environment and health actions plans
- the Protocol on Water and Health
- other strategies for NCDs, in areas such as diet and physical activity, tobacco and alcohol
- the Mental Health Declaration and Action Plan for Europe (see Box 4)
- the EU health strategy 2008–2013, which includes chapters on HiAP and on global health
- the European Regional Framework for Action for protecting health from climate change.

Box 3. Implementation of the IHR in the WHO European Region

In 2005, WHO Member States adopted the current IHR, which entered into force in June 2007. Since then, the States Parties and WHO have reiterated their commitment and taken important steps towards meeting the legally binding IHR requirements. Between June 2007 and July 2009, the national focal points and the WHO IHR Contact Point were in contact in respect of over 200 public health events in more than 40 States Parties in the WHO European Region.

The purpose and scope of the IHR are “to prevent, protect against, control and provide a public health response to the international spread of disease in ways that are commensurate with and restricted to public health risks, and which avoid unnecessary interference with international traffic and trade” (IHR, Article 2). Hence, the IHR adopt a multisectoral approach and encompass a broad range of public health hazards (biological, chemical, radionuclear and of unknown etiology). Implementation of the IHR represents a unique opportunity to mobilize resources and develop sustainable public health capacities, serving both domestic and global public health.

Since their entry into force, States Parties to the IHR and WHO have reiterated their commitment and taken important steps towards meeting their legally binding IHR requirements, which is a challenge that requires time, commitment and a willingness to change. The WHO Regional Office for Europe has been providing assistance to States Parties to implement the IHR, and the wide range of activities carried out have generally corresponded to the areas of work outlined in the WHO document *International Health Regulations (2005): Areas of work for implementation*, published in 2007: namely, fostering global partnerships; strengthening national disease prevention, surveillance, control and response systems; strengthening public health security in travel and transport; strengthening WHO global/regional alert and response systems; the management of specific risks; sustaining rights, obligations and procedures; and conducting studies and monitoring progress.

The IHR implementation process depends on the tireless engagement of professionals from different disciplines and sectors at subnational, national and international levels. The implementation process will also be supported by the extraction and documentation of lessons learned, so that these can lead to change and serve to optimize event management and capacity strengthening under the IHR framework.

The key challenges are:

- maintaining a balance between theoretical monitoring exercises and the spirit of the IHR, to improve domestic and international public health capacities;
- facilitating mechanisms to extract and build on the lessons learned from practice in a continuous, consultative and systematic fashion, to harmonize interpretation of the IHR and related practices, and ultimately to further improve the application of the IHR and maximize their anticipated benefits; and
- reviewing the tools, mechanisms and provisions outlined in the IHR, building on the lessons learned, and without jeopardizing the spirit of the IHR and those provisions that efficiently serve the interests of public health.

Source: WHO (34).

70. Governance of health in the European Region has become increasingly complex. Over time, there has been a tendency to move from comprehensive, overarching policy frameworks such as the Health for All strategy (first published in 1981; last updated in 2005) – which acted as a prominent umbrella for setting public health goals and policy initiatives – to an increasing

differentiation and specialization of public health strategies into an ever-larger number of individual instruments covering specific fields, as illustrated in the list above.

71. In this respect, mental health policy (see Box 4) provides one example of an area of public health where the Regional Office has successfully shown leadership by policy action that has focused on a specific field of public health concern. Mental health policy is a good example to illustrate the need for focused action: it remains one of the most important public health issues and is high in the burden of disease rankings, including when economic costs are taken into consideration. Moreover, mental health is an indispensable part of public health, but mental health policy was a neglected field for a long time, as a result of stigma and discrimination.

Box 4. The Helsinki Mental Health Declaration and Action Plan for Europe: a milestone for public mental health

Mental health was put prominently on the political agenda in January 2005 when ministers from Member States and key stakeholders, including service user representatives, met at the WHO European Ministerial Conference on Mental Health in Helsinki. The Conference was a response to concern about the increasing burden of mental disorders in Europe, and to the awareness of a need to develop community-based mental health services.

The ministers endorsed the Mental Health Declaration and Action Plan for Europe. The Conference defined the scope of mental health policy, stating that it encompasses promotion of mental well-being; tackling of stigma, discrimination and social exclusion; prevention of mental health problems; care for people with mental health problems; and social inclusion of those who have experienced mental health problems. The ministers committed themselves to implementation of mental health policy actions and to report back to WHO on the progress of implementation of the Declaration at an intergovernmental meeting, yet to be organized.

The Conference had a decisive impact on mental health policy in Europe. An evaluation performed by the WHO Regional Office for Europe in 2008 concluded that nearly all countries have made significant progress. More than half the responding Member States reported adopting new mental health policies or updating their existing policies since 2005.

For the EU, the Helsinki Conference gave impetus to an extensive process, materialized through several conferences, projects and key documents. An outline of an EU mental health strategy, based on the Conference results, was launched in the EU Green Paper on mental health, supported by a European Parliament resolution, and in 2009 the EU launched the European Pact for Mental Health and Well-being.

Source: Di Fiandra (35).

72. Two further trends have added to the complexity of the current mix of public health policy instruments: the increasing number of instruments and partnerships at the global level and the growing role of the European Commission in the public health agenda in the Region. Moreover, the recognition of the importance of strengthening health systems and the links of health with other social and economic policies, which at a regional level culminated in the Tallinn Charter, have further widened the range of ways of working with Member States.

73. Inevitably, the process of negotiation, implementation and monitoring of legally binding instruments comes at a considerably higher cost than that of “softer” policy instruments that do not have a legally binding nature. In the EU context, “‘soft law’ is the term applied to EU measures, such as guidelines, declarations and opinions, which, in contrast to directives, regulations and decisions, are not binding” (36), but derive from primary “hard” law, such as treaties, conventions, directives, regulations and decisions, and have to respect the legal

frameworks and boundaries expressed in these documents. Examples of these in the European Region are:

- Together for health: a strategic approach for the EU 2008–2013
- Community strategy 2007–2012 on health and safety at work
- European Code against Cancer
- European Road Safety Action Programme
- European Road Safety Observatory.

74. Although soft law instruments do not have legally binding force, they can be classified as legal acts since they can contain principles and basic or fundamental rules, or represent an early stage of the legislative process, or may contain rules adopted into national law. It is also possible that national courts take these instruments into consideration when they are called to decide issues related with the interpretation of national measures. In recent years, soft law instruments are “sometimes presented as a more flexible instrument in achieving policy objectives” (36).

75. Other non-legally binding but ethically and politically binding instruments and tools put in place by the activity and powers of WHO include charters, declarations, statements, strategies, policies, guidelines, standards, frameworks, codes of conduct and reports (such as the world health report and the European health report). The research undertaken as part of WHO’s remit could also be considered a public health instrument, especially when it comes to governance and decision-making.

76. Both new and re-emerging public health threats call for global cooperation and increasingly complex policy instruments and partnerships. An important example is the Green Light Committee (GLC) to control multidrug-resistant (MDR) and extensively drug-resistant (XDR) TB, especially in countries with a high burden of M/XDR-TB (see Box 5).

77. These examples illustrate that agreements on public health action are an important part of the governance of public health. But are they sufficient in themselves to achieve priority health goals that countries in the Region have identified? As well as exploring what other actions are needed at the international level, it is also important to develop strategies for their implementation at national level, including cross-government commitment that can ensure that policies in all sectors are consistent with health goals, and actively support them. How core health services can support a wider public health strategy is also an important consideration.

78. WHO has given technical support to the development of strategies at the national level in many areas of public health, and how best to link international policy instruments to implementation at national and subnational level is an important consideration for the design of any new mix of policy instruments, bearing in mind the important role played by the Regional Office in this respect for a number of public health challenges. One such example is food and nutrition action plans, which had been endorsed in 45 of the Region’s Member States by 2005. These aim through a variety of activities to address nutritional deficiencies and unbalanced diets and to ensure the availability of healthy food to the general population.

Box 5. Controlling MDR-TB: the GLC

The GLC was formed in 2000 by the Stop TB Partnership. It was established as a multi-institutional partnership to promote access to life-saving high-quality second-line drugs at reduced prices for the treatment of MDR-TB and under rigorous monitoring to prevent the creation of resistance to second-line drugs, the last line of defence against TB. Major reductions in the prices of second-line drugs were achieved through negotiations with pharmaceutical companies and pooled procurement of drugs.

Before the creation of the GLC, most resource-limited countries did not diagnose and treat MDR-TB patients, whereas today 65 countries have been approved by the GLC for MDR-TB management, with approved treatments to almost 60 000 people in 2009.

In 2002, the Global Fund to Fight AIDS, Tuberculosis and Malaria decided that all procurement of medications to treat MDR-TB must be conducted through the GLC. A few years later, UNITAID, which supports the supply of commodities for AIDS, TB and malaria from taxes on airline tickets, also committed significant funding for second-line anti-TB drugs to resource-limited countries. These decisions were major moves to ensure availability of adequate quantities of quality-assured drugs and technical assistance to resource-limited settings.

The first years of the GLC were crucial for developing a replicable model for feasible and cost-effective MDR-TB control in resource-limited countries. The initial phase ended in 2005, when compelling evidence on feasibility, effectiveness and cost-effectiveness of MDR-TB management under programmatic conditions was obtained from the projects approved and monitored by the GLC. Drawing upon the experiences of the GLC projects, WHO developed international guidelines for the programmatic management of drug-resistant TB.

Countries that meet the WHO guidelines, with a strong Directly Observed Treatment Short course (DOTS) foundation and a solid plan to manage MDR-TB, can benefit from the GLC services: quality-assured second-line drugs at reduced prices, horizontal collaboration and knowledge-sharing facilities. The GLC also offers technical assistance and help with monitoring performance. Furthermore, it helps to raise potential donors' interest and operates in collaboration with the Global Fund, UNITAID, United States Agency for International Development and corporate sector stakeholders.

Sources: Stop TB Partnership (37); Green Light Committee Initiative (38).

Instruments and tools classified by EPHO

79. All the policy instruments and tools reviewed were classified in terms of the 10 EPHOs, whose relevance and importance is highlighted in the EAP. Such classification thus has the potential to enable the establishment of a complete toolkit for the delivery of EPHOs across the WHO European Region. Furthermore, it facilitates identification of major gaps in terms of tools.

80. A first step in the classification of documents into the EPHO subdivisions consisted of reading the texts of the documents in question. When a clear identification with the EPHOs was not possible, the authors sought the area of closest proximity; this may have led to a loss of information and bias on further analysis of the documents in light of the goals pursued by the study.

81. The change in the wording of the EPHOs following resolution EUR/RC61/R2 forced a revision of the review's classification system. Nevertheless, to date the majority of instruments and tools – especially those with global scope – fall under EPHO 3 (health protection), EPHO 4 (health promotion) and EPHO 6 (governance) (see Table 4).

Table 4. Numbers of legally binding and non-legally binding public health policy instruments by EPHO

EPHO	1	2	3	4	5	6	7	8	9	10
Legally binding	21	12	306	31	2	41	3	1	0	0
Non-legally binding	37	25	90	39	15	259	11	5	5	2
Total	58	37	396	70	17	300	14	6	5	2

82. The 396 different tools for EPHO 3 (health protection) and the 300 for EPHO 6 (governance) represent more than 75% of the total number of public health tools available, and are particularly developed for EU countries. While CIS and SEEHN countries have historically strong services in EPHOs 1–3, capacity and laboratory equipment have often become outdated, and legislation and policy also need updating.

83. At the global level, legally binding instruments and tools are mainly concentrated in EPHO 3 (health protection) with 306 tools, EPHO 4 (health promotion) with 31 and EPHO 6 (governance) with 41. This corresponds to more than 90% of the total number of tools. However, no legally binding tools are available for EPHO 9 (communication) and EPHO 10 (research).

84. EPHO 6 (governance) appears here as an individual category, and those documents involving the whole of society, which may be classified as instruments of governance, were listed in subdivision A (ensuring a whole-of-government and whole-of-society approach to health and well-being). This choice is justified by a sense of coherence with other European health strategies, such as the Health for All policy.

85. In addition to the documents directly related to governance, this category also contains a set of instruments that are not legally binding, but are ethically and politically binding; these constitute the basic texts in the sense that they contain the reference values and principles to which stakeholders, Member States and international organizations are bound, and which they must implement within their powers and mandates.

86. The current classification system cannot be seen as a closed process, since it stems from the need to analyse the full texts of some documents, followed by the need to change the category to which they belong in some cases.

87. A continuing survey of these instruments will allow monitoring of how the health impact assessment strategy is reflected in all sectors, including development of the international texts that often frame national legislative initiatives. The issue of monitoring and impact assessment, which should be considered both a concern and a necessity, would require a change in the proper juridical techniques of drafting these documents. In the medium and long term, inclusion of comparable monitoring and evaluation mechanisms could contribute to a better adaptation of the legislation to the real needs of different stakeholders.

88. The use of EPHOs as criteria for the classification of legal documents highlights a difficulty arising from the fact that the EPHOs were not set up to have this purpose or goal.

Another difficulty arises from the operational nature of EPHOs and their subdivisions, which are a checklist for countries to assess their capacity in terms of public health and health services; this difficulty is even more clearly demonstrated with the latest version of the EPHOs (see Box 1), in which the definitions are much more operational than in previous versions.

89. In addition, the number of documents and their size seems to justify the creation of a platform to serve as a repository for all these documents, which would enable swift access to the necessary information.

Effectiveness of instruments and tools

90. The use of these public health instruments and tools – including actions to reduce alcohol consumption through taxation and advertising bans, tobacco control measures and road safety – can be highly cost-effective. While many of these actions would already be justified for other reasons, the cost–effectiveness evidence is a further argument in favour of their implementation.

91. Specific evidence on the effectiveness of different public health policy and legal instruments is currently limited, which makes it difficult to recommend one tool over another. The following section summarizes examples of targets in the main areas where evaluations were found. Overall, further evaluation is needed to inform the future effectiveness of different instruments and tools, including cost–effectiveness and feasibility of implementation.

92. A recent WHO report on “best buy” interventions for NCDs concludes that there is a set of interventions that have significant public health impact and are highly cost-effective, inexpensive and feasible to implement within the constraints of health systems; these can be considered “best buys” for investors (see Box 6). A range of other interventions that constitute “good buys” is also identified (3).

Box 6. “Best buy” interventions for NCDs

The set of “best buy” interventions includes:

- tobacco use
 - tax increases
 - smoke-free indoor workplaces and public places
 - health information and warnings
 - bans on tobacco advertising, promotion and sponsorship
- harmful alcohol use
 - tax increases
 - restricted access to retailed alcohol
 - bans on alcohol advertising
- unhealthy diet and physical inactivity
 - reduced salt intake in food
 - replacement of trans fat with polyunsaturated fat
 - public awareness through mass media on diet and physical activity.

Source: WHO (3).

93. The primary benefit is a reduction in premature mortality from NCDs. Studies have found that implementing a specific set of “best buy” interventions for NCDs in 23 large LMICs could prevent 30 million premature deaths from 2006 to 2015, or an average of 3 million per year. Total deaths from the four NCDs that were the focus of the United Nations high-level meeting on NCDs in 2011 amounted to 23.7 million in 2004, which indicates that at least 10–15% of premature deaths could be successfully averted through the scaled-up implementation of a core intervention package.

94. Population-based measures for reducing tobacco and harmful alcohol use, as well as unhealthy diet and physical inactivity, are estimated to cost US\$ 2 billion per year for all LMICs – less than US\$ 0.40 per person. Individual-based “best buy” interventions for NCDs – which range from counselling and drug therapy for cardiovascular disease to measures to prevent cervical cancer – bring the total annual cost to US\$ 11.4 billion. On a per-person basis, the annual investment ranges from under US\$ 1 in low-income countries to US\$ 3 in upper middle-income countries. In health terms, the return on this investment will be many millions of avoided premature deaths. In economic terms, the return will be many billions of dollars of additional output. For example, reducing the mortality rate for ischaemic heart disease and stroke by 10% would reduce economic losses in LMICs by an estimated US\$ 25 billion per year, which is three times greater than the investment needed for the measures to achieve these benefits. The WHO report (3) supplements existing knowledge by demonstrating the costs and benefits related to addressing the challenges posed by NCDs.

95. Concern with evaluation and monitoring, which initially arose in the context of environmental protection, is now present in all sectors of activity and in various instruments and tools. It was possible to find examples of evaluation and monitoring at different levels of action and within different initiatives, treaties, conventions, strategies and actions plans, as demonstrated in the “evaluation notes” category of the classification matrix. The analysis shows that different bodies of United Nations and EU institutions, and more recently WHO – as in the cases of the WHO FCTC and IHR – are the entities that provide more tools for assessing and monitoring (such as convention sites, assessment reports and “guideline kits”).

96. In the case of legal instruments, such as conventions and treaties, the monitoring process usually focuses on the process of ratification and entry into force. So far, only a few well-defined documents refer to systems of health impact assessment; a move towards this can be seen in the WHO FCTC and IHR initiatives and EU legislative activity.

97. The WHO FCTC demonstrates continued global commitment to decisive action against the global tobacco epidemic, which kills millions of people and costs hundreds of billions of dollars each year. A total of 173 parties to the WHO FCTC, covering about 87% of the world’s population, have made a legally binding commitment to implement effective tobacco control policies. The WHO FCTC provides countries with the necessary tobacco control tools that, when implemented and enforced, will reduce tobacco use and save lives (see Box 7).

98. Evaluation of the impact of the WHO FCTC and its measures is essential. At the same time, it is crucial that measurements are not monitored prematurely. Otherwise, there is a risk of incorrectly portraying low levels of impact and endangering political support for the policy. Additionally, caution should be taken when interpreting the impact of policies. The nature of the measures and exemptions and possible loopholes that could impact the compliance and enforcement must be understood. Such shortfalls could, in turn, affect the appearance of the effectiveness of the WHO FCTC, and this needs to be recognized.

Box 7. The WHO FCTC

The WHO FCTC, which entered into force in February 2005, is the world's first global public health treaty, designed to tackle the devastating health, social, environmental and economic consequences of tobacco consumption and exposure. As of July 2012, 49 of the 53 WHO European Member States, as well as the European Community, have become parties to the convention, committing themselves to developing and implementing a comprehensive mix of evidence-based tobacco control measures. Globalization of the tobacco epidemic diminishes the capacity of individual countries to regulate tobacco through domestic measures alone. A coordinated, international response is essential. The international community is committed to a shared goal and the idea that with collective action, obstacles can be overcome and creative solutions can be found.

The WHO FCTC adopts a whole-of-government and intersectoral approach, expanding beyond health into the arena of education, customs and trade sectors and finance. It is a concrete example of the whole-of-government approach: increasing tax on tobacco is the most effective way of reducing tobacco use and has the added benefit of increasing government revenue. The WHO FCTC recommends increasing the excise tax on tobacco products to at least 70% of the price. It is clear that to implement this measure, collaboration between the health and the finance sectors is necessary. In addition, to control a possible increase in illicit trade as a result of the higher taxes, the customs and trade sectors should also be involved. Intersectoral collaboration is also essential for the successful implementation of other key measures, such as banning advertising, protecting people from second-hand smoke and warning the public about the dangers of tobacco use.

Approximately 3.8 billion people (55% of the world's population) are covered by at least one tobacco control measure at the highest level of policy achievement, according to the latest WHO report on the global tobacco epidemic, including 1.1 billion covered by a new policy since 2008. In the WHO European Region, over 244 million people (27% of the population in the Region) became newly covered by at least one tobacco control measure at the highest level of achievement between 2008 and 2010. This has great potential to make remarkable improvements in health.

For example, comprehensive smoke-free policies can reduce mortality and morbidity from exposure to second-hand tobacco smoke, even within a few months after the implementation of the law. The scientific literature indicates that just a few months after the implementation of smoke-free laws, improvements in respiratory health are experienced very quickly, and hospitalizations for myocardial infarctions can decrease. For example:

- just three months after the comprehensive smoke-free legislation was enacted in Scotland, bar workers reported a 26% decrease in respiratory symptoms and asthmatic bar workers showed reduced airway inflammation;
- within the first year of the introduction of the tobacco control law in Turkey there was a substantial decrease of 24.2% in the number of patients with smoking-related diseases.

Additionally, increasing the price of tobacco through higher taxes is the single most effective way to decrease consumption and encourage tobacco users to quit. Increasing tobacco taxes by 10% generally decreases tobacco consumption by 4% in high-income countries and by about 8% in LMICs, while tobacco revenues increase by nearly 7%. In Ukraine, the average excise per cigarette pack increased more than six-fold between September 2008 and January 2010. This was accompanied by a decline of 16% for adolescent and young adult (12–29 years old) smokers. Furthermore, contrary to tobacco industry claims, tax increases do not create increased smuggling. When Spain raised tobacco taxes and strengthened law enforcement in the late 1990s, smuggling declined dramatically, while tobacco revenues increased by 25%.

The use of time-bound targets and tools for monitoring and evaluation

99. Time-bound targets and tools for monitoring and evaluation of health trends and policy implementation at the global, regional and national level have played a prominent role in a broad range of policy instruments and health policy strategies governing the work of the Regional Office. Examples of important initiatives are:

- the Health for All initiatives (the original version of 1981/1985 and the 1991, 1998 and 2005 updates);
- the health-related Millennium Development Goals;
- the objectives set in WHO's Eleventh General Programme of Work (GPW11);
- the Tallinn Charter, with its commitment to accountability and health systems performance assessment;
- several specific public health instruments and strategies, such as those on environment and health or on mental health that all have subsections on evaluation and monitoring, and sometimes more specific strategies on indicator and measurement development, including recommendations on what action is needed at the international level (including setting of standards, norms and cross-country information gathering).

100. The challenges of target setting have been clearly formulated since the first version of the Health for All strategy, which stated that targets should be:

- formulated on the basis of scientific knowledge
- directed towards a significant health problem
- reliable, realistic, and simply and clearly expressed
- quantified as far as possible (making progress measurable)
- relevant to the regional strategy, politically acceptable and meaningful
- attractive to the public, politicians, administrators and professionals (39).

101. It has been noted that health targets are particularly relevant for supporting policies that go beyond health care services to other key sectors, addressing the broader socioeconomic determinants of health (40). Since the original Health for All strategy in the early 1980s there has been a gradual shift of emphasis, with more focus on encouraging countries to set national targets as key governance tools to help them implement their own, national (and subnational) health policies (26; 31) (see also Box 8), with a growing reluctance to include normative tools for the whole European Region.

102. In comparison, the original set of Health for All targets aimed at a high level of precision, defining targets on the basis of the magnitude of the (public health) problem, past trends in its development, the expected magnitude and nature of the problem at the target date if nothing were done (based on projections), the effectiveness of proposed actions in dealing with the problems and the desired situation for the target date, for which actions were proposed. However, as the 2005 Health for All review among Member States of the European Region showed, one of the main success stories from the Health for All legacy was the fact that national policies that include health targets had been extensively adopted or drafted, "although their nature and implementation varied widely" (40).

Box 8. The evolving role of targets in WHO Health for All policies

Health for All by the year 2000 (1981)

The initial Health for All policy contained 38 non-legally binding targets that covered a rather comprehensive range of public health and health system goals ranging from health status improvements to promotion of healthy lifestyles, healthy environment, quality-oriented and cost-effective health care and health development strategies (including health information support).

The targets varied, some of them being rather ambitious, some defined in very precise terms, whereas other were defined more generally, for example in terms of desirable policy developments. Monitoring of progress on targets was initially based on a list of over 200 originally approved indicators (65 of which were considered essential). These were assessed and published (enhancing completion and accountability) at three-year intervals.

Some measurements used in the monitoring and evaluation were related to changes in absolute values (averages, proportions or ratios, prevalence, incidence or mortality from different conditions or ratios characteristic) and differences (relative reductions of the indicators) between and within countries and their subpopulations.

In 1996 it was agreed that basic health statistics would be reported annually and survey data every three years, and that national coordinators would be appointed in countries to ensure direct transfer of the data to the Regional Office, with a full-scale evaluation every six years.

Health21 (1998 update)

The Health for All process was renewed in the mid-1990s, also based on the recognition that many targets were not achievable in the foreseeable future, or only in a few countries. The experience gained from Health for All suggested the need for more realistic and achievable targets. Except for those related to disease elimination, targets were not expected to be equally applicable to all countries but based on their situation and their ability to achieve them. Selection and monitoring of indicators were aimed at ensuring continuity of the previous Health for All experience. Most health-related indicators were collected routinely or otherwise available at national or international levels, but WHO provided a health survey platform (EUROHIS) for some important indicators. Target levels were set using projections based on historical trends and current situation analysis, subject to availability and quality of data. Target levels were defined as regional averages and were assessed against a 1995 baseline with an end date of 2020.

Finally, the 2005 update, which is currently the latest version, no longer includes any normative targets for the whole European Region.

Sources: WHO (41; 42; 43).

103. A preliminary review of existing policy instruments illustrates that these differ greatly in their approach towards monitoring and targeting.

- Numerical target setting coexists with more broadly formulated policy targets for which no specific indicators were proposed (sometimes in the same documents, such as the Health for All strategies).
- Where targets are mentioned explicitly, strategies for their measurement are often missing, such as in collaborative arrangements to establish international statistical norms and in systematic support to Member States for their implementation.

- It is often unclear whether the right balance has been struck between resources devoted to implementation and those devoted to systematic evaluation.
- Evaluation may suffer from “myopia”, focusing on accountability of special action and programmes rather than establishing a sustainable infrastructure (at national, but also at international level) for long-term monitoring and analysis, including for international comparisons and cross-country learning from good practice examples of public health policies.
- There is some evidence that the policy pendulum swings over time between enthusiasm for regional and global target setting in public health and periods that are more sceptical of the virtue of targets.

104. The analysis enabled verification of an increasing number of articles relating to impact assessment models, both in the environmental sector and in cross-sector research (44), as well as among communities (45). Impact assessment is also an important instrument for policy and programmes. Some research includes the concept of equity as a fundamental tool for health impact assessment although more research is needed in this area.

105. As a health impact assessment aims to assess the potential impacts of a proposal and make recommendations to improve the potential, it is possible to verify in the classification matrix that the legally binding documents are those where the health impact assessment methodology is evident, and where comparison between countries is easier. The main areas where health impact assessments are found are those of environmental and occupational safety, although they should be applied to all areas and levels of governance as an instrument to improve health outcomes and minimize inequalities (41).

106. The matrix analysis presents a wide variety of options for monitoring and evaluation. In some cases, as with conventions and treaties, the process sometimes combines aspects of a strictly juridical nature (such as ratification or entry into force) with others on impact assessment. Although the EU initiatives have broad provision of assessment tools, it would be useful to analyse the existing models and identify the best practices to benchmark both the findings and the health outcomes and gains – as well as the instruments to obtain them – in the different countries of the EU Region, particularly in terms of surveillance, access to health care, financing, involvement and empowerment of the communities and issues related with health professionals and research.

107. As already stated, progress with comparable health indicators, as well as with health information at the country level has been uneven in the Region, both in terms of availability and of data quality, and in particular in the coverage of topics relevant to monitoring public health trends and health determinants, such as inequality in health and health care, lifestyles, and trends in threats and morbidity from chronic diseases, NCDs and mental health disorders. Data fragmentation and data quality problems are present for some of the most fundamental public health information topics, such as tobacco and alcohol consumption and diabetes prevalence, as well as the most common diseases, such as cancer.

Conclusions

108. The renewed focus on, and commitment to, strengthening public health capacities and services calls for a comprehensive action plan, centred on actions that are strategic, that reflect modern public health practice (including a focus on both structural determinants and individual actions) and that are fully integrated with the main conclusions and messages of Health 2020. The purpose of the EAP is to ensure that public health services are strengthened to respond to the current and emerging public health challenges facing the WHO European Region.

109. This report underpins and complements the EAP by reviewing the range of available public health instruments in order to develop evidence-based policies and tools for future programmes. The review makes a classification and analysis of available policy instruments and tools. By putting together all the current tools, it provides an assessment of the toolkit and identifies major gaps to be tackled in the future.

110. The purpose of this review is to provide the Regional Office, Member States and other partners with direction in addressing, among others, the questions below.

- What are the relative advantages of the different types of public health instruments and tools available?
- How can the effectiveness of public health instruments and tools be enhanced at Member State level?
- How can gaps in the toolkit of available instruments and strategies be addressed?
- How can evaluation and monitoring of these instruments and tools be made more effective?

111. It was not possible to answer these questions in full, but this study advances our understanding of the effective use of public health instruments and tools across the European Region. The following summarizes the responses to these questions.

What are the relative advantages of the different types of public health instruments and tools available?

112. A recent report from the WHO Regional Office for Europe highlights four major roles for the law in advancing public health. These are: defining the objectives of public health and influencing its policy agenda; authorizing and limiting public health action with respect to protection of individual rights, as appropriate; serving as a tool for prevention; and facilitating the planning and coordination of governmental and nongovernmental health activities (2).

113. While for some areas (such as health protection) legally binding tools can reflect higher potential gains, for other areas (such as health promotion) the use of influence mechanisms can be more effective. Furthermore, both definition and enforcement of legally binding public health tools need to be considered when assessing the cost-effectiveness of these tools. It is particularly important to achieve a balanced approach with the different tools. While legislation is enforced through legal systems, national governments try to ensure implementation of national health strategies and policies through a range of monitoring, audit and performance management arrangements often associated with meeting standards.

114. This report concludes that an array of instruments and tools for policy and legislation is available to support the delivery of EPHOs in a wide variety of settings. The number and complexity of tools developed at the global and European levels has increased in recent years, as illustrated by the WHO FCTC and the IHR. While international regulations are non-negotiable, the degree and nature of governance arrangements, including regulation and legal enforcement, will vary across Member States. However, evaluation of these instruments and tools is not widely available; it is therefore difficult to compare the relative advantage of public health instruments and tools in different countries or at a regional level, or to recommend one tool over another.

115. The findings point out that the wide range of instruments available to WHO (including conventions, regulations, recommendations and standards) reflects the variations in deployment of specific instruments by different countries, and note changes in national regulatory frameworks arising from a growth in pluralism and democratization. There is a need to

familiarize government and public health agencies with a range of current public health instruments and tools, and to provide guidance on how to deploy them in tackling the major challenges of population health.

How can the effectiveness of public health instruments and tools be enhanced at Member State level?

116. The use of these public health instruments and tools – including actions to reduce alcohol consumption through taxation and advertising bans, tobacco control measures and road safety – can be highly cost-effective. While many of these actions would already be justified for other reasons, the cost-effectiveness evidence is a further argument in favour of their implementation.

117. Specific evidence on the effectiveness of different public health policy and legal instruments is currently limited, which makes it difficult to recommend one tool over another. Further evaluation is needed to inform the future effectiveness of different instruments and tools, including cost-effectiveness and feasibility of implementation.

118. A recent WHO report on “best buy” interventions for NCDs concludes that there is a set of interventions that have significant public health impact and are highly cost-effective, inexpensive and feasible to implement within the constraints of health systems (3). The primary benefit is a reduction in premature mortality from NCDs. Studies have found that implementing a specific set of “best buy” interventions for NCDs in 23 large LMICs could prevent 30 million premature deaths between 2006 and 2015, or an average of 3 million per year. Population-based measures for reducing tobacco and harmful alcohol use, as well as unhealthy diet and physical inactivity, are estimated to cost US\$ 2 billion per year for all LMICs; less than US\$ 0.40 per person.

119. Approximately 3.8 billion people (55% of the world’s population) are covered by at least one tobacco control measure at the highest level of policy achievement, according to the latest WHO report on the global tobacco epidemic (4), including 1.1 billion covered by a new policy since 2008. In the WHO European Region, over 244 million people (27% of the population in the Region) became newly covered by at least one tobacco control measure at the highest level of achievement between 2008 and 2010. This has great potential to make remarkable improvements in health.

How can gaps in the toolkit of available instruments and strategies be addressed?

120. A common feature of many health policy strategies and other public health instruments of the WHO Regional Office for Europe (and at the global level) has been the explicit recognition that gaps in knowledge are themselves one of the major health challenges of the future. Several important gaps emerged from the classification and mapping exercise, including gaps in the evidence to support the creation of policy instruments and tools.

121. The extensive mapping exercise undertaken for this review, structured along the lines of the 10 EPHOs set out in the EAP, indicates the EPHOs for which public health instruments and tools are available, as well as critical gaps, and highlights six major points.

- There are 396 different tools for EPHO 3 (health protection) and 300 for EPHO 6 (governance). These two areas reflect more than 75% of the total number of public health tools available, and are particularly developed in EU countries.
- There are 58 instruments and tools for EPHO 1 (surveillance), 37 for EPHO 2 (response to health hazards and emergencies), 70 for EPHO 4 (health promotion), 17 for EPHO 5

(disease prevention), 14 for EPHO 7 (workforce) and 6 for EPHO 8 (organizational structures and financing).

- EPHOs 9 (communication) and 10 (research) have only non-legally binding tools and instruments.
- While countries of the CIS and SEEHN have historically strong services in EPHOs 1–3, capacity and laboratory equipment have often become outdated, and legislation and policy also need updating.
- At the global level, legally binding instruments and tools are mainly concentrated in EPHO 3 (health protection) with 306 tools, EPHO 4 (health promotion) with 31 and EPHO 6 (governance) with 41 tools. This corresponds to more than 90% of the total number of tools.
- The WHO European Region has a particularly strong record of adopting legal public health measures compared to the global picture. Legally binding public health tools represent one-third of the total number of available tools in the Region: this proportion is more than double the global average.

122. This report explores and embraces an HiAP approach for its synergistic potential. Laws and public policies enacted in other sectors may have unintended consequences on public health areas. Therefore, laws and policies in other sectors should be designed and implemented through a broader approach to maximize their positive effects on population's health. For example, alcohol policy is influenced by EU trade law, but case law has often supported alcohol policy measures supportive of public health. Two available tools – health impact assessment and intersectoral targets – are of particular relevance. These will strengthen policy-making across all sectors, involving a range of actors both in decision-making and in accountability practices.

123. Another key question is whether and how international agreements and instruments can provide a framework for multidimensional actions. The WHO FCTC is perhaps a good example of success, as it sets out many types of actions at many levels involving legislation, regulation, partnership and cooperation. In the long term, its eventual aims will require the building of consensus across organizations, groups, economic and social actors and populations as a whole.

How can evaluation and monitoring of these instruments and tools be made more effective?

124. The major gaps identified in the public health policy instruments and tools surveyed include a lack of explicit monitoring and impact assessment mechanisms, which should be addressed in the medium and long term. This would contribute to a better adaptation of the legislation in response to expressed needs of stakeholders at different levels of implementation.

125. The findings of this review suggest the relevance of a broader approach, based on performance measurement and accountability mechanisms. Further possible research for evaluation could include analysis of the processes, population health outcomes and cost-effectiveness of a wider range of legal and policy interventions, as well as comparison with other instruments and tools. For example, compliance with international agreements should be reflected in the assessment of the relevant EPHOs, in order to identify national progress towards meeting internationally agreed standards.

126. The effectiveness of policy interventions is especially noteworthy against a backdrop of current and future economic exigencies and the high premium placed on efficiency and accountability. Adding a cost component to the assessment of the impact of public health laws and policies allows the identification of a set of strategies with the greatest value for money. A focus on improving both the processes and the health outcomes would allow a dynamic system

of accountability. In line with this, standards for the delivery of public health services should be made explicit and their quality ensured through regular scrutiny, inspection or assessment arrangements and accreditation.

127. Evidence is also scarce to support improvement of the global and regional architecture of policy instruments that reduce inequalities by improving production and delivery of global and regional public goods, including financial and other resource commitments that need to be made sustainable. There is a clear need to expand the current review of instruments and tools to the national and subnational levels, while still updating evidence at the regional level. Theoretical models of policy change should be included in further phases of analysis to help describe policy at different levels, to explain unanticipated rapid policy changes – such as have been seen following the WHO FCTC – and to identify idiosyncratic elements of policy change.

128. Further analysis at national level should also include more explicit concern about contextual factors and the quality of the sources of evidence used to avoid biased and incomplete explanations that do not take dynamic factors into account when analysing policy change. Approaches based on different models of analysis and on narratives of change are also possibilities for further research.

Recommendations

129. Besides tackling the major gaps in public health tools by EPHO, there is also a need to reach a balance between regulation and persuasion. In fact, the effectiveness of traditional public health instruments and tools – including legislation, sanctions, regulations and taxes – may be limited without additional tools more focused on citizen engagement in behavioural changes. As the WHO report on governance states, “smart governance” is mainly evaluative, with regard not only to the tool being used but also to the choice and use of the tool in the context of a plurality of tools and modes of application (7). With this in mind, the information collected in this review makes it possible to offer the following recommendations to Member States of the WHO European Region.

Advocate for effective tools and apply evidence to different settings

- Advocate for tools with good evidence of effectiveness, such as “best buy” interventions for NCDs, the WHO FCTC and IHR.
- Advocate for tobacco control, including tax increases, smoke-free indoor workplaces and public places, health information and warnings, and bans on tobacco advertising, promotion and sponsorship.
- Advocate for control of harmful alcohol use, including tax increases, restricted access to retailed alcohol, and bans on alcohol advertising.
- Advocate for promotion of healthy diet and physical activity, including reduced salt intake in food, replacement of trans fats with polyunsaturated fats, and raising public awareness of diet and physical activity through mass media.

Strike a balance between regulation and persuasion

- Balance different instruments and tools, such as HiAP, governance, and both legally and non-legally binding tools; for example, toolkits, guidelines, approaches to citizen engagement, advocacy and communication.

Strengthen intersectoral responses and governance

- Develop and employ an HiAP approach to consider the health effects of major legislation, regulations, and other policies that could potentially have a meaningful impact on public health.
- Make use of health impact assessment tools to strengthen health gains in an HiAP approach.
- Strengthen the governance and accountability arrangements of cross-sectoral policy.

Address gaps in instruments and tools

- Consider appropriate instruments and tools, and respond to the relative gaps in the toolkit to support the delivery of the 10 EPHOs.
- Specifically, consider the development of tools for EPHOs 5, 7, 8, 9 and 10 (disease prevention, workforce, organizational structures and financing, communication and research).
- Focus on enhancing the integration of health promotion, health protection and disease prevention by strengthening primary health care.

Strengthen tools for monitoring performance and accountability

- Enhance effective use of time-bound targets and tools for monitoring and evaluating health trends and policy implementation at national, regional and global levels.
- Develop standards for the delivery of public health services and ensure their quality through regular scrutiny, inspection or assessment arrangements and accreditation.

Strengthen evidence

- Create a resource map and gap analysis of a wider range of instruments and tools, including toolkits and guidelines at the national level.
- Based on findings from the systematic review on legal and policy tools, summarize the main types of evaluation report and the key findings on the effectiveness of tools.
- Evaluate the population health outcomes and costs of major legislation, regulations and policies: such evaluation should occur before and after enactment.
- Evaluate the process and feasibility of developing and enforcing legislation and policy.
- Develop research on the cost-effectiveness of public health tools to inform policy-makers of the interventions with higher value for money.
- Enhance methodologies to evaluate the relative effectiveness on health of a range of different instruments and tools.

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