

ÉCOLE POLYTECHNIQUE
FÉDÉRALE DE LAUSANNE



EPFL



Medical Devices: definition (Short)

An article, instrument, apparatus or machine that is used in the prevention, diagnosis or treatment of illness or disease, or for detecting, measuring, restoring, correcting or modifying the structure or function of the body **for some health purpose**. Typically, the purpose of a medical device is **not achieved by pharmacological, immunological or metabolic means**.

Technology Innovation for Sustainable Development

Hello. The little girl we just saw had an x-ray taken in a large hospital in Cameroon. Perhaps have you noticed that she had to climb on a stool to be at the right height in front of the x-ray imaging detector? The reason was that the electrical motors allowing to position the height of the detector had failed. The hospital does not have the resources to have it fixed. This story illustrates a great problem in hospitals in low and middle income countries: the lack of proper access to essential medical devices. Medical devices are really an essential technology in the sense of our MOOC. Let me now define this category a little better. According to the World Health Organization there are over 10 000 types of medical devices. They range from the simplest tongue depressor or thermometer to the most complex nuclear medicine machine. It is not easy to give a general definition of what is or is not a medical device. Basically it is an article, instrument, apparatus or machine that is used in the prevention, diagnosis or treatment of illness or disease or for detecting, measuring, restoring, correcting or modifying the structure or function of the body for some health purpose.

Notes

Summary



0m 18s



Medical Devices: definition (Short)



An article, instrument, apparatus or machine that is used in the prevention, diagnosis or treatment of illness or disease, or for detecting, measuring, restoring, correcting or modifying the structure or function of the body **for some health purpose**. Typically, the purpose of a medical device is **not achieved by pharmacological, immunological or metabolic means**.

Technology Innovation for Sustainable Development

Typically, the purpose of a medical device is not achieved by pharmacological, immunological or metabolic means. This is the World Health Organization's summarized definition of medical devices as there is actually a longer one. This definition shows how vast the domain is. In order to understand the importance of medical devices we must try to better understand how they fit into health care processes, and in particular into health systems.

Notes

Summary



1m 39s



Alma Ata Declaration, 1978

Primary Health Care:

- Scientifically sound
- Socially acceptable
- Accessible and affordable
- Community participation

Technology Innovation for Sustainable Development

Let us take a step back and consider the outcomes of an important international conference which took place in 1978 in the city of Almaty in Kazakhstan or Alma Ata as it was then called. This conference stressed health as a basic human right and called all of the World Health Organization's member states to urgent action to reach health for all by the year 2000. This goal has obviously not been met. However the conference delivered another very important message. It stressed the key role of primary health care, particularly in developing countries. The famous Alma Ata Declaration which resulted from the conference includes a series of very important principles which are still highly pertinent to the organization of health care today. In particular, it defines primary health care as : "Essential health care based on practical, scientifically sound and socially acceptable methods and technology made universally accessible to individuals and families in the community through their full participation and at a cost that the community and country can afford to maintain at every stage of their development, in the spirit of self reliance and self determination,".

Notes

Summary





Alma Ata Declaration, 1978

Primary Health Care:

- Scientifically sound
- Socially acceptable
- Accessible and affordable
- Community participation
- First level of contact
- Close to people

Technology Innovation for Sustainable Development

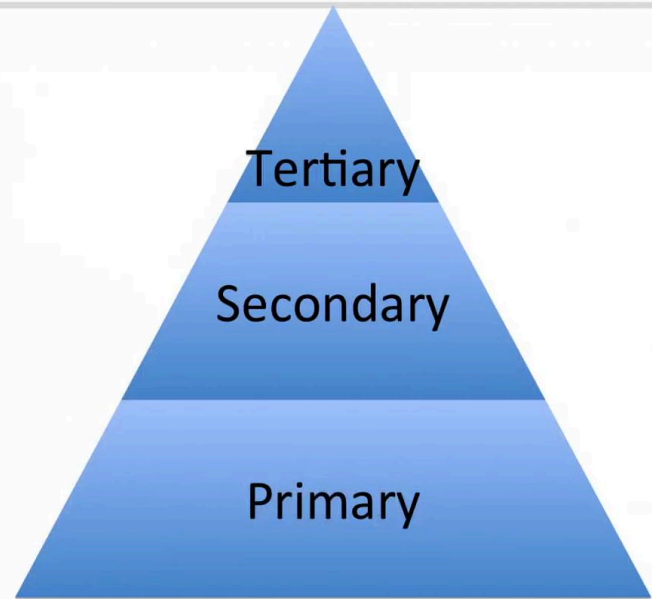
The declaration goes on to say that "it is the first level of contact of individuals, the family and community with the national health system bringing health care as close as possible to where people live and work and constitutes the first element of a continuing health care process,".

Notes

Summary



3m 37s



Technology Innovation for Sustainable Development

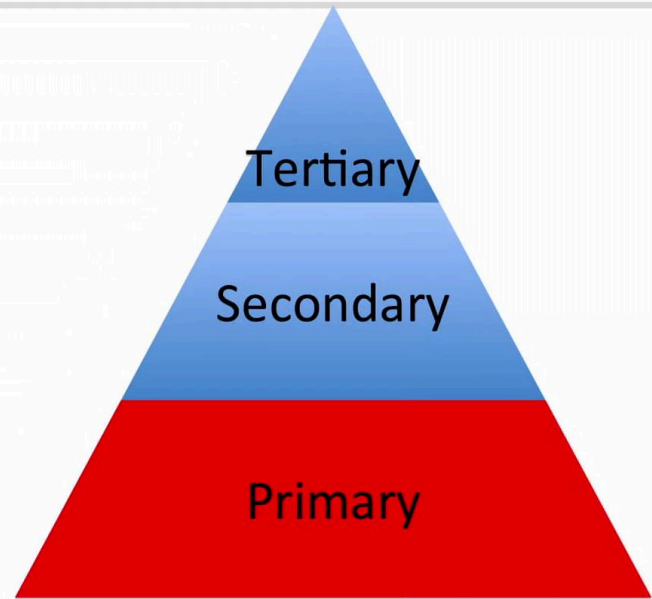
The declaration also states that primary health care is a central function and main focus of the country's health system and that it is closely intertwined with social and economic development. This declaration, although it is a high level document, has very practical implications. In particular, it gave the fundamental principles of how health systems must be organized. Health systems are not only composed of public hospitals providing diagnosis and care. Primary health care stretches far into the community as we know that determinants of health can be found in domains as diverse as education, communication, agriculture, infrastructure and so forth. It involves a variety of very important roles, such as promotion of proper nutrition, supply of safe water, family planning and education concerning prevention of major health problems. Also, health systems involve not only public but also private health structures, which can be operated by faith based organizations or charities as well as for-profit enterprises. We will remain focussed on the public health care system for the purpose of this course.

Notes

Summary



4m 00s



Technology Innovation for Sustainable Development

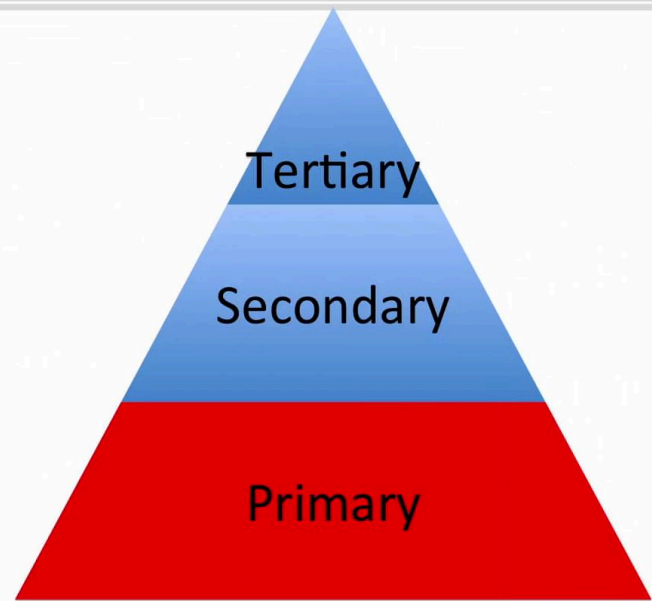
Every country has its own way to organize the different layers of the public health system but in general it is or should be influenced by the principles of primary health care, which we have just described. These different layers can be represented in the form of a pyramid to express the number of facilities at each level as well as the degree of specialization. One generally finds a first contact point at the base of the pyramid, which is the primary level properly speaking. In other words, if you have a health problem that is where you will enter into contact with the health system. If your case cannot be treated at the primary level, you will be referred to the upper layer called secondary health care. This will typically be a regional hospital with capacity to perform more advanced surgical interventions and to perform more sophisticated diagnostic procedures. The tertiary layer is for more complex cases, which require highly specialized services. These will typically be found in larger structures such as central hospitals. The primary level is ideally where a majority of the health problems affecting the community will be taken care of.

Notes

Summary



5m 22s



Technology Innovation for Sustainable Development

It may involve independent general practitioners, health posts operated by community health workers, health centers or small district hospitals located close to the communities. This level will, for example, include the capacity to assist child deliveries, to diagnose frequent and simple conditions and provide basic care. Ideally the health services at this level should also include the capacity to perform basic surgeries such as C-sections. As we think about improving health and reinforcing health systems with innovative medical devices this layer is precisely where we should focus our attention first. Crucial technologies here will include for example ultrasound for antenatal exams, sphygmomanometers to detect high blood pressure, oxygen concentrators for acute respiratory distress or radiology for diagnosing trauma from road traffic accidents. This is also where a close follow-up of patients, such as adherence to medication should be provided. Many other crucial medical activities should take place at this primary level; close to the communities such as campaigns for vaccination, screening campaigns for specific diseases or awareness campaigns for reproductive health.

Notes

Summary



6m 45s



Medical Devices: WHO building blocks



Health Services

Health Workforce

Health
Information

Medical Products,
Vaccines and
Technologies

Health Financing

Leadership &
Governance

Technology Innovation for Sustainable Development

Now that we know the different layers of a health system focused on primary health care, let's look into the conditions which make them function well. The World Health Organization has defined a framework of 6 building blocks for health systems. Each of these building blocks is of crucial importance.

Notes

Summary



8m 12s



Medical Devices: WHO building blocks



Health Services

Health Workforce

Health
Information

Medical Products,
Vaccines and
Technologies

Health Financing

Leadership &
Governance

Technology Innovation for Sustainable Development

First a health system needs adequate health services, which means services that deliver effective, safe quality health intervention with a minimum waste of resources. The system also requires a well performing workforce. That is, one that is well trained, sufficiently staffed and fairly distributed. Health information systems must be in place which ensure the production, analysis, dissemination and use of reliable information on health determinants, health system performance and health status. As you can see, our fourth block involves having equitable access to essential medical products, vaccines and technologies of assured quality, safety, efficacy and cost effectiveness and which are scientifically sound. This is crucially important. It is out of question to rely on sub-standard solutions just because the country is poor.

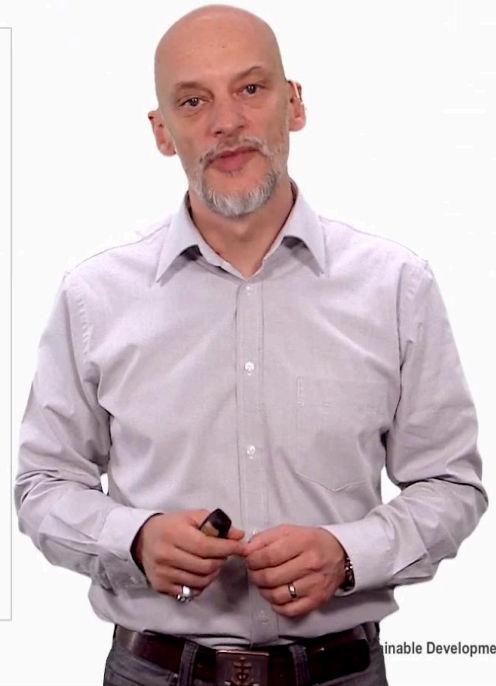
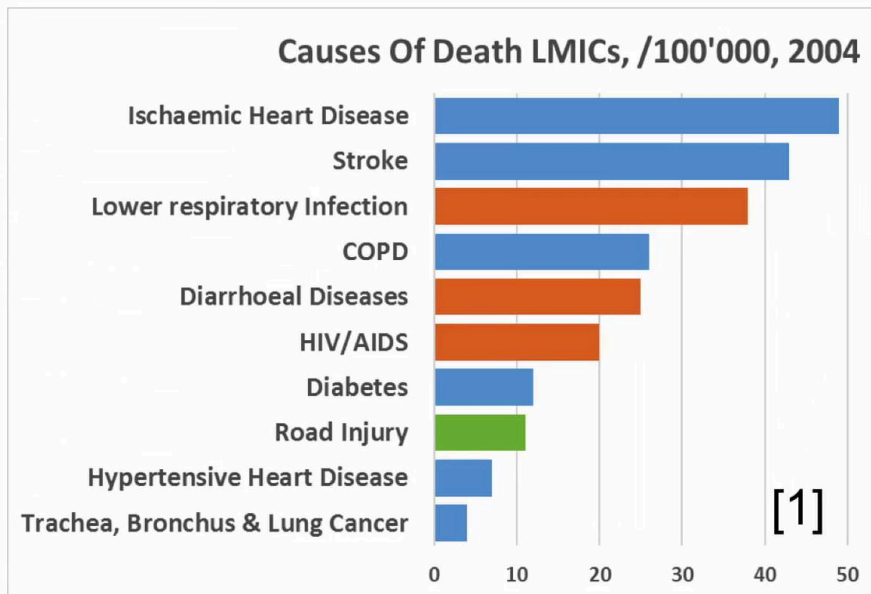
Notes

Summary





Medical devices: Disease Burden



inable Development

The next block concerns health financing, which is not only about raising adequate funds for health, but also about protecting people from impoverishment associated with having to pay for health services. Finally, leadership and governance involves ensuring strategic policy frameworks exist, combined with effective oversight, as well as regulation and accountability. As we can see, reinforcing health systems will necessarily involve the provision of adequate medical devices. However we need to carefully assess the insertion of these medial devices into the system in order to ensure that they contribute to strengthen it as a whole. As we will see, it is for example absolutely crucial to know who will provide maintenance and repair for these medical devices. I would like to discuss yet another important angle from which we need to consider the importance of medical devices. It is related to what is called the burden of disease. There are different metrics available to characterize disease burden, but let us just have a look at the overall mortality per 100 000 people over all age groups. Here we have a graph showing the 10 main causes of death recorded by the World Health Organization for low and lower middle income countries in 2004.

Notes

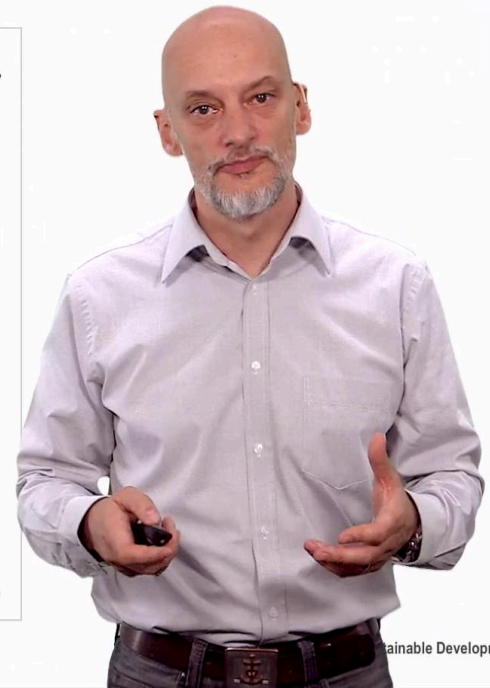
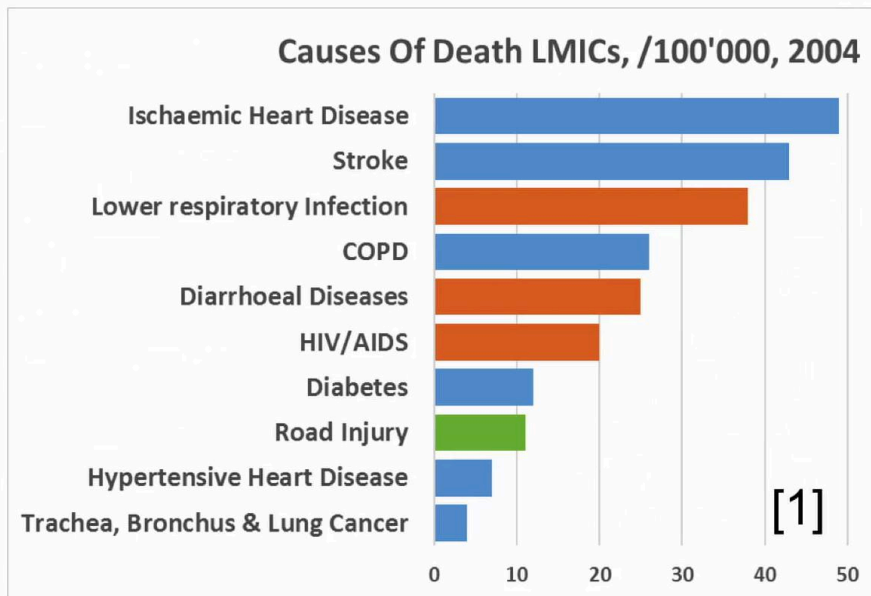
Summary



9m 35s



Medical devices: Disease Burden



Sustainable Development

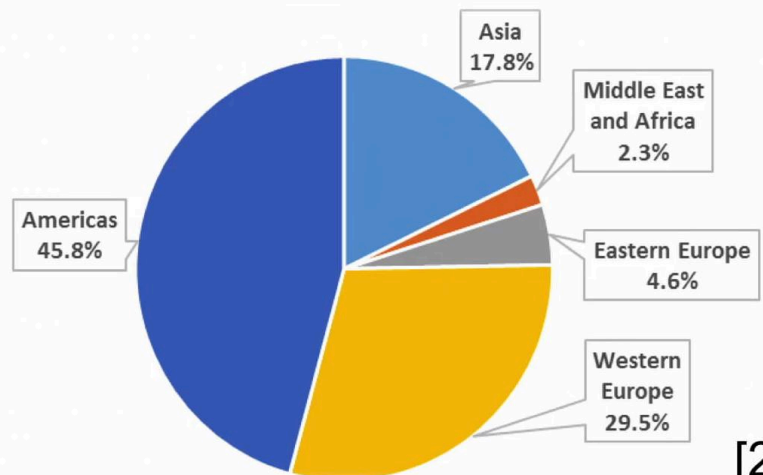
There are 3 different types of causes: infectious diseases, highlighted in orange, non-communicable diseases in blue and injuries and in particular road injuries in green. Note the importance of non-communicable diseases such as cardiovascular and respiratory diseases, as well as diabetes and cancers. They represent an overwhelming majority of the causes of death represented here with 60%. Also note the importance of road traffic accidents which will tend to increase in the coming years. Finally, there is still the important number of deaths related to perinatal conditions; that is deaths of newborns which are not shown here. According to the World Health Organization, perinatal deaths - of which the main causes are prematurity, asphyxia and infections - will represent over 8% of all deaths in 2030. This table gives us a blueprint on how to determine where priorities must be set as we think of developing essential medical devices.

Notes

Summary



11m 08s



[2]

~2/3 of market consumed
by <9% of world's population.

Technology Innovation for Sustainable Development

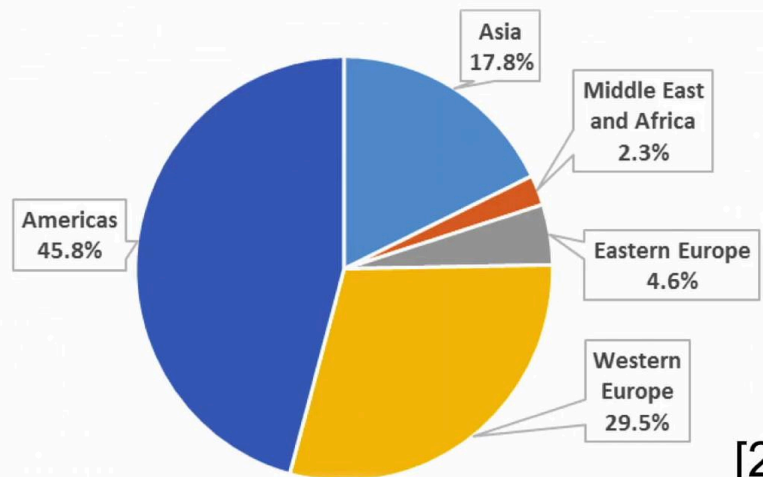
Now that we understand the importance of medical devices in the framework of health systems let us get a sense of how available medical devices really are. As you may have suspected, medical devices are not available to a large fraction of the world's population. This graph shows you an estimate based on 67 countries, which account for more than 90% of total medical devices sales revenues. As you can see the Middle East and African market is virtually non-existent, in spite of the high burden of disease in these regions. Even in Asia the numbers are bleak when we realize that in fact Japan alone consumes 10% out of the 17% for Asia. In fact, in 2009 only 10 countries accounted for over 80% of the world's sales revenues with the US alone consuming 40% followed by Japan, 10% Germany, 8% and France, 4%. The imbalance is absolutely striking and the numbers speak for themselves. Nearly 2/3 of the global medical devices are consumed by these 4 countries alone while they represent less than 9% of the world's population. The design of medical devices is very dependent on the context for which they were intended.

Notes

Summary



12m 20s



[2]

~2/3 of market consumed
by <9% of world's population.

Technology Innovation for Sustainable Development

Medical devices developed to work in industrialized countries rely on quality infrastructure, sufficient financial resources, adequately trained personal and controlled environmental conditions. You will have recognized the main challenges caused by the context of low and middle income countries. As a consequence there is a large mismatch between what low and middle income countries need and what is available in the market today. As we have seen, the need for adequate medical devices is phenomenal and we hope that many of you will now start to think about innovative medical devices. Goodbye.

Notes

Summary



13m 49s