World Health Organization

Access to medical devices for Universal Health Coverage and achievement of SDGs

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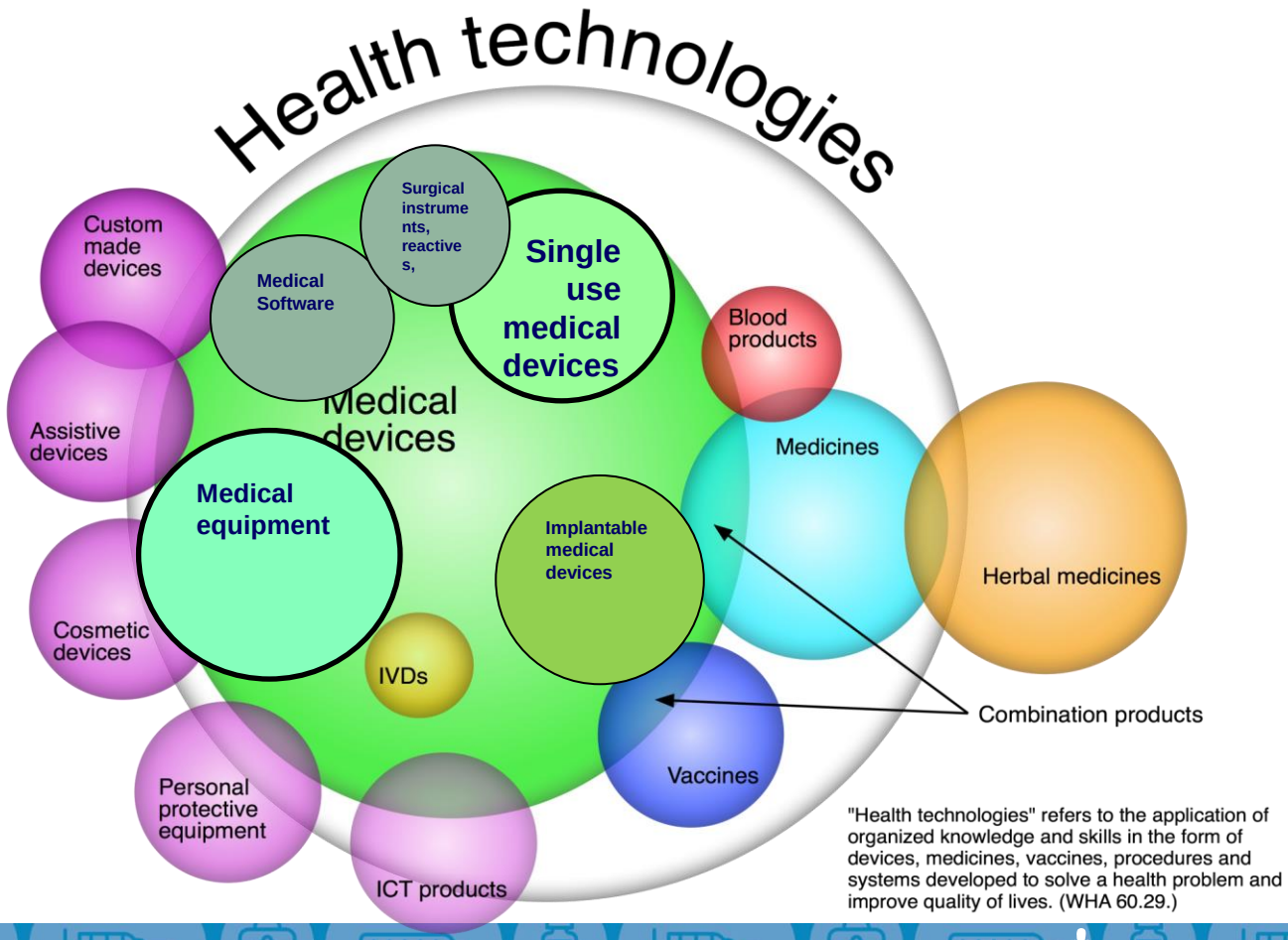
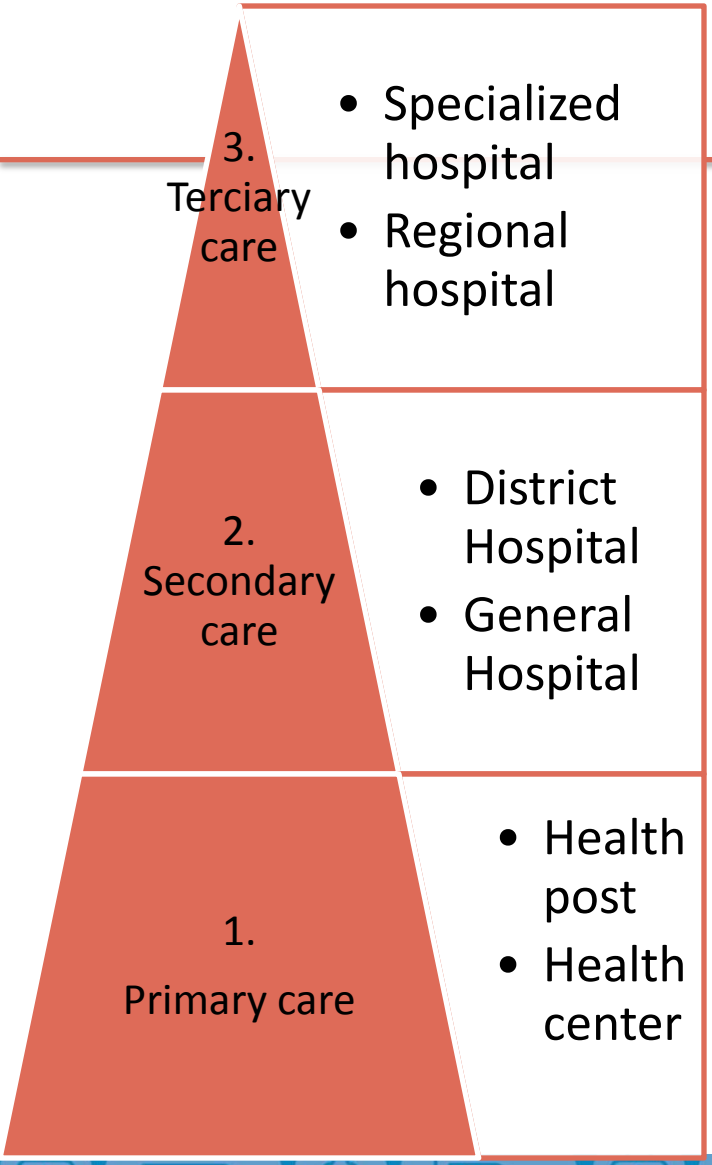
SUSTAINABLE DEVELOPMENT GOALS
17 GOALS TO TRANSFORM OUR WORLD
1 NO POVERTY
2 ZERO HUNGER
3 GOOD HEALTH AND WELL-BEING
4 QUALITY EDUCATION
5 GENDER EQUALITY
6 CLEAN WATER AND SANITATION
7 AFFORDABLE AND CLEAN ENERGY
8 DECENT WORK AND ECONOMIC GROWTH
9 INDUSTRY, INNOVATION AND INFRASTRUCTURE
10 REDUCED INEQUALITIES
11 SUSTAINABLE CITIES AND COMMUNITIES
12 RESPONSIBLE CONSUMPTION AND PRODUCTION
13 CLIMATE ACTION
14 LIFE BELOW WATER
15 LIFE ON LAND
16 PEACE, JUSTICE AND STRONG INSTITUTIONS
17 PARTNERSHIPS FOR THE GOALS
SUSTAINABLE DEVELOPMENT GOALS

Definitions: Medical devices are health technologies that include: in vitro diagnostics, implantables, medical equipment, software, surgical instruments, …



Medical devices need to be appropriate for each Health Care Facility



Medical equipment (niveau 3)

- Are medical devices that require installation, maintenance , callibration, consumables, spare parts.

- Their design, evaluation , procurement, planning, training, maintenance and decommissioning usually done by biomedical engineers.

Medical devices that do not need maintenance:

Single use devices

- Cathéters
- IV sets
- Syringes
- Condom
- …

- Last secondes
- / minutes/ heures
- Incinérable, single use
- $- $$

Implantables

- Prothesis
- Pacemaker
- Stent
- Intramedular

- Many years
- Biocompatible
- Patient monitoring
- $$- $$$$$

The performance does not depend on the device itself but on the way they are used , this has to be safe and correct,

- Most medical devices require intermediary
- Device - doctor/ nurse/ technician – patient

More devices are being used by the persons themselves

Medical and assistive devices, point of care in vitro diagnostics, personal protective equipment, mobile apps w diagnostics.

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➢ 10,000 Types of medical devices

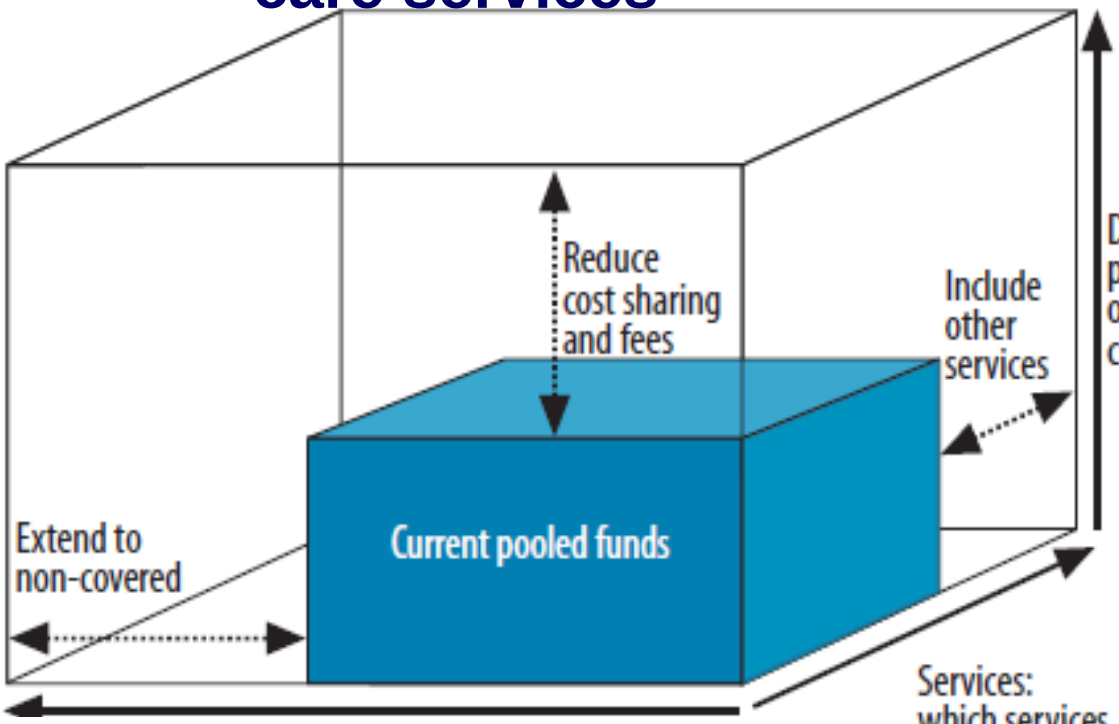
➢ 500,000 different products commercially available

- All medical equipment for patient care
- Diagnostic imaging
- Laboratory and pathology equipment
- Implantable medical devices
- Personal protective equipment
- Prosthesis and orthesis
- Quality assurance
- Radiation protection devices
- Single use devices (IV)
- Solutions and reagents
- Sterilization equipment
- Surgical instruments

Medical devices are technologies indispensable to accomplish the health related SDGs: prevent, diagnose, treat, palliate, assist.

Target	Example of health technology/ medical device
3.1 by 2030 reduce the global maternal mortality ratio to less than 70 per 100,000 live births	Blood pressure meters, pregnancy tests, surgical instruments, cord clamps..
3.2 by 2030 end preventable deaths of newborns and under-five children	Neonatal resuscitation devices, warming devices/ incubators, diagnostics
3.3 by 2030 end the epidemics of AIDS, tuberculosis, malaria, and neglected tropical diseases and combat hepatitis, water-borne diseases, and other communicable diseases	In vitro diagnostics to initiate the right treatment.
3.4 by 2030 reduce by one-third pre-mature mortality from non-communicable diseases (NCDs) through prevention and treatment, and promote mental health and wellbeing	Diagnostics: in vitro, blood glucose meters, pathology; x rays…imaging , Treatment: surgical instruments, implants, radiotherapy, inhalers chemotherapy, cardiac support
3.7 by 2030 ensure universal access to sexual and reproductive health care services, including for family planning, information and education, and the integration of reproductive health into national strategies and programmes	From condoms to contraceptive devices

Medical devices are required to achive SDG3: universal health coverage, including financial risk protection, access to quality essential health-care services



Modified from , Health systems financing: the path to universal coverage. Executive summary, The World Health Report, WHO/IER//WHR/10.1, 2010

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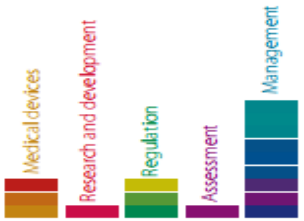
2011


2017


2017

Research and development



Regulation


2017

Medical devices

Management

2011

Assessment

2011

2016 2017

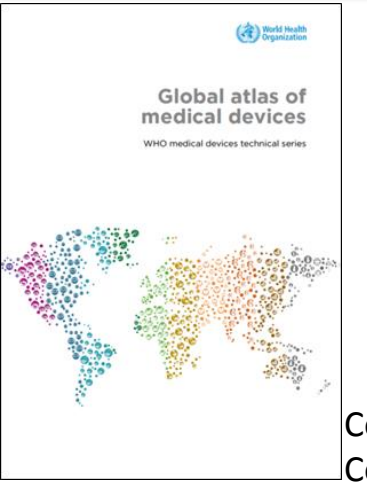
2011 2011

2011 2011 2011

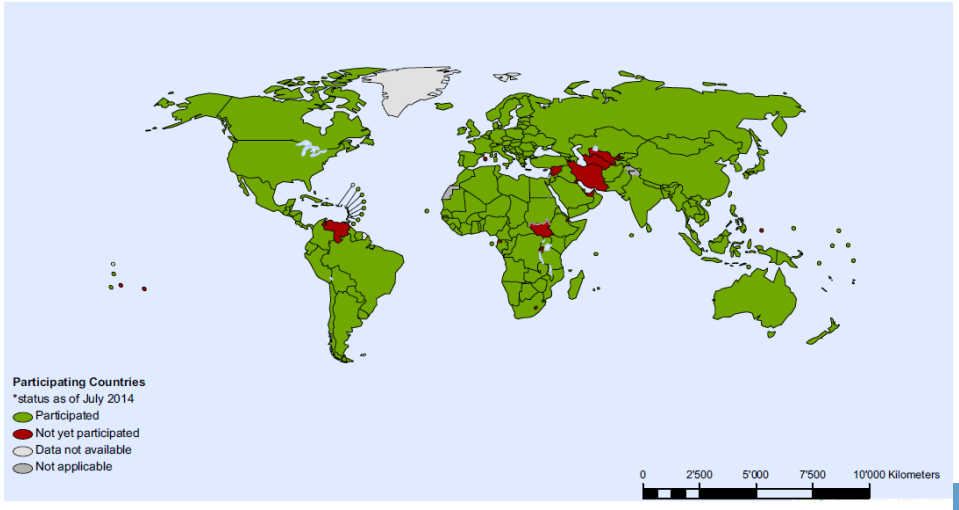
QUALITY

ld Health
anization

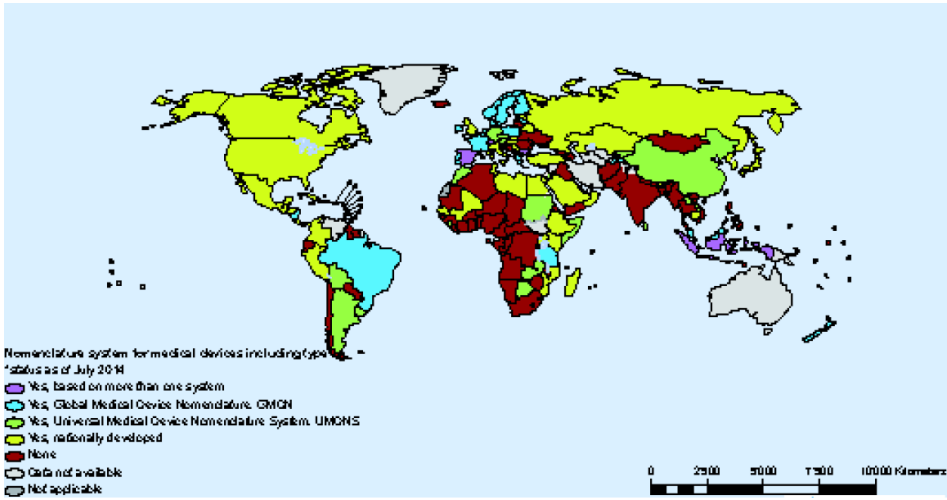
Global Atlas of Medical Devices 2017 includes global, regional and country profiles

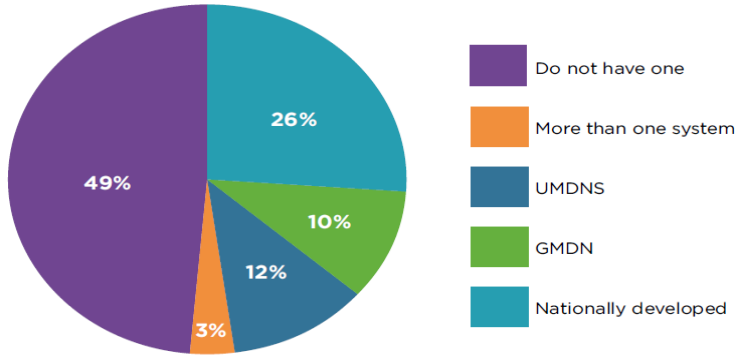


Country participation in the Baseline Country Survey of Medical Devices



Nomenclature systems for medical devices





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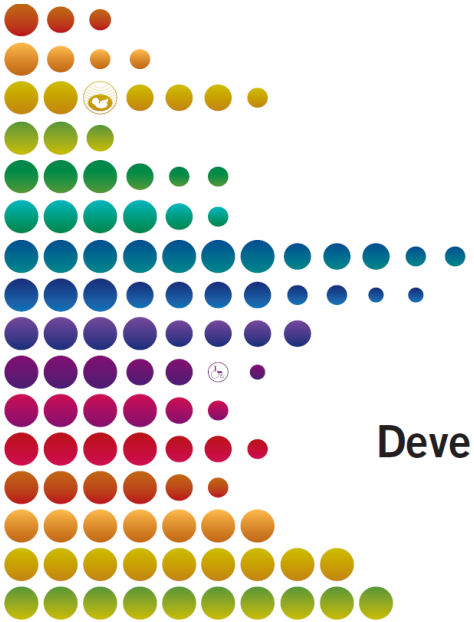
Government establishes national policies, regulates and selects and supplies medical devices

To define national policies

'he medical device agenda within a national health policy

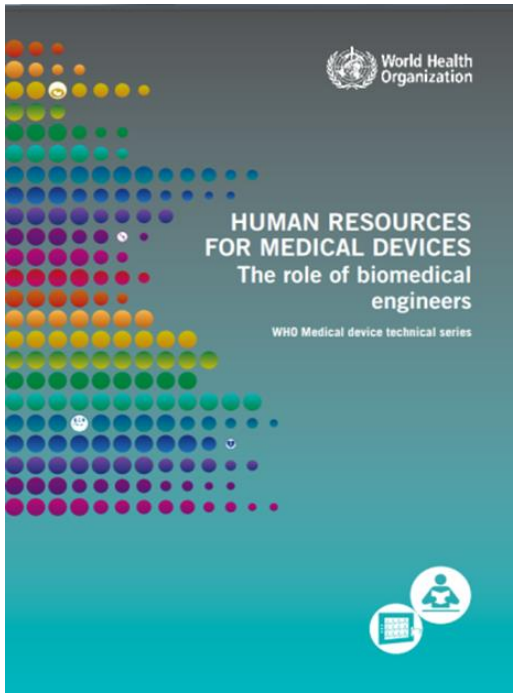


World Health Organization

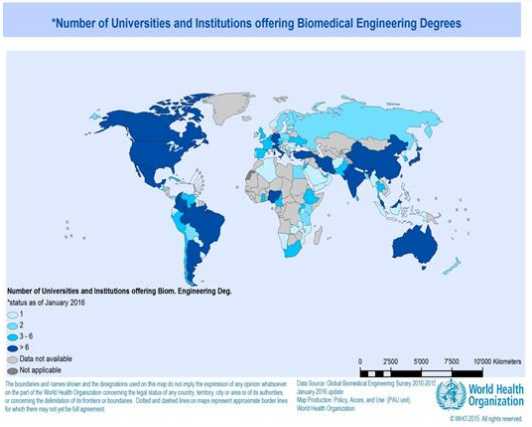
Development of medical device policies

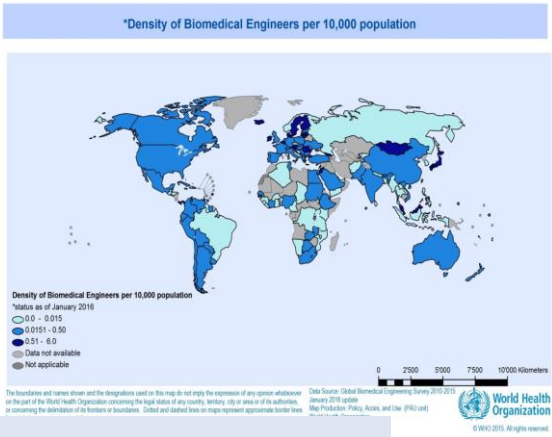
WHO Medical device technical series

Pharmacists are to medicines as biomedical engineers are to medical devices!!.



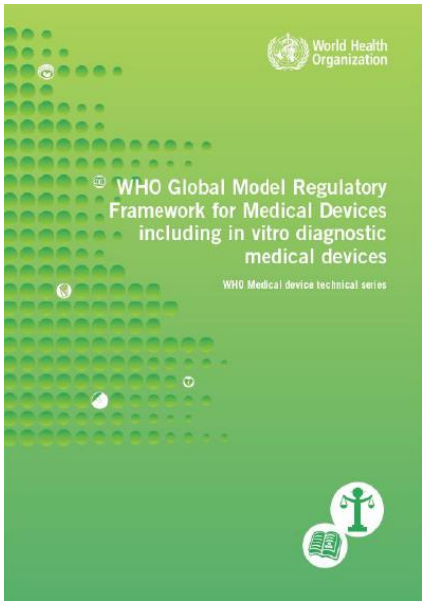
- Country information on the number of biomedical engineers and technicians,
- Educational institutions
- Professional societies
- roles in the life cycle of a medical device, from conception to use.



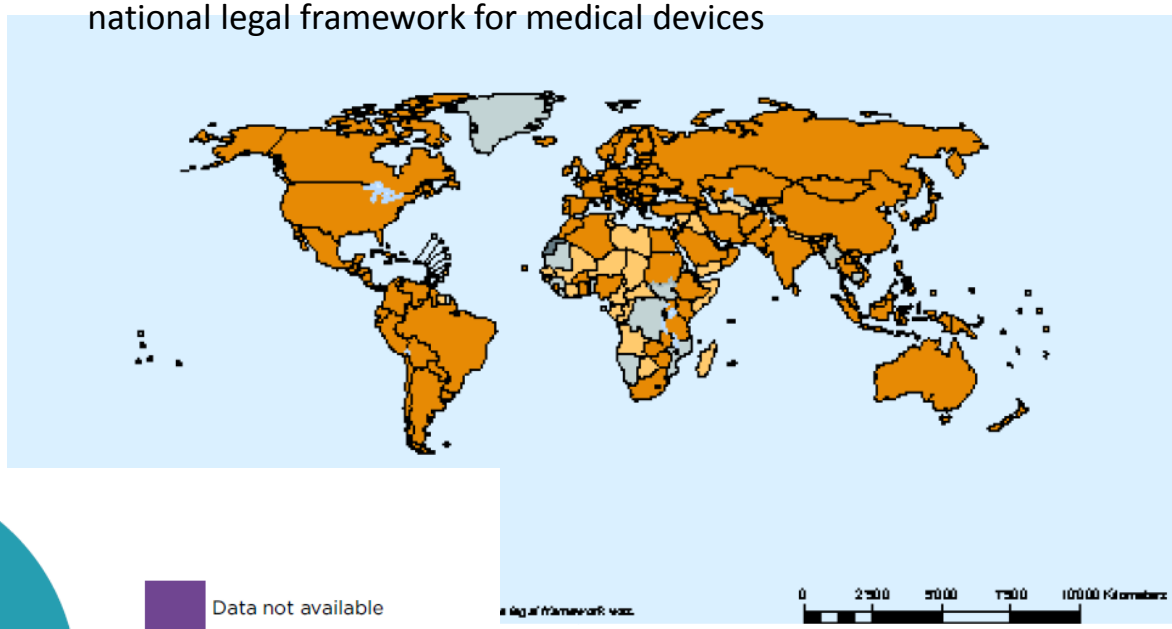


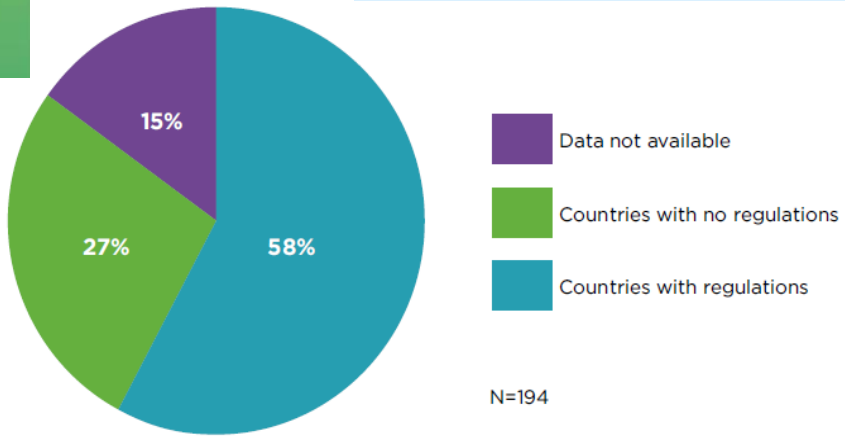
Biomedical engineers study: math, calculus, chemistry, biology, pathology, physiology, electronics, mechanics, physics, biochemistry, biomechanics, transducers, optics, …

National regulatory authorities in the governments decide which medical devices can enter the local market. (WHA67.20)



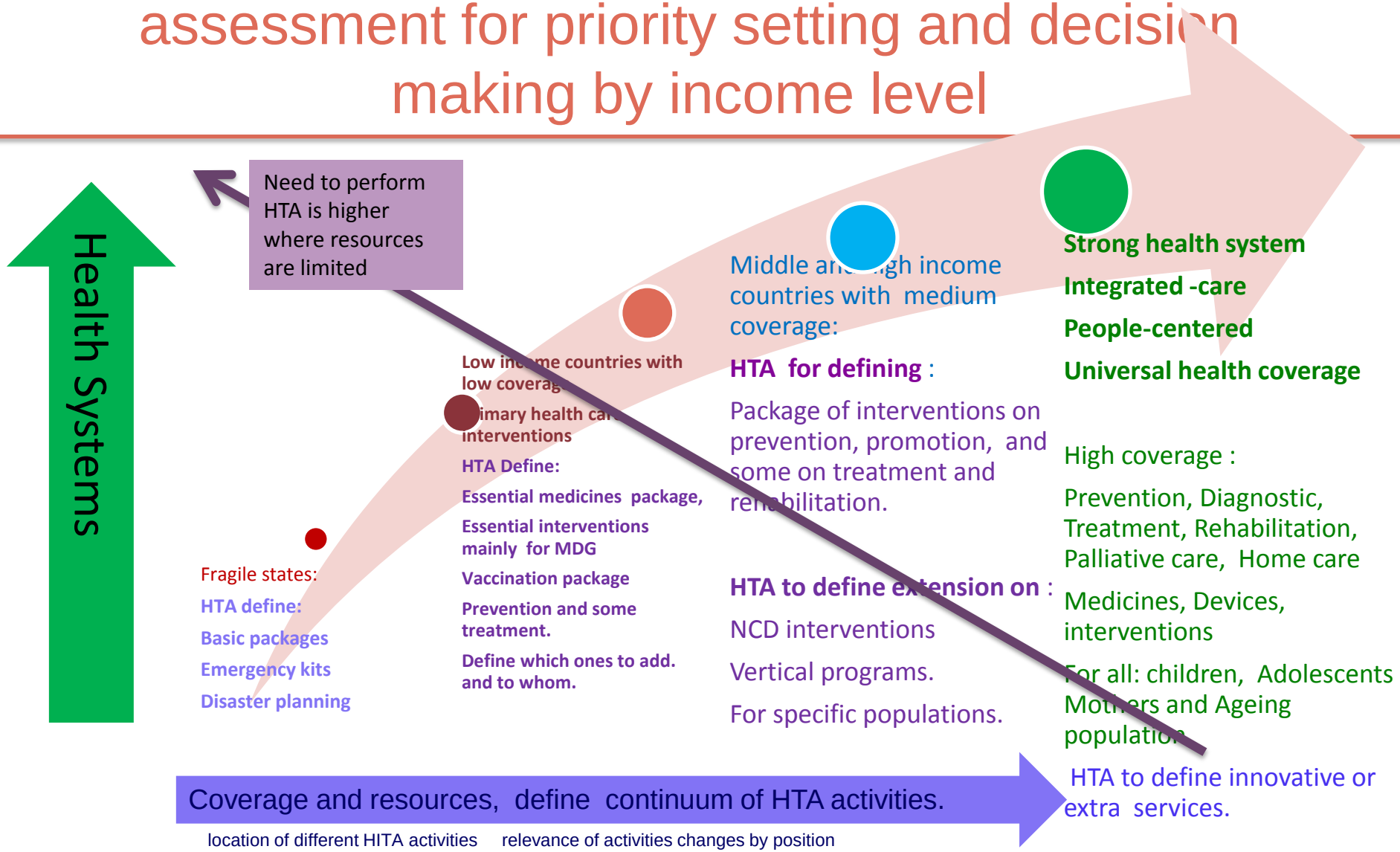
Global current status of medical device regulations; existence of a national legal framework for medical devices



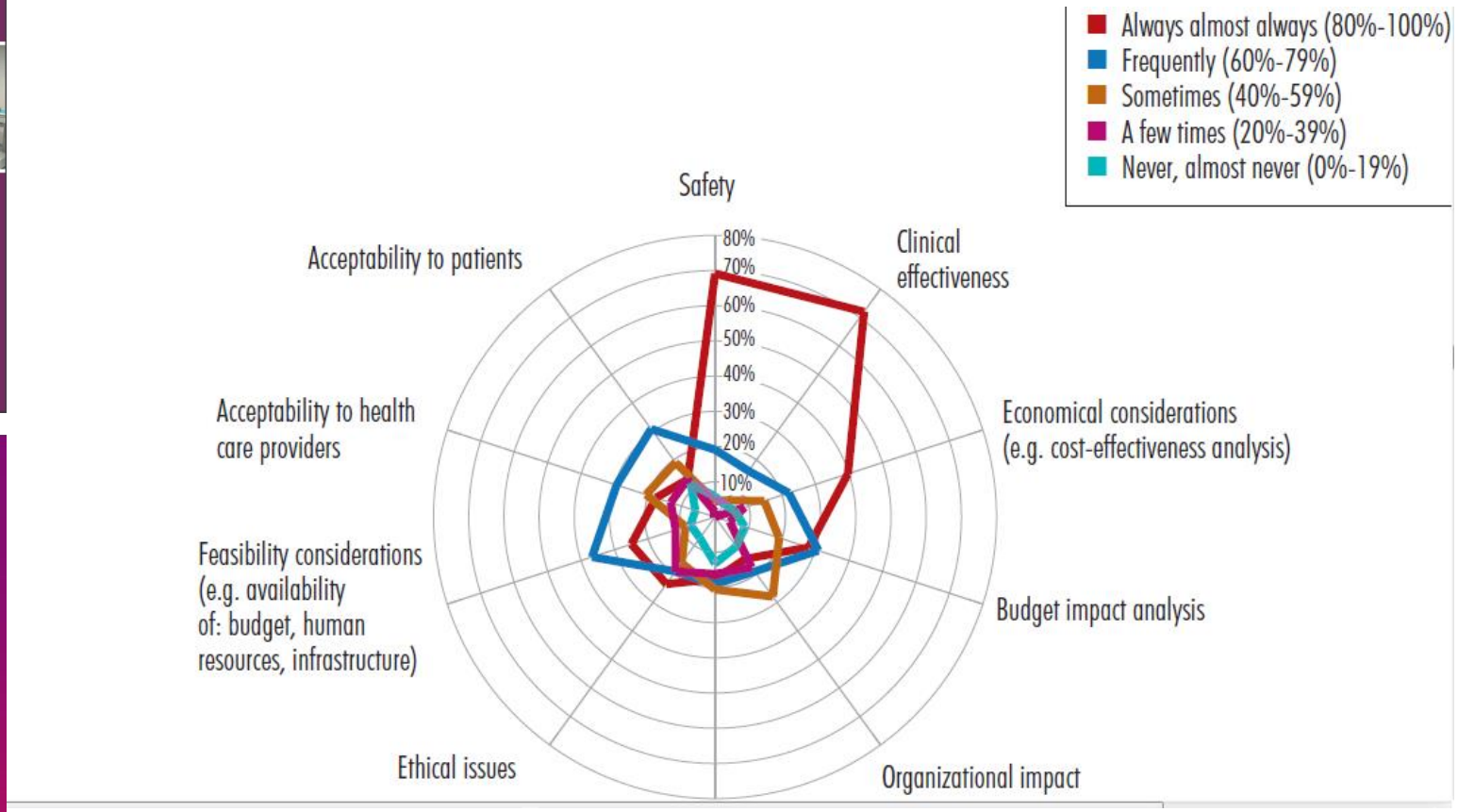


2. Sequence of process to warranty access to appropriate and safe medical devices.

Continuous Spectrum of health technology assessment for priority setting and decision making by income level



2015 WHO survey on national authorities on HTA indicated the following areas are/are not being assessed for medical devices. (WHA60.23)



Lists of priority medical devices

http://www.who.int/medical_devices/publications/priority_med_dev_cancer_management/en/

Medical devices

- Medical devices
- Policies and resolutions
- Quality and safety regulations
- Health technology assessment
- Health technology management
- Priority medical devices
- Innovation
- Country data
- Global collaborations
- Publications

Priority medical devices

List of priority medical devices

Core medical equipment refers to technologies that are commonly considered as important or necessary for specific preventive, diagnostic, treatment or rehabilitation procedures carried out in most health care facilities. WHO has been working, along with experts, collaborating centres and Member States, to develop several tools for better resource allocation, selection, incorporation and safe use.

Nomenclature of medical devices

Key initiatives | List of priority medical devices | Priority medical devices project

List of medical devices by health care facility
Specialized Hospital - Critical Medicine

Localization			Identification						
			Type*			GMDN**		UMDNS***	
Area	Unit	Subunit	ME, MF, IN	AC	Name	Code	Term name	Code	Term name
Critical Medicine	Coronary Care Unit	Bed	ME		Bed scale	35321	Scale, patient, bed	13458	Scales, Patient, Underbed
Critical Medicine	Coronary Care Unit	Bed	ME		Blood pressure instrument	16156	Sphygmomanometer, aneroid	13106	Sphygmomanometers
Critical Medicine	Coronary Care Unit	Bed	ME		Cardiac output module	36561	Patient monitoring system module, cardiac output	20774	Physiologic Monitor Modules, Cardiac Output
Critical Medicine	Coronary Care Unit	Bed	ME		Examination light	36843	Light, examination, mobile	12276	Lights, Examination
Critical Medicine	Coronary Care Unit	Bed	ME		Flowmeter for oxygen therapy (with humidification)	37132	Flowmeter, oxygen therapy	11746	Flowmeters
Critical Medicine	Coronary Care Unit	Bed	ME		Hemodynamic parameters module		NA		NA
Critical Medicine	Coronary Care Unit	Bed	ME		Invasive blood pressure module	36550	Patient monitoring system module, blood pressure, invasive		NA
Critical Medicine	Coronary Care Unit	Bed	ME		Multichannel infusion pump	17634	Infusion pump, multichannel	17634	Infusion Pumps, Multichannel

9 Global NCD targets to be attained by 2025 (against a 2010 baseline)

A 25% relative reduction in risk of premature mortality from cardiovascular disease, cancer, diabetes or chronic respiratory diseases

A 30% relative reduction in prevalence of current tobacco use

Halt the rise in diabetes and obesity

At least a 10% relative reduction in the harmful use of alcohol

A 30% relative reduction in mean population intake of salt/sodium

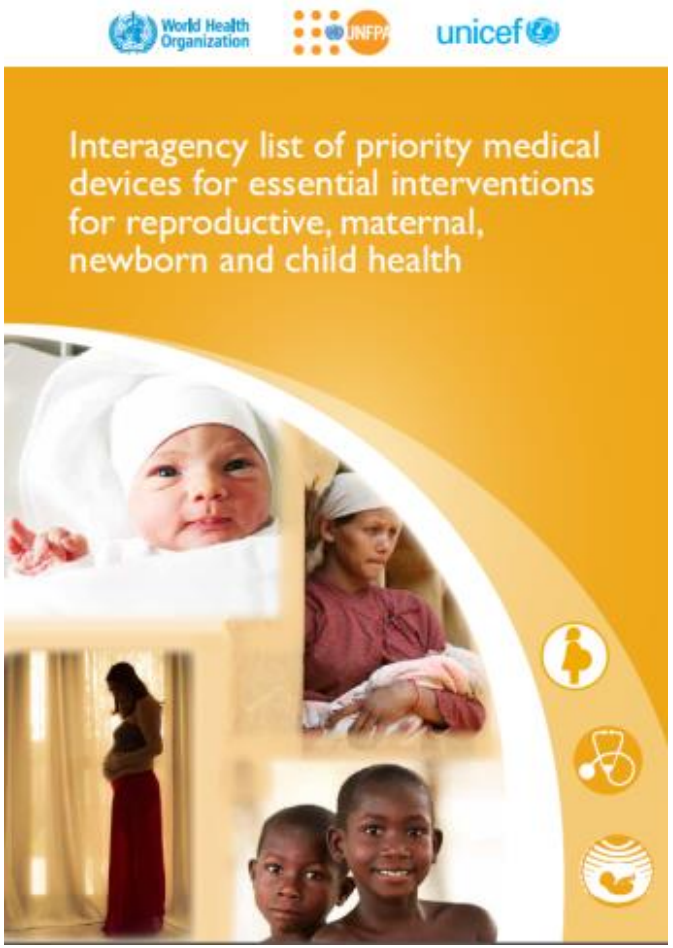
A 10% relative reduction in prevalence of insufficient physical activity

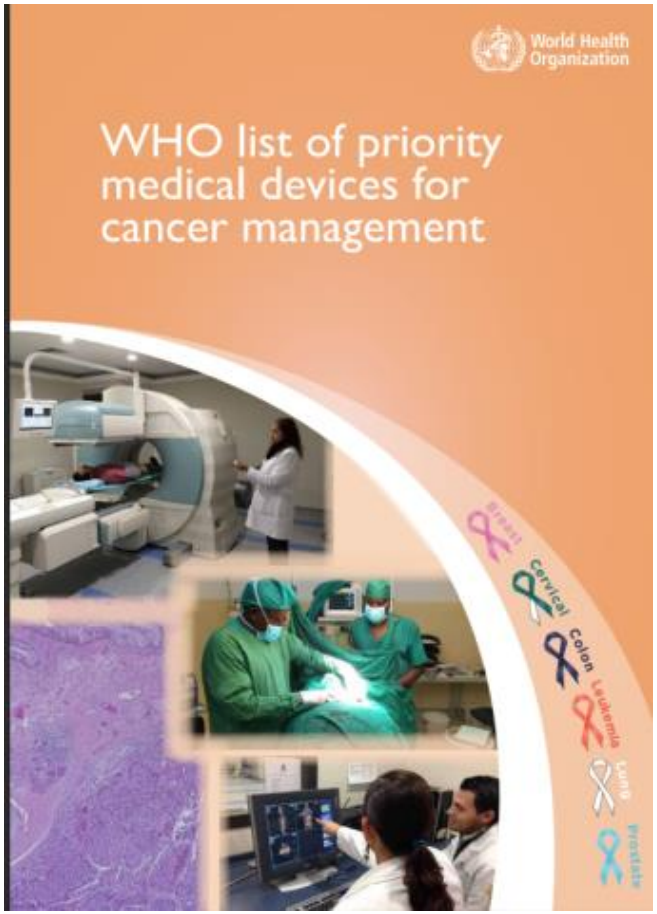
An 80% availability of the affordable basic technologies and essential medicines, incl. generics, required to treat NCDs

A 25% relative reduction in prevalence of raised blood pressure or contain the prevalence of raised blood pressure

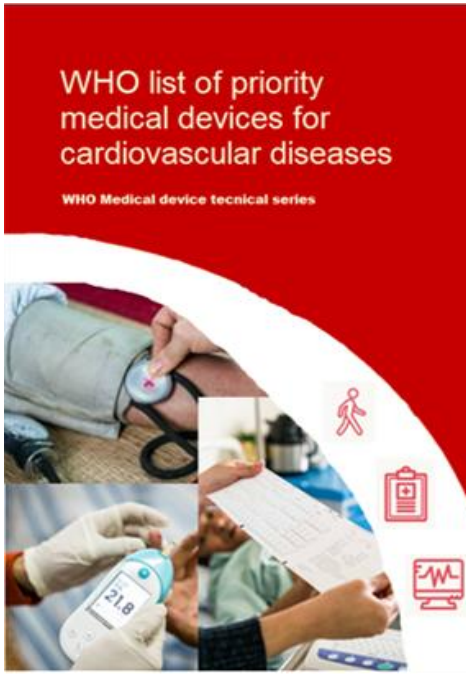
At least 50% of eligible people receive drug therapy and counselling to prevent heart attacks and strokes

Defining, Guidelines, Interventions, and medical devices by levels of care. Work on priority medical devices 2014- 2016





In development: 2017-2018



Interventions

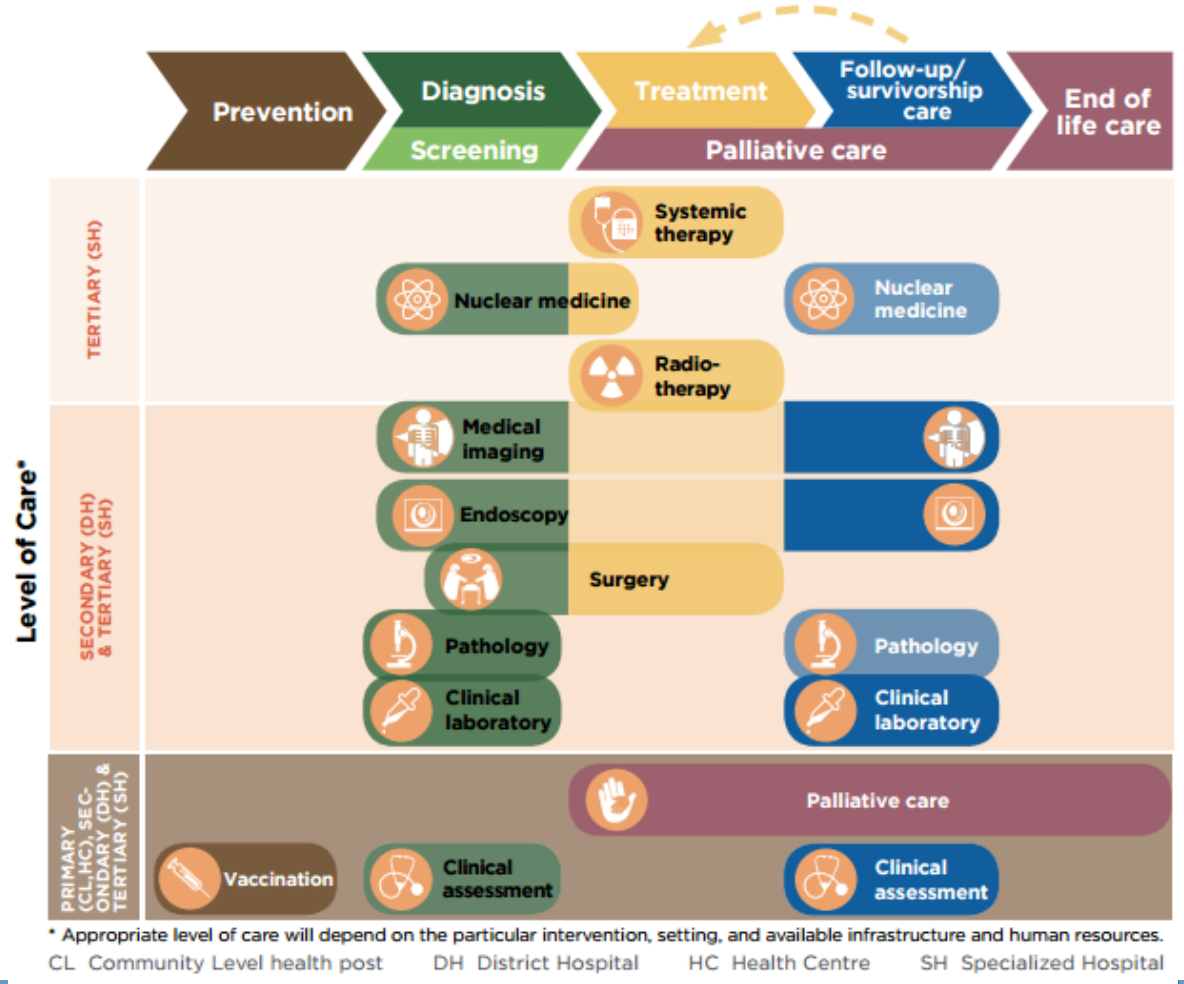
Table 5-4: Family Planning and Reproductive Health, Referral Hospital

Page 1

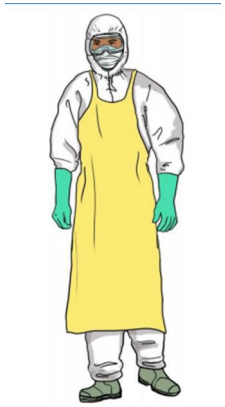
Medical Devices

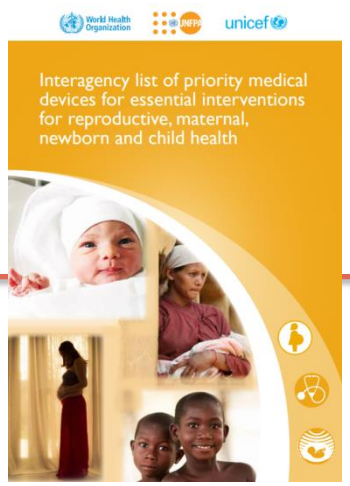
CATEGORY	SUBCATEGORY	NAME	Basic Medical Examination: a) Check-up vital signs / measuring weight and height / Anthropometry	Basic Medical Examination: b) Breast and pelvic examination	Preventive Immunization: a) Vaccine for Hepatitis B	Provision of contraceptives: b) Provision of injectable contraceptives	Provision of contraceptives: c) Insertion and removal of IUDs	Provision of contraceptives: d) Insertion and removal of contraceptive implants with local anaesthesia	Provision of contraceptives: e) Provision of barriers methods	Provision of contraceptives: f) Provision of emergency contraception	Provision of contraceptives: g) Provision of vaginal rings and patches
Family planning supply	Family Planning Consumables	Cervical cap							X		
		Diaphragm							X		
		Female condoms							X		
		Intra-Uterine Devices (only prequalified copper IUDs)					X			X	
		Levonorgestrel IUD					X				
		Lubricants							X		
		Male condoms							X		
		Sub-dermal implants (included the insertion device)						X			
		Acetic acid, 36 %, bottle									
		Acetone, bottle									
		Buffer, tablets, PH 7.2, box									
		Ethanol, denaturised, 70 %, bottle	X								
		Formaldehyde, 10%, 10ml, ampoule									
		Glycerol, bottle									

Definition of list of all priority medical devices for cancer management (continuum of care) to support to implement country cancer programs



Total: 11 MD

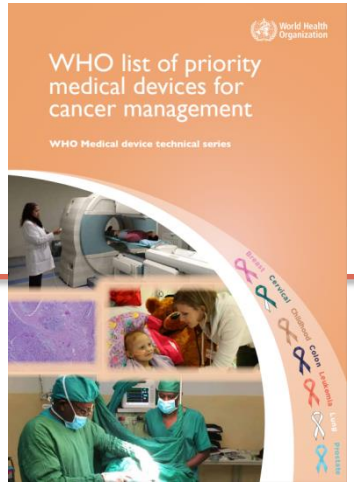




Total: 484 MD

Medical equipment for…

Examination & diagnosis	58
Referral	101
Labor	67
Surgery & anesthesia	83
Inpatient care – mother & newborn	49
Inpatient care – child	47
Intensive care	79
Total:	**484**



Total: 684 MD

Capital equipment

Medical equipment	82
Laboratory & pathology equipment	62
Quality assurance devices	28
Surgical instruments	81
Total:	**253**

Single use, consumables…

Laboratory & pathology eq.	26
Personal protective eq. & clothing	22
Radiation protection /monitoring devices	23
Single use devices/disposables/medical supplies	179
Solutions and reagents	108
Other (glassware, utensils, etc.)	70
Software	3
Total:	**431**

GMDN – X-ray

Mobile specimen x-ray system, analogue (42279)

Mobile specimen x-ray system, digital (42280)

Stationary specimen x-ray system, analogue (42284)

Stationary specimen x-ray system, digital (42282)

Basic diagnostic x-ray system application software (40866)

Basic diagnostic x-ray system operation software (40821)

Diagnostic x-ray digital imaging system workstation application software (58473)

X-ray system tube support, ceiling mount (40946)

X-ray system tube support, floor stand (37076)

X-ray system tube support, gantry mount (40949)

X-ray system tube support, table mount (40951)

X-ray system tube support, wall mount (40947)

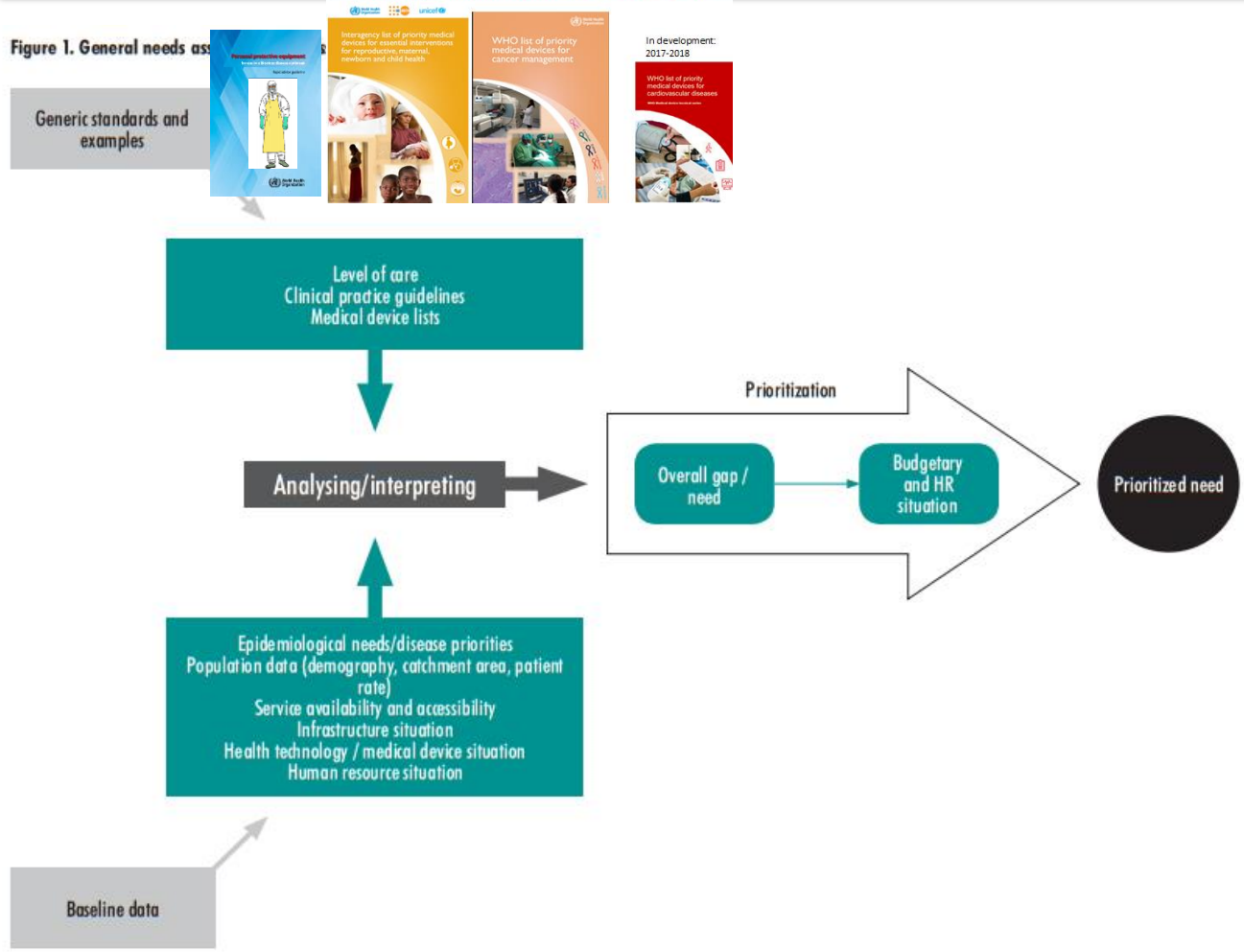
Basic diagnostic x-ray system table, non-powered (40654)

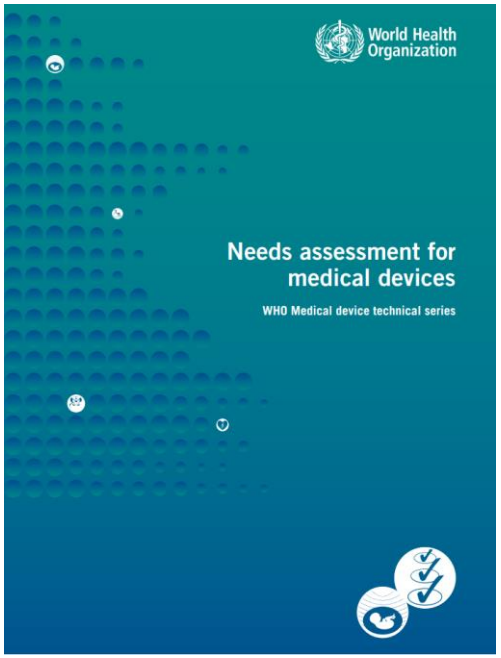
Basic diagnostic x-ray system table, powered (40655)

….

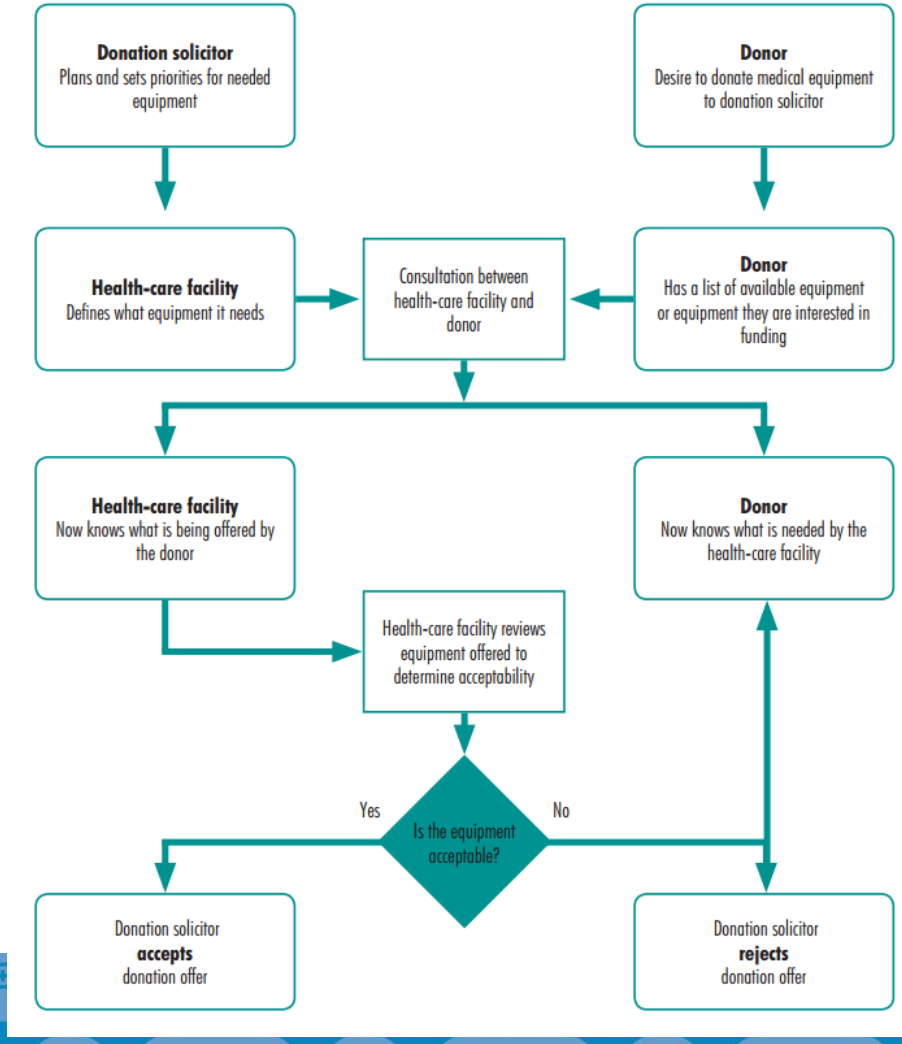
Using the priority list of medical devices, to determine the gaps: needs assessment

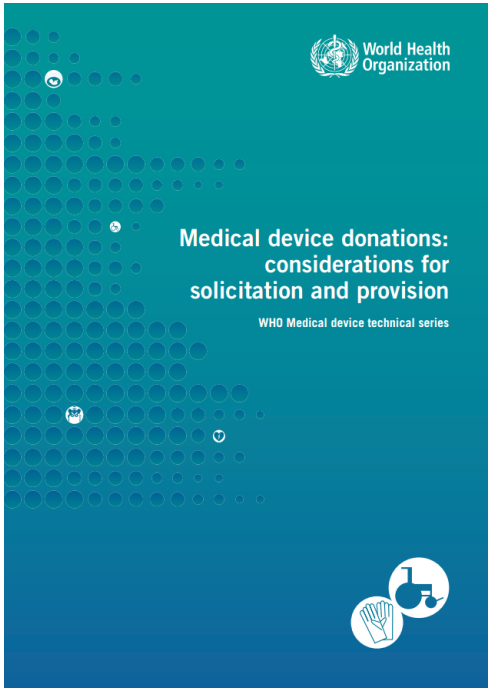
Defining, Guidelines, Interventions, and medical devices by levels of care
Work on priority medical devices 2014- 2016



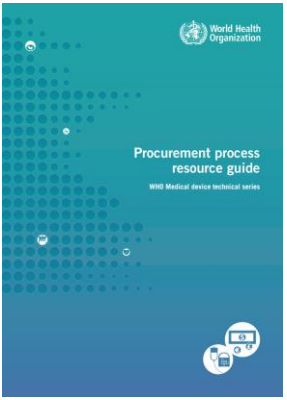


Medical Device Donations represent more problems than benefits if wrongly done





Procurement of medical devices



plus 60 technical specifications for procurement

Figure 5.1 The hidden costs of medical devices

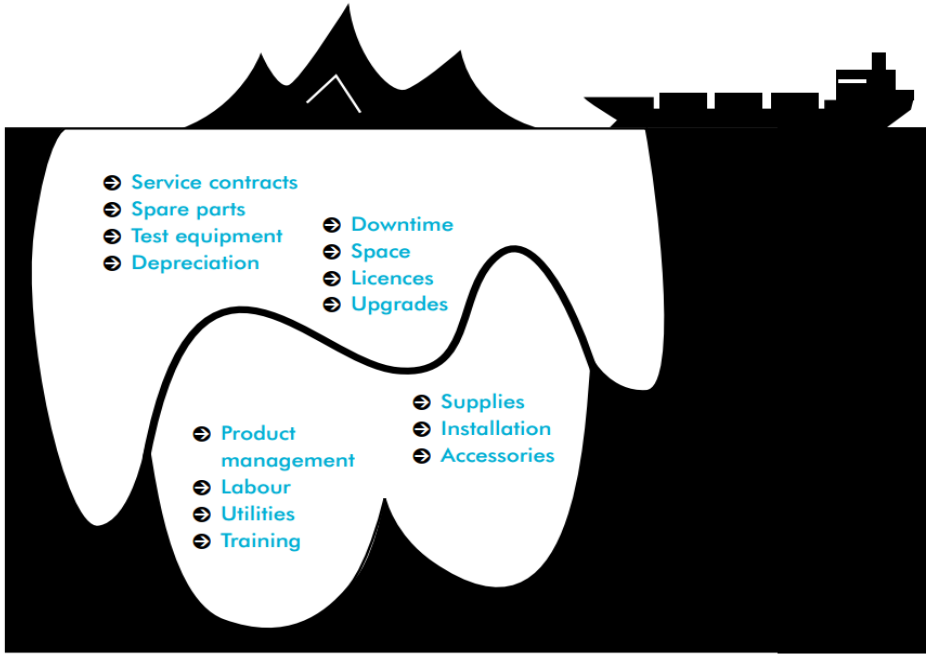
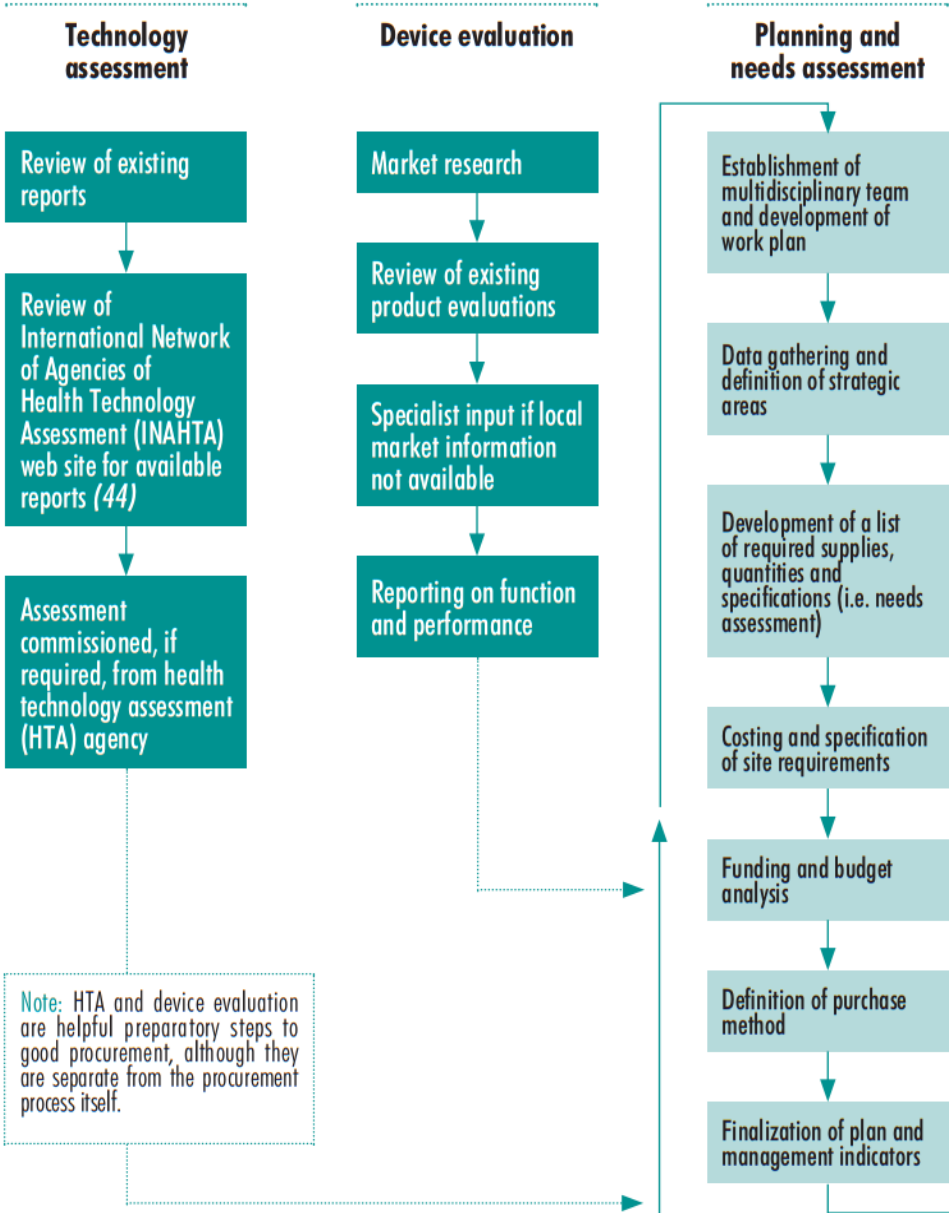


Figure 2. Summary flow chart of standard procurement procedures



Technical specifications of Neonatal resuscitation devices

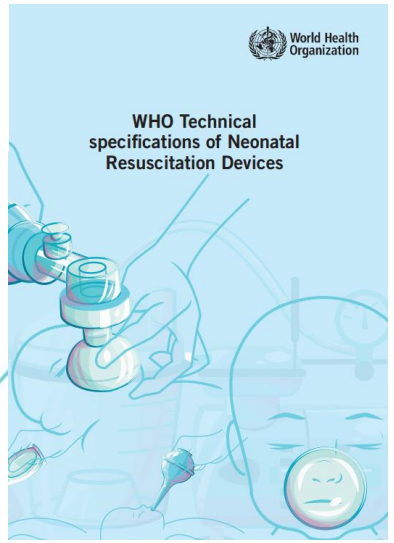


Figure 1. Sample neonatal resuscitation bag with mask

Figure 2. How to use a neonatal resuscitation bag with mask

Technical specifications of oxygen concentrators

- http://www.who.int/medical_devices/publications/
- tech_specs_oxygen-concentrators/en/

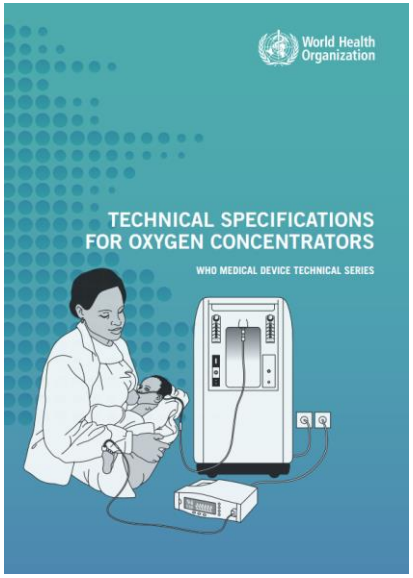
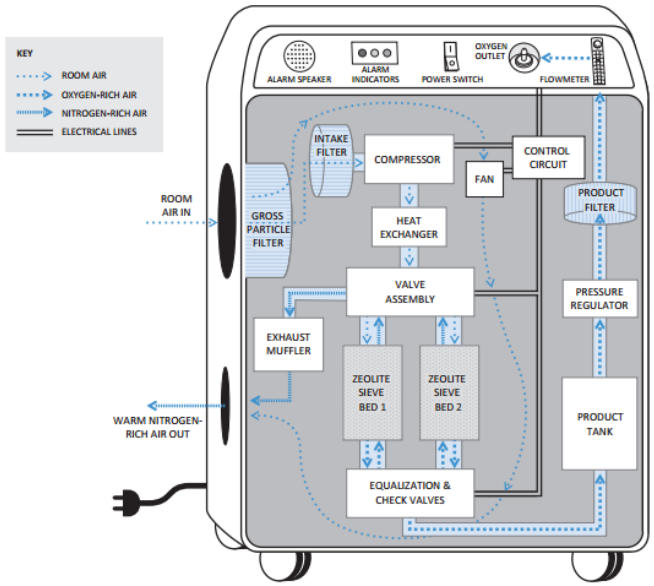


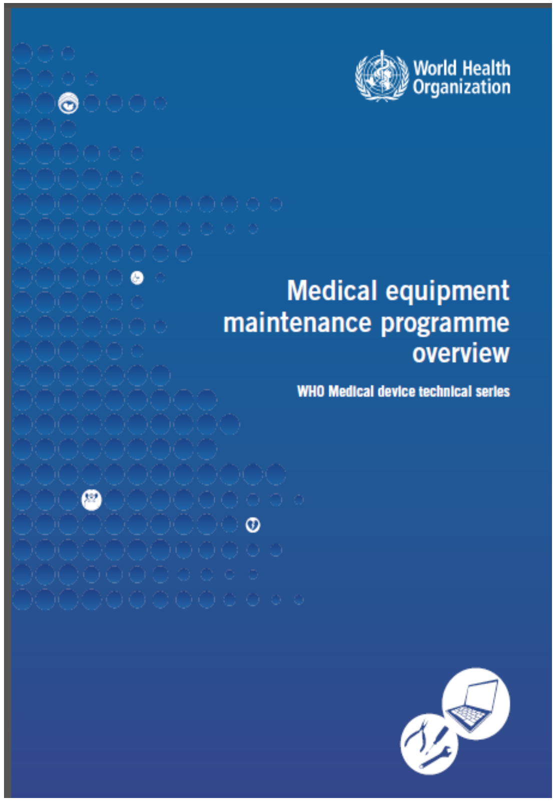
Figure 1. Process flow and components of a typical oxygen concentrator



Source: Provided by PATH (2015).

Purpose of use		
14	Clinical or other purpose	Provide positive air pressure ventilation to newborn babies with asphyxia, babies who experience respiratory arrest, apnoea or respiratory distress requiring assisted ventilation, and babies who require assisted ventilation during procedures.
15	Level of use (if relevant)	Health centre/district hospital/provincial hospital/specialized hospital/other health facilities that include maternity services.
16	Clinical department/ward (if relevant)	Nursing services, surgery, paediatrics, emergency medicine, obstetrics, intensive care unit, labour and delivery room.
17	Overview of functional requirements	The resuscitator is used to ventilate newborns with a body weight less than 5 kg. The resuscitator can be used to efficiently maintain ventilation, or as resuscitation in other critical situations.
Technical characteristics		
18	Detailed requirements	A resuscitator is used to ventilate a neonate with a body weight of less than 5 kg. It is operated by hand and ventilation can be done with ambient air or with oxygen. A resuscitator can be totally disassembled, and is easy to clean and disinfect. All parts are manufactured from high-strength, long-life materials that require no special maintenance or storage conditions. A resuscitator is supplied as a complete set with: • non-rebreathing patient valve with a pressure limiting valve so that airway pressure does not exceed 4.5 kPa (45 cmH_2O) and can transmit an airway pressure of at least 3 kPa (=30 cmH_2O); • masks, translucent, in two different sizes: Size 0 (preterm and low-birth-weight baby), round type, outer diameter 35–50 mm; Size 1 (term baby), round type, outer diameter 50–65 mm silicone rubber or any material fulfilling at least the standards ISO 10993-1:2009; ISO 10993-5:2009; ISO 10993-10:2010, or equivalent; or classified as USP Class V; • compressible self-refilling ventilation bag: silicone rubber or any other material fulfilling ISO 10651-4; • bag size: 200–320 mL; intake valve with an optional nipple for O_2 tubing: polycarbonate/polysulfone or any other material fulfilling the ISO 10651-4 or any other equivalent; • bag made of silicone and valve made of polycarbonate or polysulfone or any other sterilizable material complying with ISO10651-4 or equivalent • material: polycarbonate/polysulfone or any other sterilizable material fulfilling at least ISO 10651-4.
19	Displayed parameters	N/A
20	User adjustable settings	
Physical/chemical characteristics		
21	Components (if relevant)	Self-inflating neonatal resuscitation bag with masks for preterm and term babies. Patient valves with pressure relief valves o 45 cmH_2O.
22	Mobility, portability (if relevant)	Portable and mobile.
23	Raw materials (if relevant)	Recommended material is silicone rubber for the bag and mask and polycarbonate/polysulfone for the valves. Any material fulfilling ISO 10993-1:2009; ISO 10993-5:2009; ISO 10993-10:2010 or equivalent or USP Class V is also recommended.
Utility requirements		
24	Electrical, water and/or gas supply (if relevant)	N/A

Maintenance of medical equipment



Appendix E.1

Record of inspection

This type of label indicates the date the device was serviced or inspected and may indicate when the next service is due. These tags are sometimes printed in different colours, one for each year or inspection cycle so that it is easier to identify devices that are due for inspection. This tag may be covered with plastic adhesive/cover to protect it from being defaced during the cleaning process.

SAMPLE

Appendix D.2

Equipment inspection forms

Hyper/Hypothermia Machine

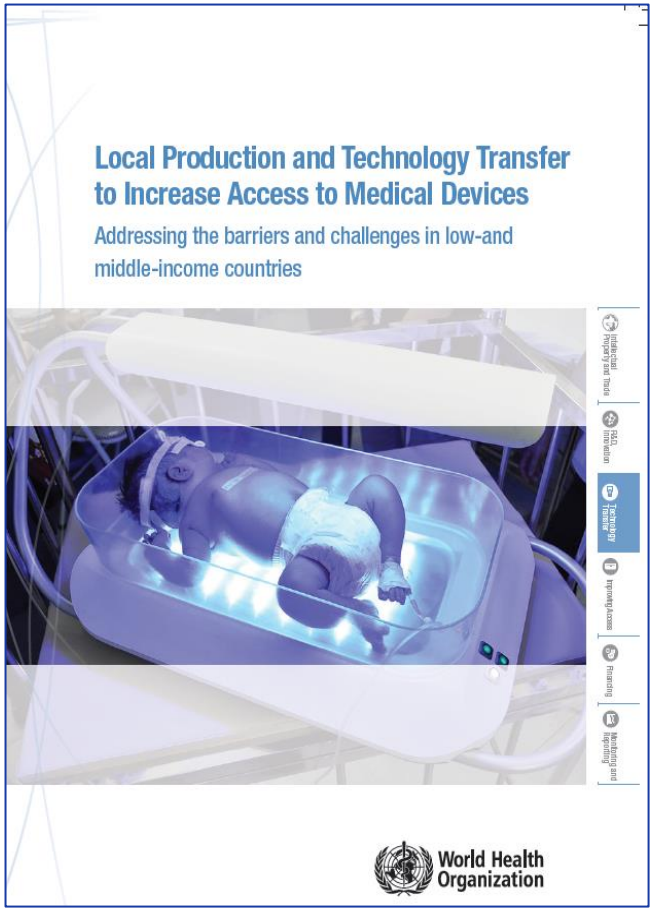
Functional check and inspection form

Location:__________________ Control number:__________________

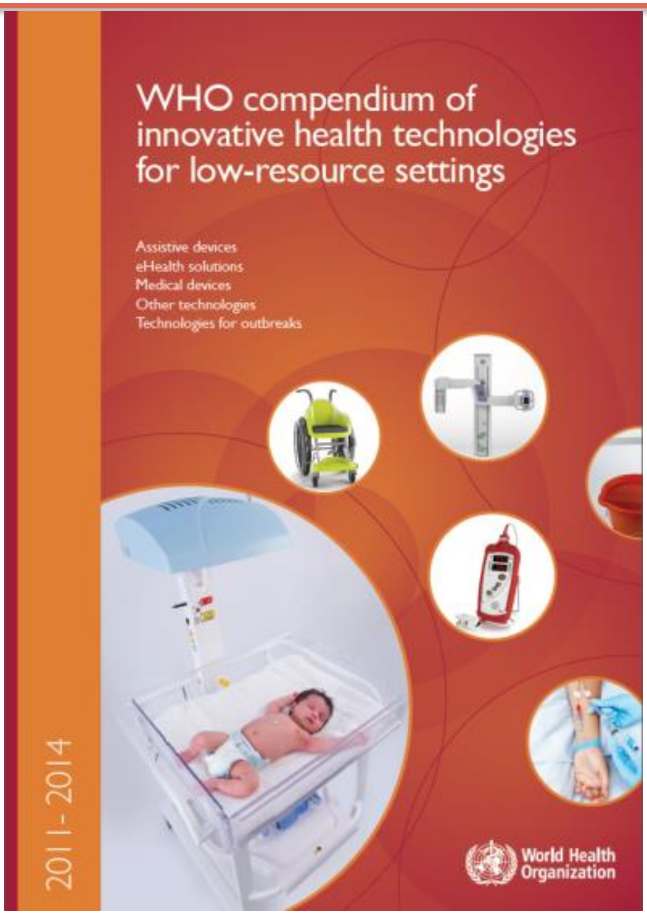
Manufacturer: __________________ Model: __________________

Item			OK? (Y/N)	Action needed	Action taken (date/initials)
a. Condition of chassis?					
b. Condition of attachment plug?					
c. Condition of line cord and strain relief?					
d. Condition of indicator lights and alarms					
e. Flow	Mode	GPM			
	Heating				
	Cooling				
	Flow switch activation				
f. Level switch activation					
g. Cold water reservoir controls					
h. Blanket water temperature controller					
Set point	Display	Thermometer			
55 deg F					
77 deg F					
105 deg F					
Display within 1 deg C (1.8 F) of set point					
Thermometer within 1 deg C (1.8 F) of set point					
i.	High temperature back-up thermostat				
	Shut down relay set point				
j. Thermometer verification test					
k. Patient temperature display test					
	Probe resistance	Patient temp display			
	1355	37 ° C ± 0.3 ° C			
	1667	32 ° C ± 0.3 ° C			
l. Low temperature backup thermostat					
m. Ground resistance less than 0.5 ohm					
n. Leakage current					
	Chassis (grounded)	10 uA			
	Chassis (ungrounded)	100 uA			
	Patient probe	50 uA			

Local production and technology transfer to increase access to medical devices.



Research, development and innovation : WHO Compendium of Innovative Health Technologies for Low Resource Settings



Infant radiant warmer for primary care

Country of origin | India

Health problem addressed

Nearly 2/3 of all newborn deaths (4 million annually) occur in 10 countries, India being largest contributor with 876,000. Lack of skilled personnel, infrastructure and affordability are big challenges to providing primary care. Hypothermia at birth is one of the most significant risk factors of neonatal mortality irrespective of birth weights and gestational ages. Urgent action is needed to address the issue of neonatal deaths and progress on MDG4, since 40% of under 5 deaths are in new-borns.

Product description

Infant radiant warmer with uniform heating: the warmer features a patented "J-profile" design that reflects heat uniformly to the bed for more thermal stability. Reduced heat loss: the heater is made with a cartridge (Calrod-like) technology that allows for rapid warming of cold surfaces, thus helping to reduce cold stress for the babies. Safe contact with the patient: All patient contact surfaces are made with biocompatible materials—chosen to be gentle on the baby's delicate skin. Rugged: The warmer's electrical system is engineered to operate without a voltage stabilizer and can withstand voltage fluctuations of upto 390V. Clear observation: With a LED-based observation lamp emitting a white light, the warmer allows for great patient observation.

Developer's claims of products benefits

Many cheap warmers available in the market are unreliable, break down frequently and do not deliver the desired level of clinical performance. There are others that are feature heavy and very highly priced and much beyond the buying capacity of primary care buyers. With Calrod technology for the best clinical outcomes, ruggedness and reliability (unique 5 years warranty) and at extremely affordable prices.

Suitability for low-resource settings

Designed for a low resource health facility with poor infrastructure (intermittent power, power fluctuations, no electricity), low-skilled nurses, lack of space, low purchasing power. Easy to use: the device is plug-in and use requires minimal training. Rugged & Reliable; can withstand voltage fluctuations up to 390V. Comes with 5 year maintenance warranty. The temperature probe is made of Kevlar (material used to make bullet proof vests) Affordable: Low purchase price, low maintenance & service costs. So far, the warmer has been installed in many challenging environments across India and ASEAN with poor room air temperature control, constant power outages, rugged environment and a limited availability of skilled clinicians. The rugged and reliable design was well suited to the challenging environment and usage conditions.

Operating steps

Plug in the assembled unit to a power source and switch on the device. The warmer performs a self test, then switch ON in the manual heating mode. Use this mode to pre-heat, if needed. Place the baby on the mattress in the bassinet and attach the skin probe to the baby. Toggle to the baby mode and set the control temperature for thermoregulation.

Regulatory status

CE certified (CE 01236). Biocompatible: All surfaces coming in contact with the patient are biocompatible (EN ISO 10993-1:2009/AC:2010). EN 60601 regulations - MedicalElectrical Equipment. The product conforms to RoHS requirements (residues of hazardous substances). Other: EN 62366 - Medical devices, EN 62304 - Medical Device software, EN ISO14971 - Application of risk management to medical devices, EN ISO 13485 - Quality Management Systems, EN 980 - Symbols for use in the labeling, EN 1041.

Future work and challenges

The product is low cost and meant for low resource settings. One of the obstacles is government specifications and tenders. The documents need to be updated with new technologies so that the product can reach the markets it is actually meant for.

Use and maintenance

User: Intended for use by a physician, nurse, or midwife

Training: Basic training manual (quick reference guide) provided and video available

Maintenance: No scheduled maintenance required

Environment of use

Setting: Designed for rural and urban indoor settings and in primary, secondary and tertiary level health care facilities.

Energy and Facility requirements: Requires a continuous power Supply of 230V and an environment within the range of 18-30 °C and 30-75%RH

Product specifications

Weight (kg): 37

Dimensions: 1500mm x 800mm x 800mm

Consumables: heat reflector skin patch

Lifetime: 7 years

Retail price (USD): 1 500

Other features: mobile

Year of commercialization: 2014

Currently sold in: India, Malaysia, Indonesia, Vietnam

Contact Sumit Mehrotra | Email lowresourcesetting@gmail.com | Telephone 918040886511 | Web www.gehealthcare.com

Source: http://www.who.int/medical_devices/innovation/compendium/en/, 15.09.2016

WHO Collaborating Centers

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INSTITUTO DE EFECTIVIDAD CLINICA Y SANITARIA

卫生部卫生技术评估重点实验室（复旦大学）
Key Lab of Health Technology Assessment, Ministry of Health (Fudan University)

IEB UFSC
Instituto de Engenharia Biomédica

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ifcc
International Federation of Clinical Chemistry and Laboratory Medicine

International Organization for Medical Physics
IOMP

GMTA
Global Medical Technology Alliance
Innovating for a Healthier World

IFHE
International Federation of Hospital Engineering

ISO

ISR
The International Society of Radiology

HTAi
Health Technology Assessment international

Hum@tem

WORLD ASSOCIATION OF SOCIETIES OF PATHOLOGY and LABORATORY MEDICINE
PARIS
1947

uia
UNION INTERNATIONALE DES ARCHITECTES

IFMBE
International Federation for Medical and Biological Engineering
A member of the International Union on Physical and Engineering Science in Medicine (IUPESM)

A Nonprofit Public Service
RAD-AID.org
Radiology serving the world

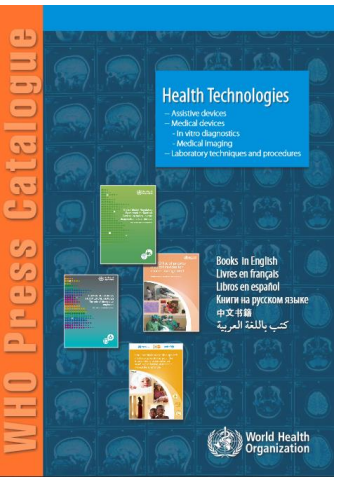
W.C.RONTGEN · 1845 - 1923
ISRRT
INTERNATIONAL SOCIETY OF RADIOGRAPHERS & RADIOLOGICAL TECHNOLOGISTS

IFBLS
International Federation of Biomedical Laboratory Science

WFUMB
World Federation for Ultrasound in Medicine and Biology
WFUMB helps bring sustainable ultrasound programs to the underserved areas of the world to improve global healthcare through collaboration, communication, and education.

WHO Publications on the safe and quality use of medical devices, example ultrasound

http://www.who.int/medical_devices/publications/en/



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- Local production

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WHO Global Model Regulatory Framework for Medical Devices including in vitro diagnostic medical devices
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2011

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Compendium of innovative health technologies for low-resource settings, 2011-2014: Assistive devices, eHealth solutions, medical devices, other technologies, technologies for outbreaks
2015

Compendium of Innovative Health Technologies for Low-resource Settings
2014

Medical Devices and eHealth Solutions
2013

Compendium of New and Emerging Health Technologies
2011

Innovative Technologies that Address Global Health Concerns
2010

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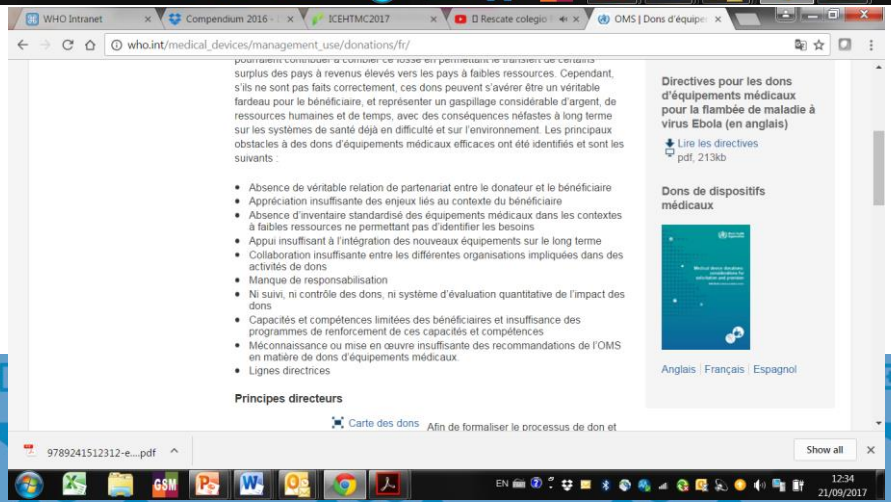

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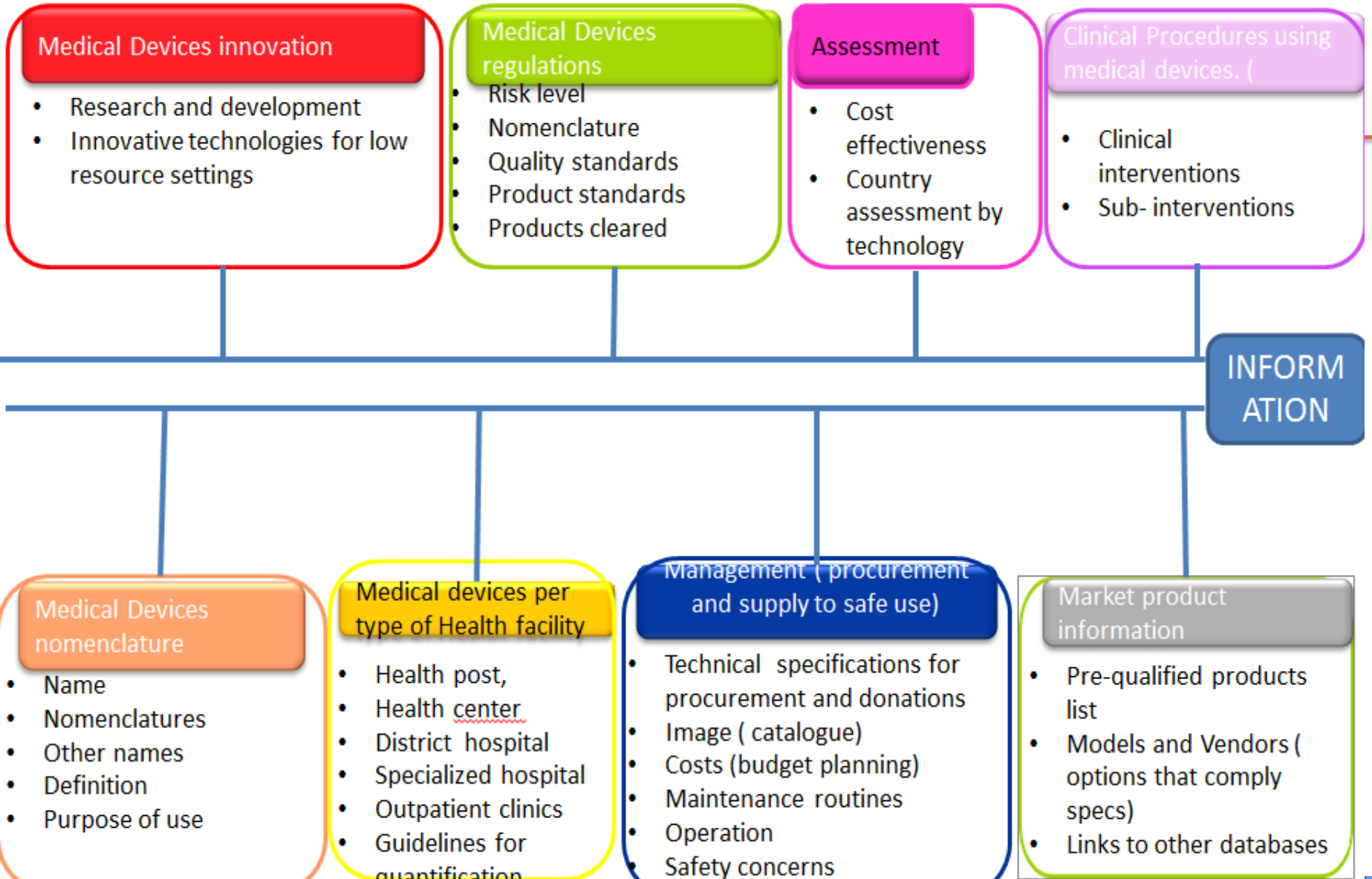

Conclusions

Science and technology are evolving daily , so are medical devices that need to be designed, regulated, assessed, managed and use properly.

Medical devices

- Are indispensable for health care provision and need to be appropriate to the setting
- Are not pharmaceuticals, do not achieve systemic biochemical changes
- Can be 1 mm to 4 mts; last 1 second or 30 years; weigh 1 gram or 1 ton..
- Require special training to be used appropriately,
- Some require maintenance and spare parts
- Require collaborative work from biomedical engineers with doctors, nurses, laboratory technicians, radiographers, IT, hospital managers…. to help in the selection, supply, training and best use of medical devices.
- Are necessary to provide universal health coverage and to achieve the health related Sustainable Development Goals.

Much work needs to be done in this area, specially in LMIC to ensure access!!

Thank you !

www.who.int/medical_devices

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