

3.1 National policy on health technology

3.1.1 Introduction

A good national health system leads to quality health coverage for all people by targeting the population's needs and delivering universal health care. However, health systems are complex, manifold and intricate. In order to help build an effective and robust health system, WHO strongly encourages the development of national health policy frameworks that – when implemented – lead to reduced morbidity and mortality, reduced risks and threats to health, and reduced inequity in health (including improved health for women and children)¹. Policies are primarily a set of standard protocols that are tailored to the national health needs, conditions and environment, and that serve as directives and guidelines on all levels of the health system. A national health policy framework includes a vision, a situation analysis, policy directions, strategies to overcome challenges, a policy implementation plan, and the leadership and governance required to achieve sustainability.

Health technologies are essential for a functioning health system, and medical devices in particular are crucial in the prevention, diagnosis, and treatment of illness and disease as well as in patient rehabilitation. An effective national health plan includes one (or more) sections on health technologies, with governmental units enacting health technology policies. The World Health Assembly, in resolution WHA60.29, acknowledged the need “to formulate as appropriate national strategies and plans for the establishment of systems for the assessment, planning, procurement and management of health technologies in particular medical devices, in collaboration with personnel involved in health-technology assessment and biomedical engineering”, as well as the need to provide technical guidance in implementing policies on health technologies.¹¹ Fig. 3.1-1 illustrates how the global agenda and mission of WHO relate to the health systems, resulting in equitable access to safe and quality medical devices through the implementation of national health policies.

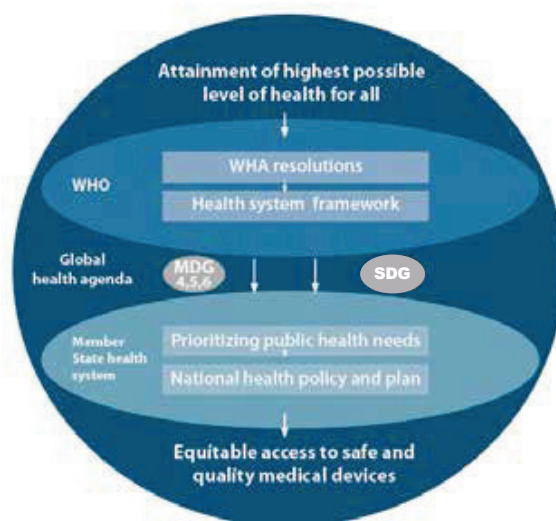
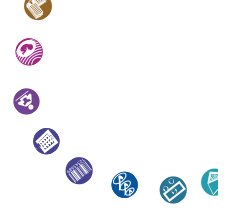


Fig. 3.1-1. Linking the global health agenda to improve medical device access via national health plans (WHA: World Health Assembly, MDG: Millennium Development Goals, SDG Sustainable Development Goals)



The array of medical devices, their uses, the settings in which they are applied, and all components of the medical device life cycle require rigorous policies. Robust policies guide health workers in their decisions and actions on each level from daily hospital routines to high-rank decision-making that impacts the future of health care in a country. The policies need to be adapted to the individual health sector functions in order to guarantee the best use of resources and serve the unique needs of the population according to local or national priorities.

Development of policies is a challenging task and requires input from many stakeholders such as academia, patients' organizations, professional organizations, specifically from biomedical engineers. Policy makers need to promote and implement useful strategies to ensure that national strategies and action plans for medical devices directly match public health priorities. This means planning medical device programmes in accordance with policies and protocols that result in equitable access to safe, appropriate and high-quality medical devices. Policies should include guidance for the rational selection of medical technology that best serves the needs of the target population, and should identify the financial and human resources to best use those technologies. Furthermore, policies should promote the safe and appropriate use of devices during their life cycle. The four areas of the medical device agenda that are above all involved in the implementation of health technology policies are:

- research and development: to develop medical technologies based on population needs (role of academia and industry);
- regulation: to authorize products to legally enter the local market;
- health technology assessment: to select the medical devices that could be used for packages of interventions or public procurement or positive lists; and
- health technology management: from selection to procurement, logistics, delivery systems and appropriate use.

Fig. 3.1-2 shows the relationships and interactions underpinning the medical device agenda and the dependence of successful functioning of each of these areas on the principles of safety, quality, universal coverage, and equity. Fig. 3.1-3 shows in more detail how these areas (including sub-areas) are linked in a health system and which supporting areas are closely involved, such as nomenclature and medical device lists.



Figure 3.1-2: The medical device agenda within a national health policy.

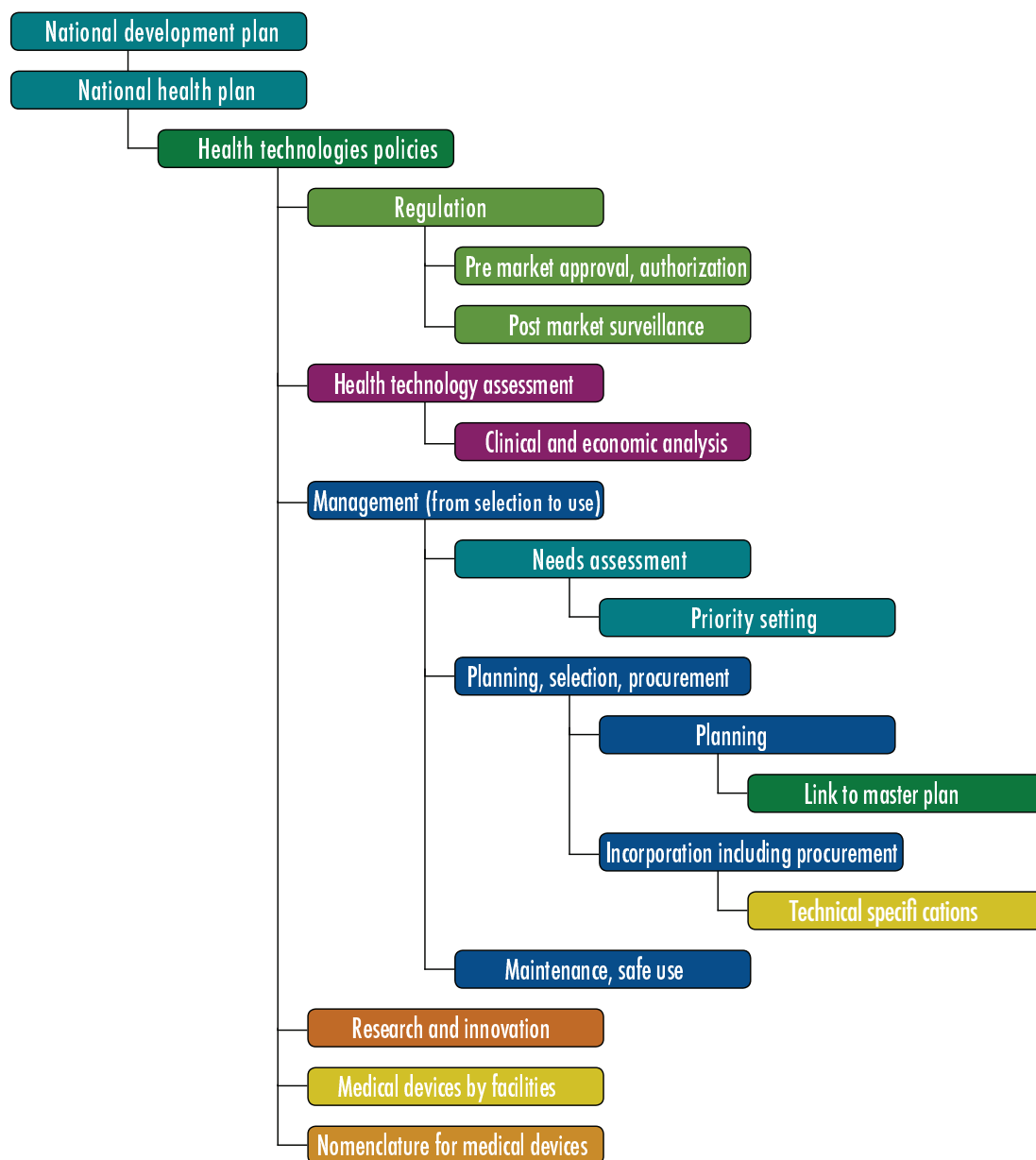


Figure 3.1-3: Areas of implementation for health technology policies

Only when all of the four areas are planned, well supported and coordinated, the overall programme can reach its desired improved health outcomes. The thorough implementation of a national health technology policy framework facilitates this process.

3.1.2. Global facts

The Baseline Country Survey on Medical Devices collected information on the presence of national health technology policies of medical devices globally. Overall results are visualized in Fig. 3.1-4.

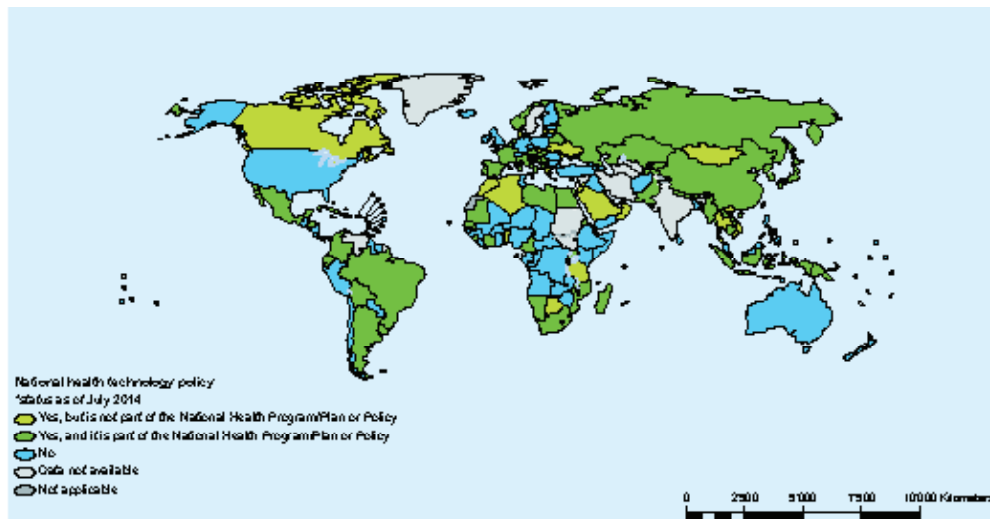


Fig. 3.1-4. Global map of national health technology policies of medical devices

From the 177 country survey respondents, 174 provided information on the subject of health technology (medical devices) policy. In total, 90 Member States (52% of 174) do not have a health technology (medical devices) policy and 83 Member States (48% of 174) do have such a policy. The latter is further subdivided into countries where this policy is part of the National Health Program (35%), countries where it is not (12%) and countries that did not specify this information (1%) as shown in Fig. 3.1-5.

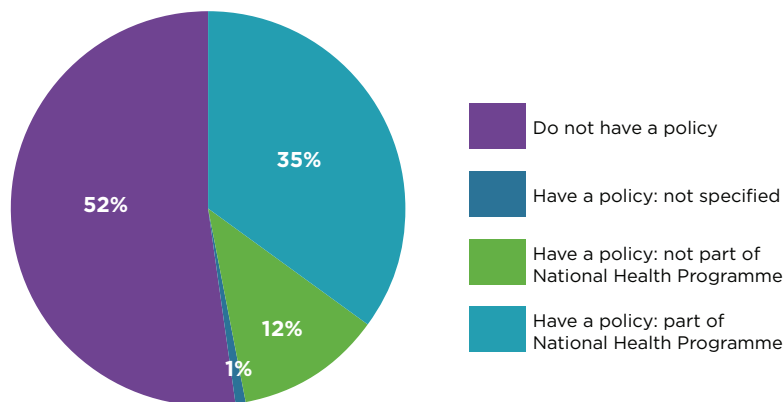


Fig. 3.1-5. Health technology policy in member states

This data was also analyzed with respect to World Bank income groups (Fig. 3.1-6). More than half of low to middle income countries do not have any health technology policy (from 124 respondent low- to middle-income economies), while 65% of high-income countries have a health technology policy (28 out of 49 respondent countries).

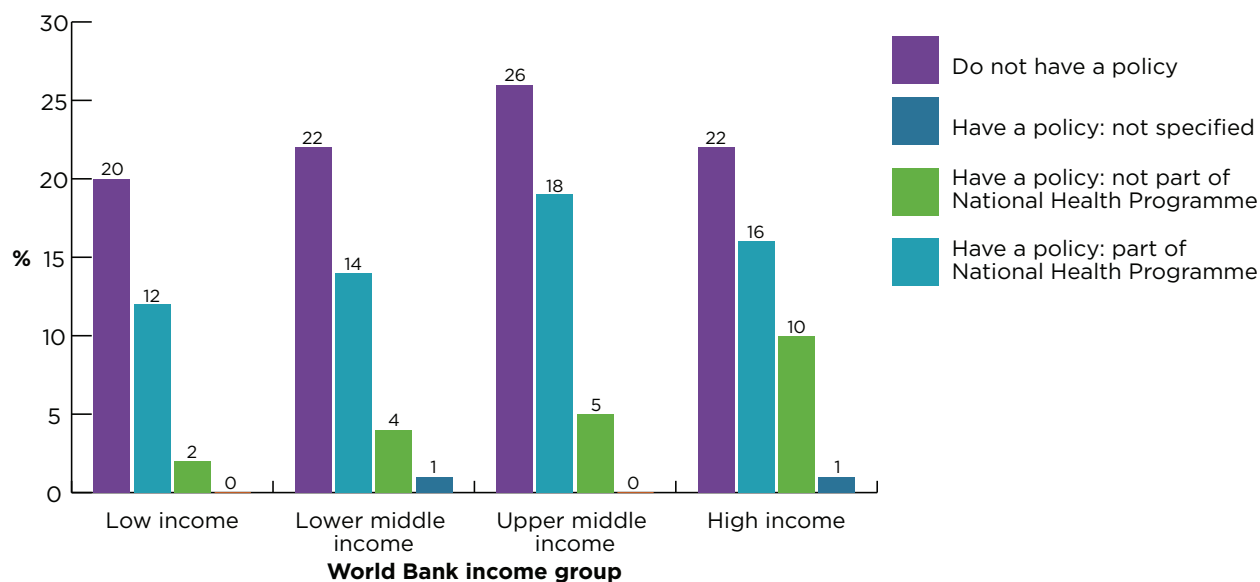


Fig. 3.1-6. Presence of a health technology policy by World Bank income group

Presenting this data with respect to WHO regions shows that more than 55% of countries from the three regions AFR, AMR, WPR have no health technology policy (with 101 respondent countries across the three regions) as shown in Fig. 3.1-7. The regions EMR, SEAR and EUR have national health policies in around 60% of respondent countries.

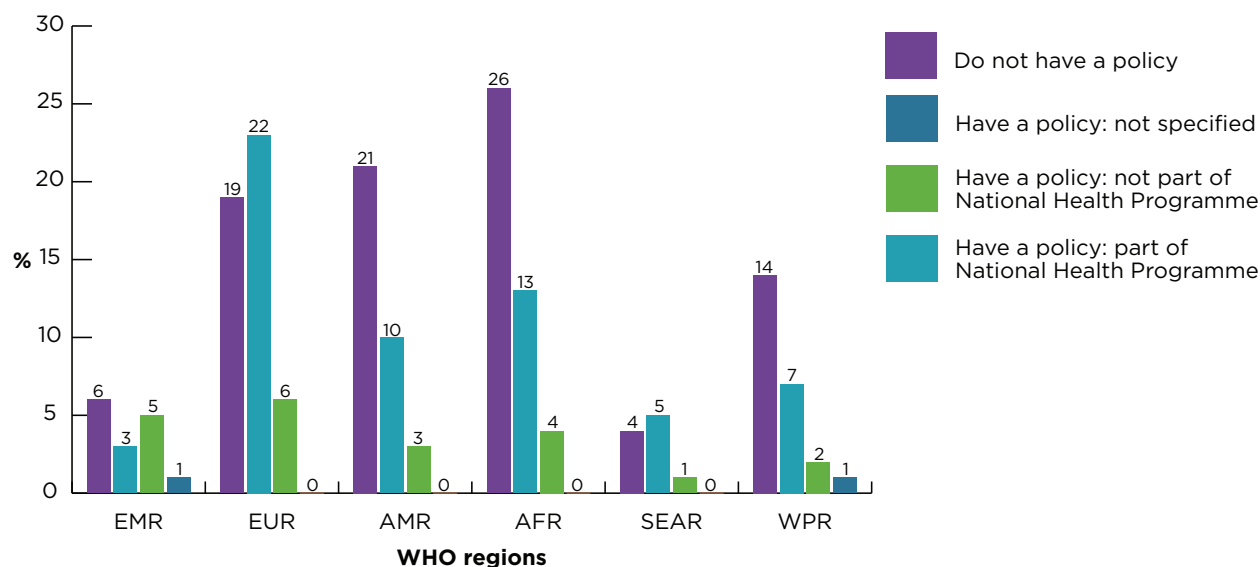


Fig. 3.1-7. Presence of a health technology policy by WHO region



A direct relationship between the Human Development Index (HDI)¹⁰ and countries with health technology policies was observed as follows: the higher the HDI, the higher the proportion of countries having a national health technology policy (Fig. 3.1-8). Countries with low HDI (i.e. lower income, education and life expectancy) also often lack health technology national policies (only 38% of the respondent countries in this group have such policies).

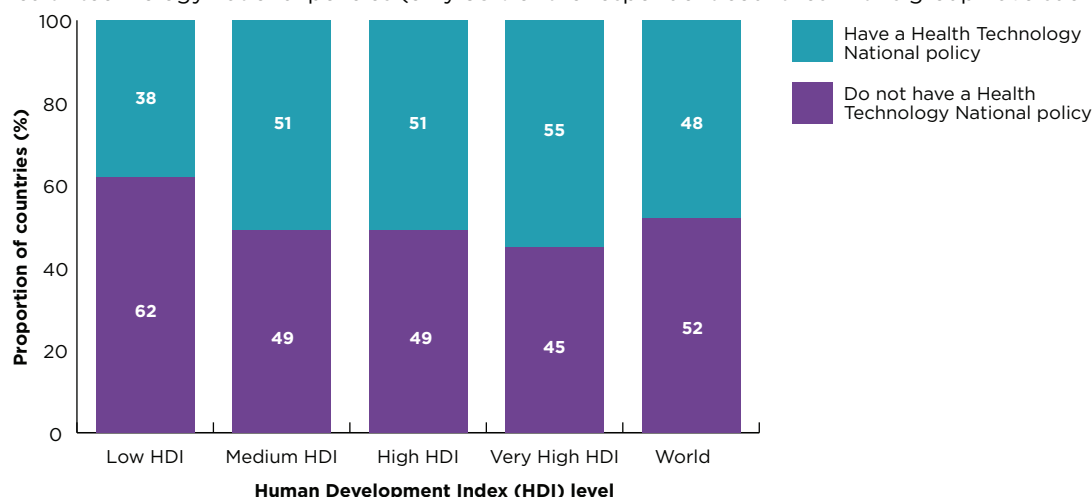


Fig. 3.1-8. Presence of a health technology national policy by Human Development Index (HDI) groups

Please find some examples of policies for medical devices in figure 3.1-9.

Country	Link to policy	Language
Canada	http://www.cadth.ca/media/policy_forum_section/1_health_tech_strategy_1.0_nov-2004_e.pdf	English
France	http://social-sante.gouv.fr/	French
Luxembourg	http://www.legilux.public.lu/leg/a/archives/2009/0054/a054.pdf	French
Mexico	http://www.cenetec.salud.gob.mx/descargas/PAES/PEDM.pdf	Spanish

Fig. 3.1-9. Examples of policies for medical devices

3.1.3 Further Readings

The following documents and websites contain further relevant information on the development of national health technology policies:

Documents:

- Development of medical device policies. WHO Medical Device Technical Series.ⁱⁱⁱ
- Alliance for Health Policy and Systems Research. Systems thinking for health systems strengthening.^{iv}

Sites:

- Health Partners International: “How to Manage” series of health care technology guides.^v

Endnotes:

- Development of national health plans and strategies, Provisional Agenda Item 10, High-Level Preparatory (HLP) Meeting for the 63rd Session of WHO/SEA Regional Committee WHO/SEARO, New Delhi, 28 June – 1 July 2010.
- Resolution WHA60.29 on “Health Technologies, 2007. http://www.who.int/healthsystems/WHA60_29.pdf, accessed April 2016.
- Development of medical device policies. WHO Medical Device Technical Series, 2011. http://www.who.int/medical_devices/publications/med-dev-policies/en/
- Alliance for Health Policy and Systems Research. Systems thinking for health systems strengthening. Geneva, World Health Organization, 2009.
- Temple-Bird C et al. ‘How to Manage’ series of health care technology guides. St Alban’s, Ziken International (Health Partners International), 2005 (<http://resources.healthpartners-int.co.uk/resource/how-to-manage-series-for-healthcare-technology>)

¹⁰ The Human Development Index (HDI) is a composite statistic of life expectancy, education, and income indices used to rank countries into four tiers of human development. The breakthrough for the HDI was the creation of a single statistic, which was to serve as a frame of reference for both social and economic development. The HDI sets a minimum and a maximum for each dimension, called goalposts, and then shows where each country stands in relation to these goalposts, expressed as a value between 0 and 1. Very High: quartile .805, High HDI: quartile .715, Medium .535, low below.