

Innovative Technology in Addressing Global Health Issues: the WHO Perspective

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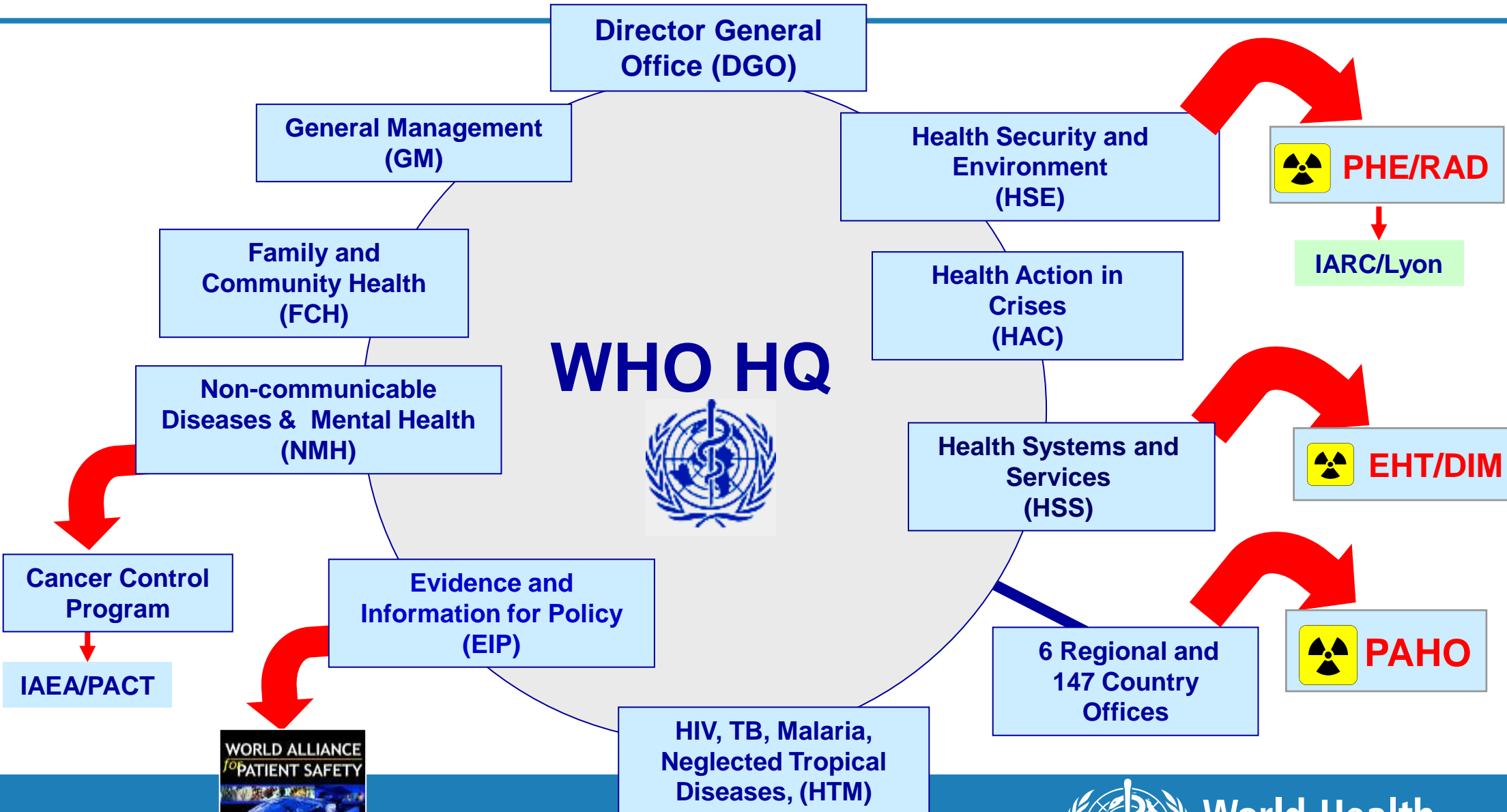
WHO/HQ/HSS/EHT/DIM

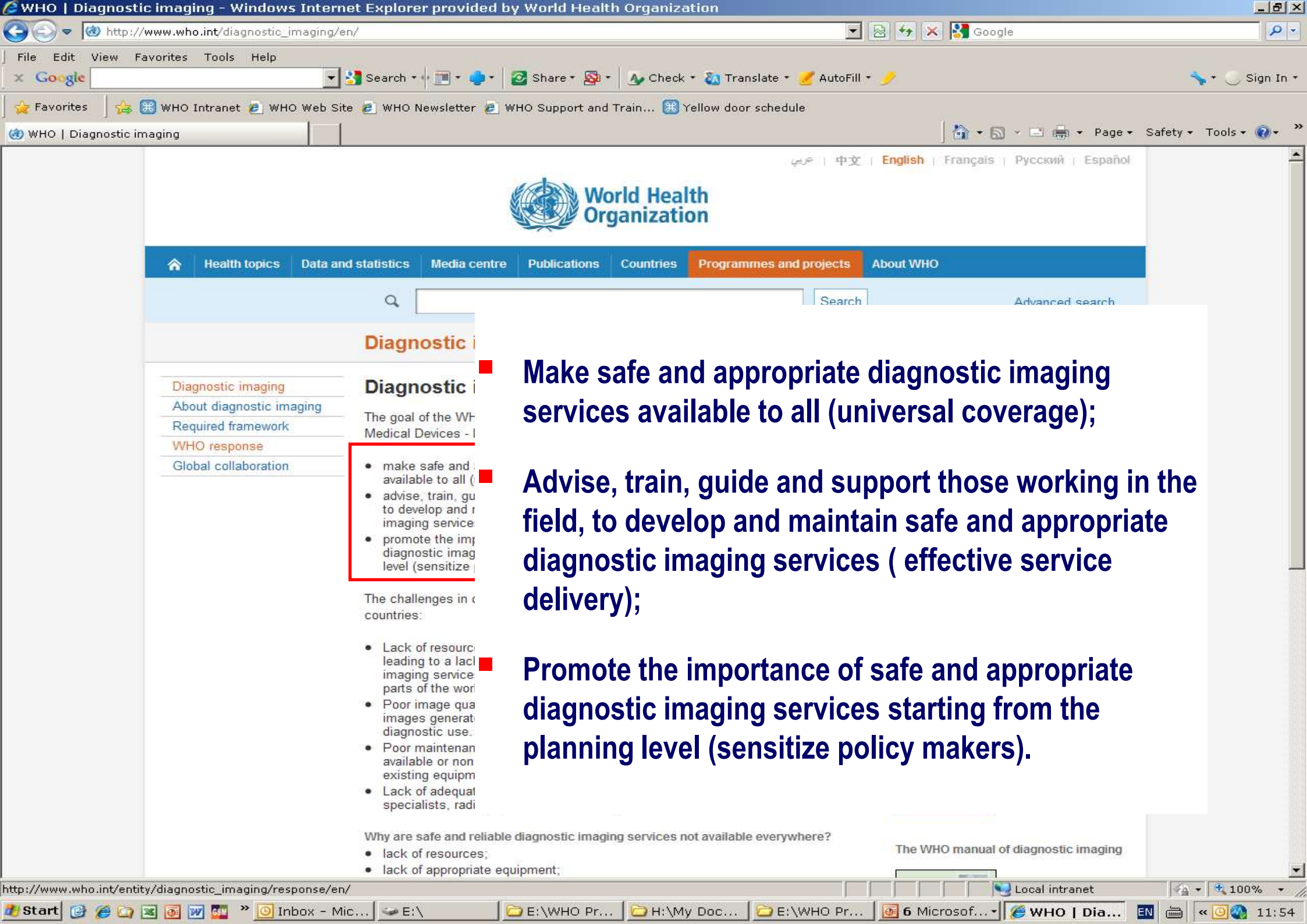


**World Health
Organization**



WHO Structure





- Home
- Health topics
- Data and statistics
- Media centre
- Publications
- Countries
- Programmes and projects
- About WHO

- Diagnostic imaging
- About diagnostic imaging
- Required framework
- WHO response
- Global collaboration

Diagnostic i

Diagnostic i

The goal of the WH Medical Devices - I

- make safe and available to all (
- advise, train, gu to develop and r imaging service
- promote the imp diagnostic imag level (sensitize

The challenges in countries:

- Lack of resource leading to a lack imaging service parts of the wor
- Poor image qua images generat diagnostic use.
- Poor maintenanc available or non existing equipm
- Lack of adequat specialists, radi

Why are safe and reliable diagnostic imaging services not available everywhere?

- lack of resources;
- lack of appropriate equipment;

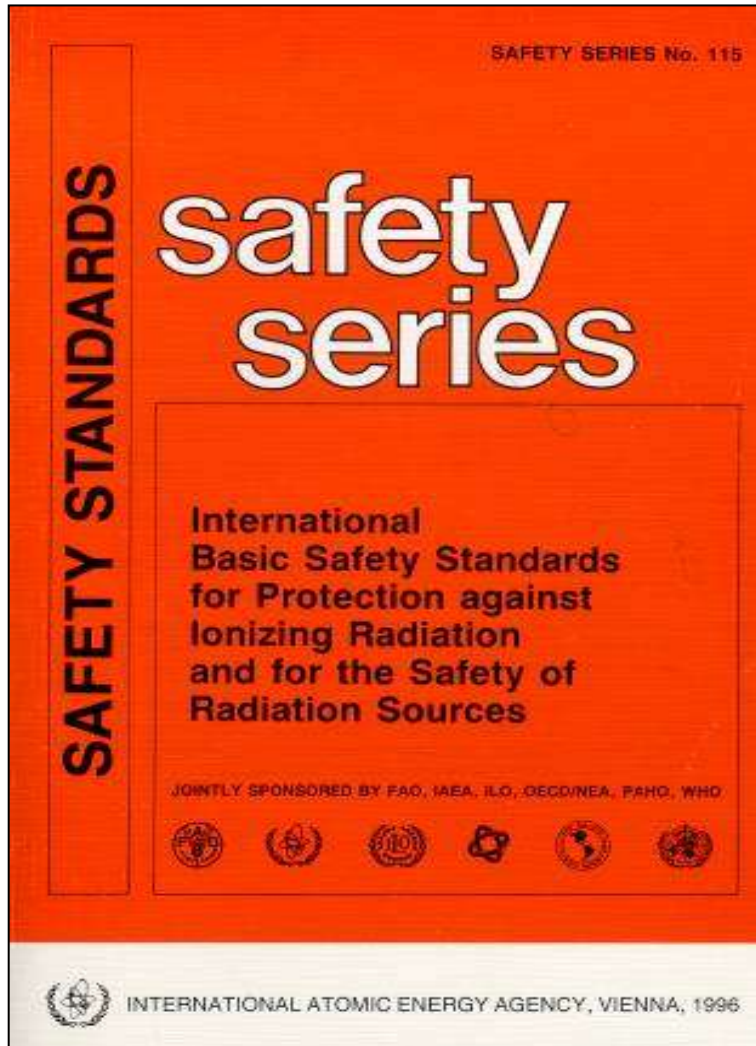
The WHO manual of diagnostic imaging

Make safe and appropriate diagnostic imaging services available to all (universal coverage);

Advise, train, guide and support those working in the field, to develop and maintain safe and appropriate diagnostic imaging services (effective service delivery);

Promote the importance of safe and appropriate diagnostic imaging services starting from the planning level (sensitize policy makers).

Activities



- **Hosting meeting of study groups and scientific groups**
- **Education and training of operators and interpreters to ensure delivery of safe and effective diagnostic imaging services**
- **Joint Global Initiative on Radiation Safety in Health Care Settings**
- **Global Steering Group for Education and Training in Diagnostic Imaging**
- **Publication of reports (guidelines, recommendations)**

Global Steering Group for Education and Training in Diagnostic Imaging



- Established 1999
- Representatives from major global and regional societies and organizations
- 'Train the trainers'
- Local 'centres of excellence' for capacity building



Professional Societies Members of Steering Group

Permanent members

ISR, ISRRT, WFUMB, WFNMB

Regional societies

**ESR, CIR, RSNA, MASU, AFSUMB, AOSR,
SFR, ACR, ARRS**

Temporary members

Related to activities



Other Forms of Collaboration

Expert Advisory Panel on Radiation

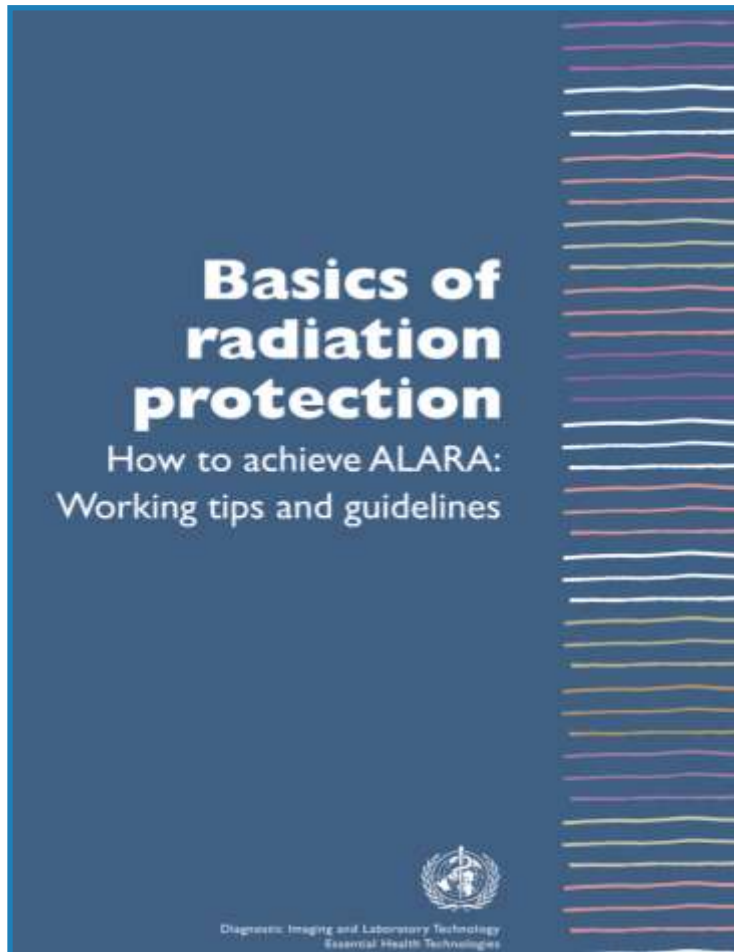
Collaborating Centres

1. WHO Collaborating Centre for Continuing and General Education in Diagnostic Ultrasound, Philadelphia, USA
2. WHO Collaborating Centre for Breast Diagnostic Imaging in Mammary Pathology, Buenos Aires, ARGENTINA
3. WHO Collaborating Centre for Diagnostic Ultrasound in Obstetrics and Gynaecology, Trondheim, NORWAY
4. WHO Collaborating Centre for Secondary Standard Radiation Dosimetry, Nonthaburi, THAILAND
5. WHO Collaborating Centre for Secondary Standard Radiation Dosimetry, Mumbai, INDIA
6. Centre collaborateur de l'OMS pour la Formation et la Recherche en Maintenance hospitalière, Diourbel
SENEGAL
7. WHO Collaborating Centre for Patient Safety, Risk Management and Health Care Technology, Plymouth Meeting, USA
8. WHO Collaborating Centre on Environmental and Occupational Health Impact Assessment and Surveillance, Sainte-Foy, CANADA
9. WHO Collaborating Centre for Health Technology Assessment, Barcelona, SPAIN
10. WHO Collaborating Centre for Health Technology Assessment and Management, Shanghai, CHINA



Publications (2001 - 2006)

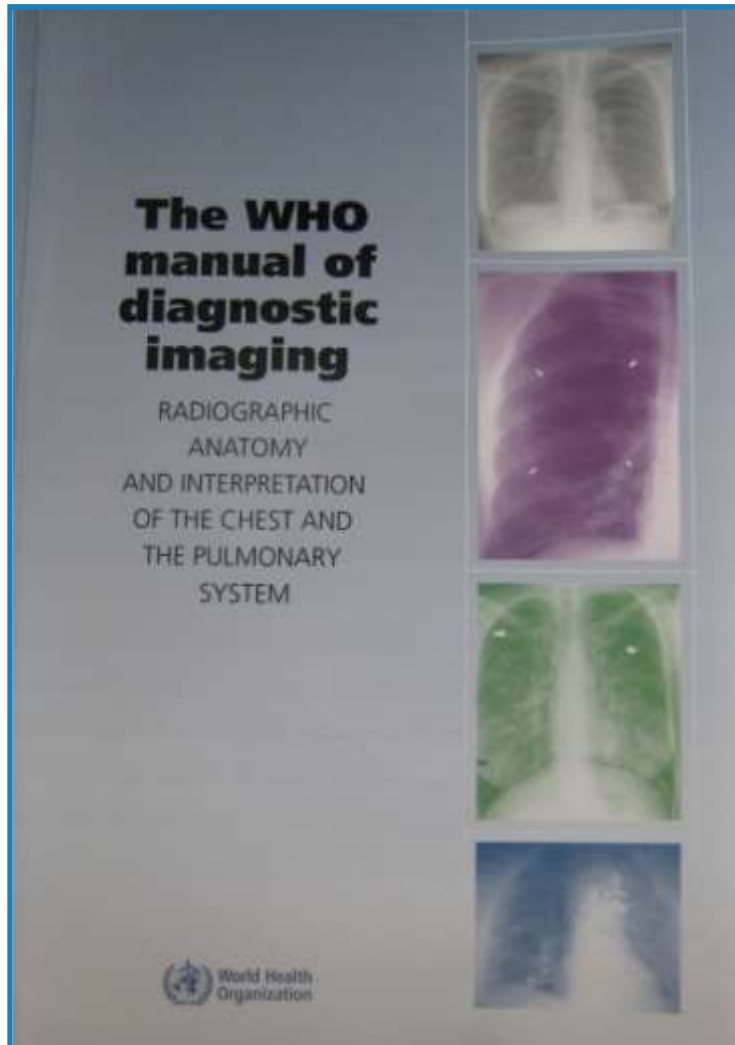
Technical Series



- Diagnostic Imaging: What is it? When and how to use it where resources are limited? (WHO/DIL/01.1)
- Quality assurance workbook for radiographers and radiological technologists (WHO/DIL/01.3), (ISBN 9 789241 546423)
- Consumer Guide for the purchase of X-ray equipment (WHO/DIL/00.1 Rev. 1)
- Basic radiation protection. How to achieve ALARA. Working tips and guidelines (ISBN 92 4 159178 1)
- The WHO manual of diagnostic imaging. Radiographic technique and projections (ISBN 92 4 154608 5)
- X-ray equipment maintenance and repairs workbook for radiographers & radiological technologists (ISBN 92 4 159163 3)

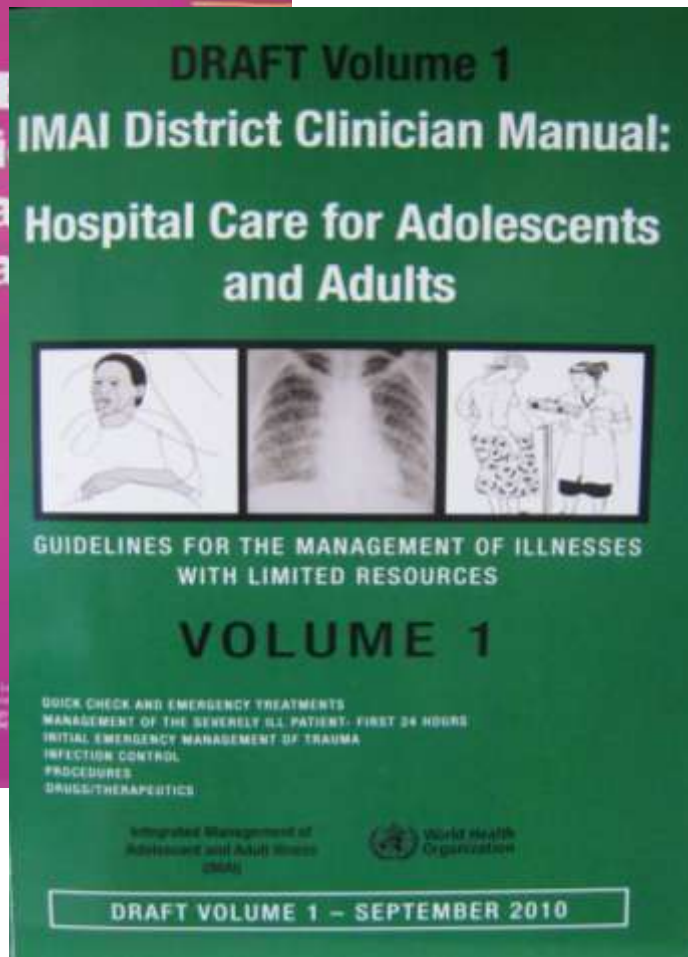
Publications (2001 - 2006)

Medical Series



- Pattern recognition in diagnostic imaging (ISBN 92 4 154632 8)
- The WHO manual of diagnostic imaging. Radiographic anatomy and interpretation of the musculoskeletal system (ISBN 92 4 154555 0)
- WHO manual of diagnostic imaging. Radiographic anatomy and interpretation of the chest and the pulmonary system (ISBN 92 4 154677 8)
- The WHO Lecture Series on Radiology and Ultrasound (CD-Rom)
- Pediatric dosimetry
- Efficacy and Radiation Safety in Interventional Radiology
- Manual of diagnostic ultrasound (ISBN 92 4 154461 9)

WHO Publications on Ultrasound



- Future Use of New Technologies in Developing Countries – WHO Technical Report Series
- Maintenance and Repair of Laboratory, Diagnostic Imaging, and Hospital Equipment – WHO Publication
- Training in Diagnostic Ultrasound: Essentials Principles and Standards – Report of a WHO Study Group
- A Practical Guide to the Standardized Use of Ultrasonography for the Assessment of Schistosomiasis-related Morbidity – Second International Workshop
- Basic Physics of Ultrasonographic Imaging – WHO Publication
- IMAI District Clinician Manual: Hospital Care for Adolescents and Adults

Manual of diagnostic ultrasound

vol. 1

During the last decades, use of ultrasonography became increasingly common in medical practice and hospitals around the world, and a large number of scientific publications reported the benefit and even the superiority of ultrasonography over commonly used X-ray techniques, resulting in significant changes in diagnostic imaging procedures.

With increasing use of ultrasonography in medical settings, the need for education and training became essential. WHO took up this challenge and in 1995 published its first training manual in ultrasonography. Soon, however, rapid developments and improvements in equipment and indications for the extension of medical ultrasonography into therapy indicated the need for a totally new ultrasonography manual.

The manual (consisting of two volumes) has been written by an international group of experts of the World Federation for Ultrasound in Medicine and Biology (WFUMB), well-known for their publications regarding the clinical use of ultrasound and with substantial experience in the teaching of ultrasonography in both developed and developing countries. The contributors (more than 50 for the two volumes) belong to five different continents, to guarantee that manual content represents all clinical, cultural and epidemiological contexts.

This new publication, which covers modern diagnostic and therapeutic ultrasonography extensively, will certainly benefit and inspire medical professionals in improving 'health for all' in both developed and emerging countries.



Second edition

Manual of diagnostic ultrasound

v o l u m e 1



World Health Organization



World Health Organization

Use Health Technology to Strengthen Health Systems

UNIVERSAL
COVERAGE

PEOPLE-CENTRED
CARE



INCLUSIVE
LEADERSHIP

PUBLIC POLICIES
FOR
PUBLIC HEALTH



WHA60.29 Resolution

Approved on 23 May, 2009

Recognizing that health technologies equip health-care providers with tools that are indispensable for effective and efficient prevention, diagnosis, treatment and rehabilitation.



URGES Member States:

- 1. To collect, verify, update and exchange information on health technologies in particular medical devices as an aid to their prioritization of needs and allocation of resources;**
- 2. 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;**



Levels of Health Care

Primary Health Care – Level I

Basic level of health care includes promotion of health, early diagnosis of disease or disability, and prevention of disease.

Primary health care centres can meet over 90% of the imaging needs of the population

Primary health care should be “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.”

International Conference on Primary Health Care, Alma Ata Declaration, 1978



Primary Health Care

Primary Health Care – Level I

Basic Radiological System (BRS)

Serving a small rural (or suburban) hospital or health centre

Effective choices for diagnostic imaging in clinical practice
Report of a WHO Scientific Group
World Health Organization
Technical Report Series 795

Future Use of new imaging technologies in developing countries
Report of a WHO Scientific Group
Technical Report Series, 723

BRS - 1980 WHO

X-RAY UNIT - SPECIFICATIONS FOR EQUIPMENT

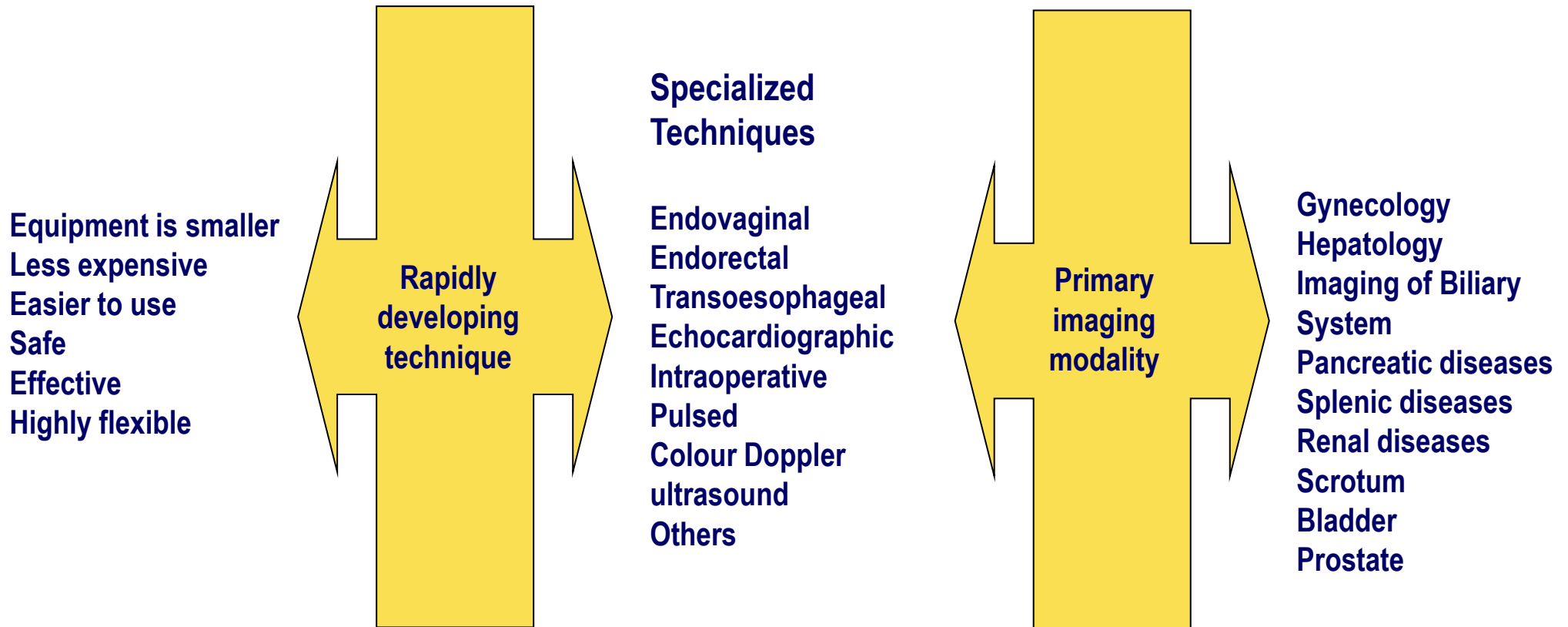
Battery powered generators
Manual for radiographers and darkroom techniques
Radiographic interpretations

ULTRASOUND UNIT

General Purpose Ultrasound Unit
Manual of Ultrasound



Diagnostic Ultrasound



Training in Diagnostic Ultrasound: Essentials, Principles and Standards
Report of a WHO Study Group
World Health Organization



Core Conditions Utilizing X-Ray in Resource-Poor Settings

Type	Condition	Intervention	Skill Level	Necessity
Chest	Pneumonia	Medical management	Basic	High
	Tuberculosis	Medical management	Basic	High
	Pneumothorax	Chest tube placement	Advanced	High
	Pleural effusion	Thoracentesis	Advanced	High
	Cardiac failure	Medical management	Advanced	Moderate
	Hemothorax	Thoracentesis	Advanced	High
	Chronic obstructive pulmonary disease	Medical management	Basic	Moderate
	Asthma	Medical management	Basic	Moderate
	Lung abscess	Medical management	Advanced	High
	Occupational lung diseases	Medical management	Basic	Moderate
Limb	Long bone fracture	Reduction and fixation	Advanced	High
	Small bone fracture	Reduction and fixation	Advanced	High
	Osteomyelitis	Medical and surgical management	Basic	Moderate
	Dietary deficiency diseases (scurvy, rickets)	Nutrient supplementation	Basic	Moderate



THE SIMAVI/BRS PROJECT
A SUCCESSFUL WHO APPROACH

Maru DSR, et al. Globalization and Health 2010;6:18.



Core Conditions Utilizing Ultrasound in Resource-Poor Settings

Type	Condition	Intervention	Skill Level	Necessity
Abdominal	Cephalopelvic disproportion	Cesarean section	Advanced	Moderate
	Ectopic pregnancy	Surgical management	Advanced	Moderate
	Retained products of conception	Dilation and Curettage	Advanced	High
	Abruptio placentae	Medical and surgical management	Advanced	High
	Peripartum hemorrhage	Medical management	Basic	Moderate
	Cholecystitis	Medical and surgical management	Advanced	High
	Tuberculosis (intra-abdominal)	Medical management	Basic	High
	Hydronephrosis	Medical and surgical management	Basic	High
	Abdominal trauma	Medical and surgical management	Advanced	High
	Abdominal masses	Medical and surgical management	Basic	High
Chest	Pleural effusion	Thoracentesis	Advanced	High
	Pneumothorax	Chest tube	Advanced	Moderate
	Hemothorax	Thoracentesis	Advanced	High
Cardiovascular	Deep vein thrombosis	Anticoagulation	Basic	High
	Cardiac failure	Medical management	Basic	Moderate
	Cardiac valve disease	Medical and surgical management	Advanced	High
	Pericardial effusion	Medical management and pericardiocentesis	Advanced	High
Orthopedic	Spine, skull trauma	Surgical management	Advanced	Moderate
	Pediatric Osteomyelitis	Medical management	Basic	Moderate
	Rib, pelvis trauma	Surgical management	Advanced	Moderate
Neurological	Neonatal hemorrhage	Medical management	Advanced	High
	Neonatal infection	Medical management	Advanced	Moderate
Procedural	Intravenous Access	Procedural guidance	Basic	Moderate
	Abscess	Procedural guidance	Basic	Moderate
	Arthrocentesis	Procedural guidance	Basic	Moderate
	Paracentesis	Procedural guidance	Advanced	High
	Thoracentesis	Procedural guidance	Advanced	High
	Pericardiocentesis	Procedural guidance	Advanced	High
	Foreign Body	Procedural guidance	Basic	Moderate
	Lumbar Puncture	Procedural guidance	Basic	Moderate

Maru DSR, et al. Globalization and Health 2010;6:18.



Health Care Levels

Secondary Health Care – Level II

Equipment

ALL LEVEL I TECHNIQUE AND:

Sophisticated radiography
Sophisticated ultrasonography
including Doppler
Mammography
Angiography
Digital subtraction angiography (DSA)
and macro-radiography
Computed tomography (CT)
Radionuclide scintigraphy, including
single photon emission computerized
tomography (SPECT)
Thermography (of limited use)

General Purpose Radiological System

In secondary care hospital with 100 – 500 beds and a number of medical specialists (surgery, medicine, obstetrics, gynaecology, paediatrics)

Effective choices for diagnostic imaging in clinical practice
Report of a WHO Scientific Group
World Health Organization
Technical Report Series 795

Future use of new imaging technologies in developing countries
Report of a WHO Scientific Group
Technical Report Series, 723



Health Care Levels

Tertiary Health Care – Level III

Equipment

Specialized Radiological System

Tertiary care hospital - usually the top-level referral hospital, often a university hospital)

ALL LEVEL II AND III TECHNIQUES AND:

Magnetic resonance imaging (MRI)
Positron emission tomography (PET)
Advanced radionuclide scanning:
labelling by means of monoclonal
antibodies (immunoscinitigraphy)

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Ultrasound Training Needs According to Equipment

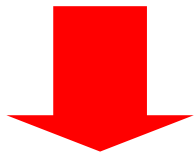
Level of health care	Level of training required	Professional Category	
		General	Specialized
I	Sufficient to perform common examinations safely and accurately	Family physician, trauma physician, sonographer	Midwife, paediatrician
II	Sufficient to accept and manage referrals	Radiologist Sonologist	Obstetrician/gynaecologist, cardiologist, other specialists
III	Advanced, for teaching and research	Radiologist Organ – oriented sub-specialist sonologist	Advanced specialists (perinatologists and sub-specialized internists and surgeons)

Training in Diagnostic Ultrasound: Essentials, Principles and Standards
Report of a WHO Study Group
World Health Organization

Need for Training

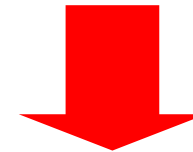
Worldwide, much of the ultrasonography is currently performed by individuals with little or no formal training.

Developed countries



Need for entry level training and continuing education

Developing countries



Maintain and increase level of competence



- Educational opportunities are often limited
- Uniform standards for training physicians do not generally exist
- Many ultrasonography practitioners do not have adequate experience



What Do We Expect From Medical Devices?

- Available
- Accessible
- Appropriate
- Affordable



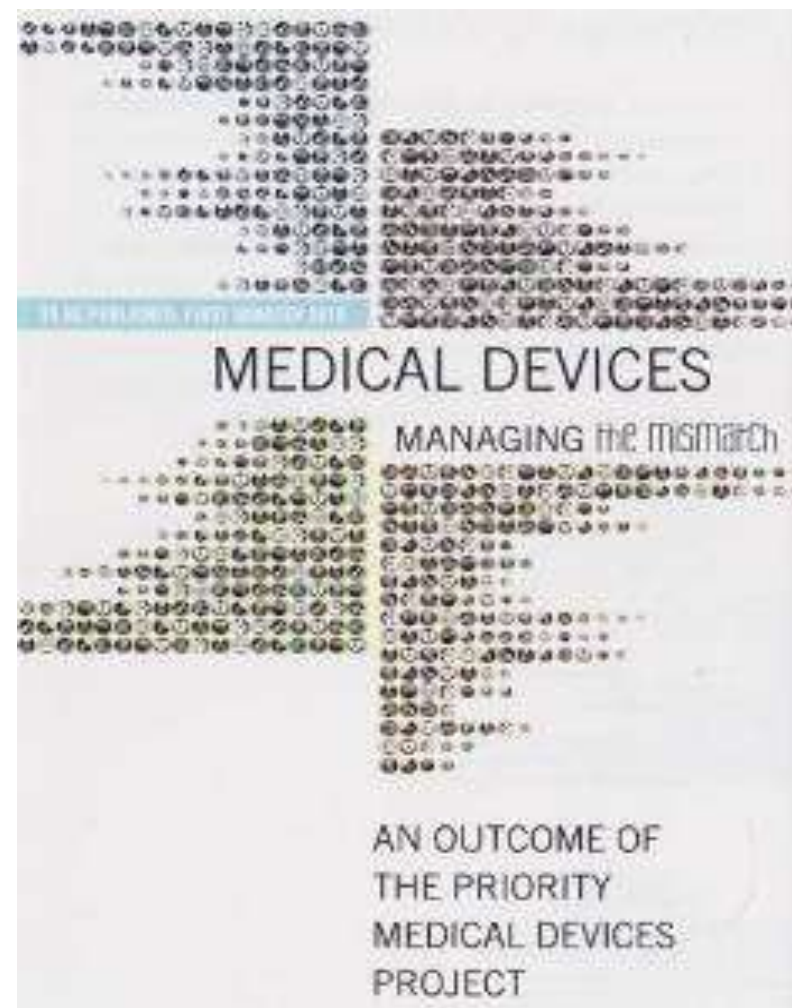
Priority Medical Devices Project

Objectives

- Identify the gaps in the availability of medical devices from a public health perspective
- Identify cross cutting themes
- Propose a research agenda

Results

- First Global Forum on Medical Devices
- Book launched in September 2010
- Background papers published on web



Guidelines and Background Material

- Landscape analysis on medical devices innovation
- Priority medical devices background papers
- Consultation documents on :
 - **Medical device regulations**
 - Medical device donations
 - Resources for procurement
 - Health technology assessment
 - Medical devices per health facility
 - Health post/ health center/ district hospital
 - Provincial Hospital/ specialized 3rd level care
 - Medical devices per 100 clinical procedures





Baseline Country Survey on Medical Devices

2010 WHO Survey

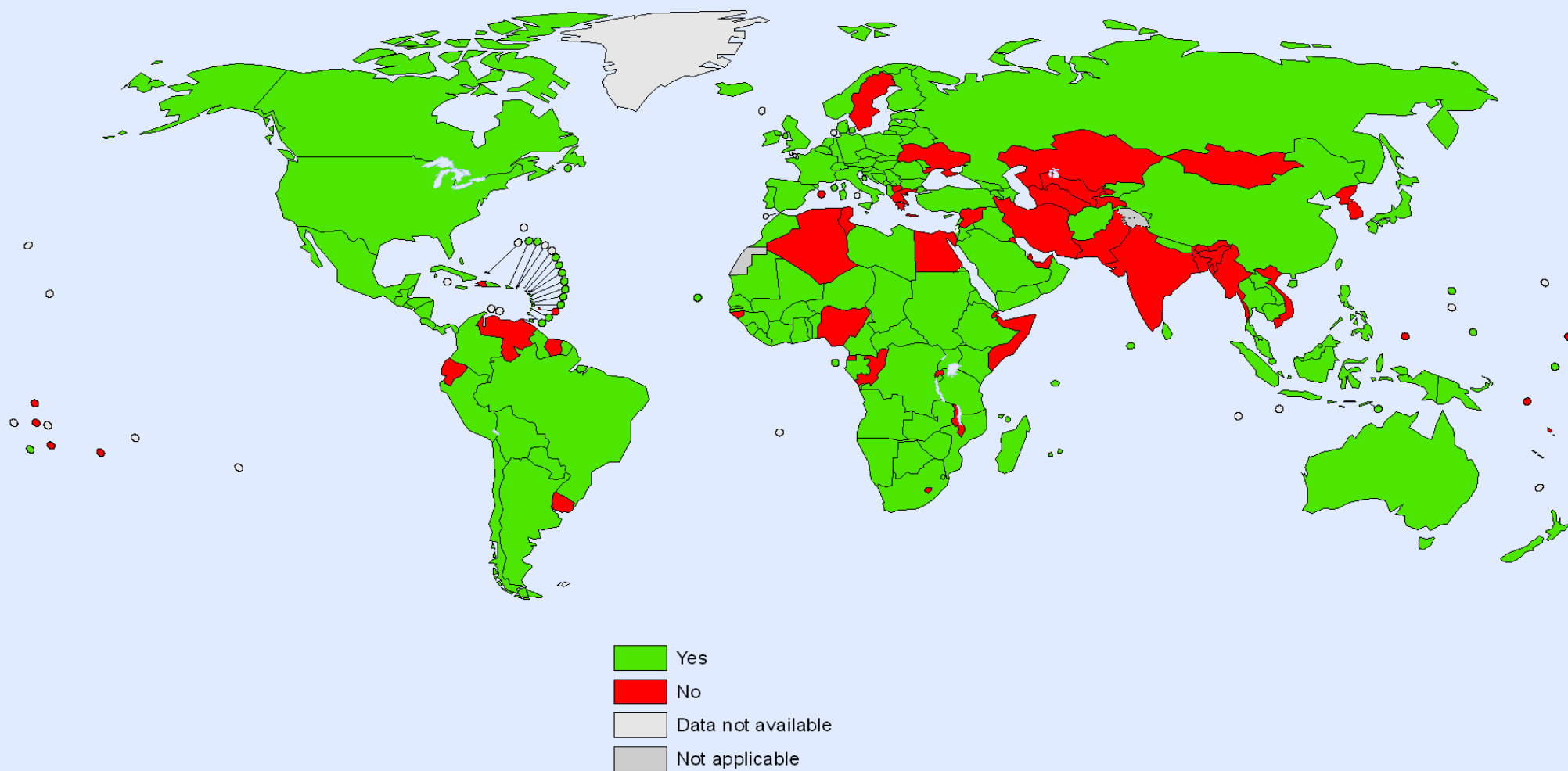
145 Countries
Members of
WHO

Ministry of Health
appointed a focal person
for data collection

- Mammography equipment
- CT scan units
- MRI scanners
- Nuclear medicine equipment
- Linear accelerators
- Telecobalt units
- PET equipments

- * Number in public sector
- * Number in private sector
- * Total number of equipment
- * Density per population

BCMD 2010 survey submissions



The boundaries and names shown and the designations used on this map do not imply the expression of any opinion whatsoever on the part of the World Health Organization concerning the legal status of any country, territory, city or area or of its authorities, or concerning the delimitation of its frontiers or boundaries. Dotted lines on maps represent approximate border lines for which there may not yet be full agreement.

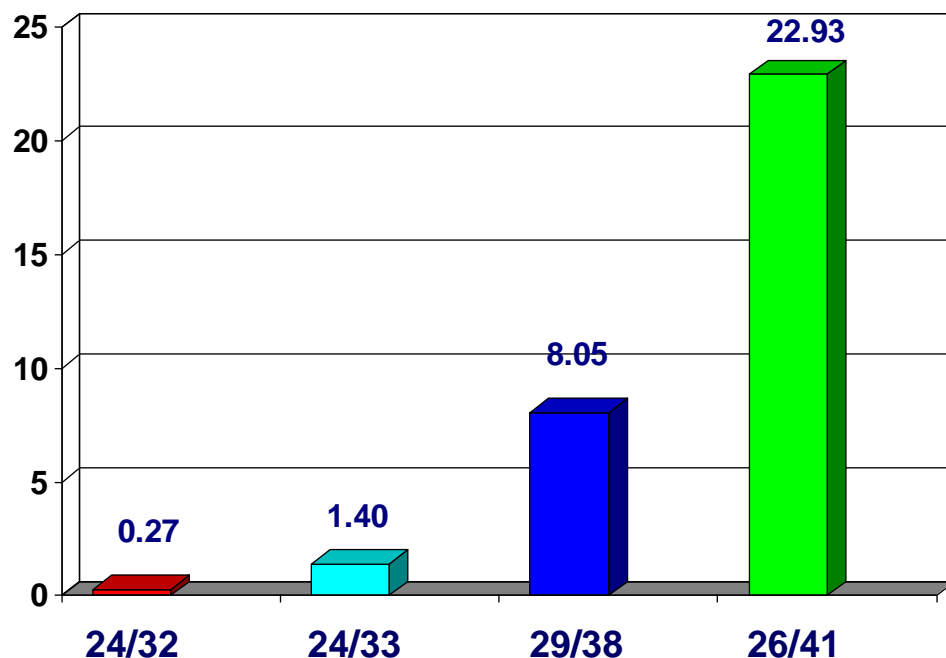
Data Source: World Health Organization
Map Production: Public Health Information and Geographic Information Systems (GIS)
World Health Organization



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Mammography Equipment

Density per 1 000 000 population

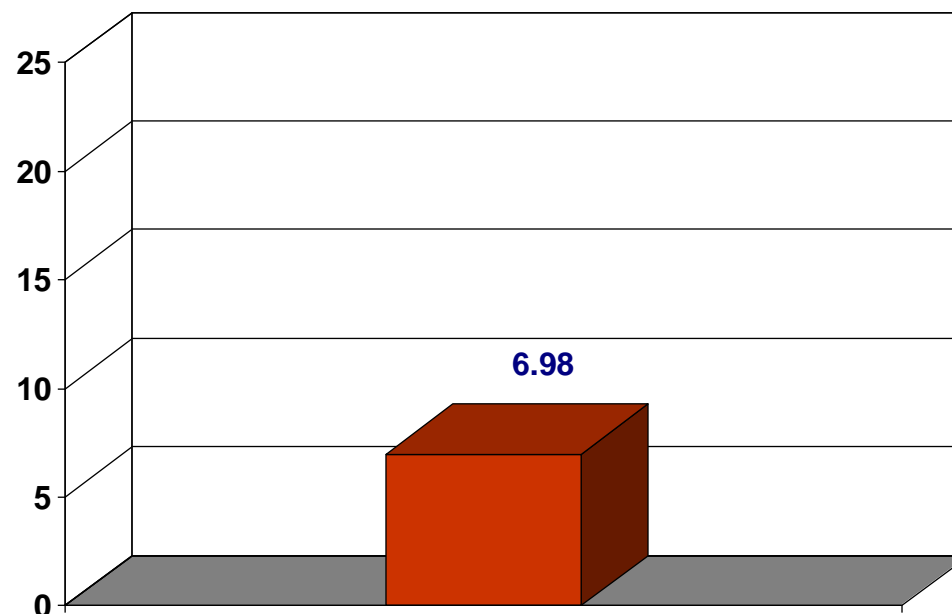


Number of countries that responded/total number of countries

Low Lower middle Upper middle High

Income Country Group

Density per 1 000 000 population



Number of countries 103

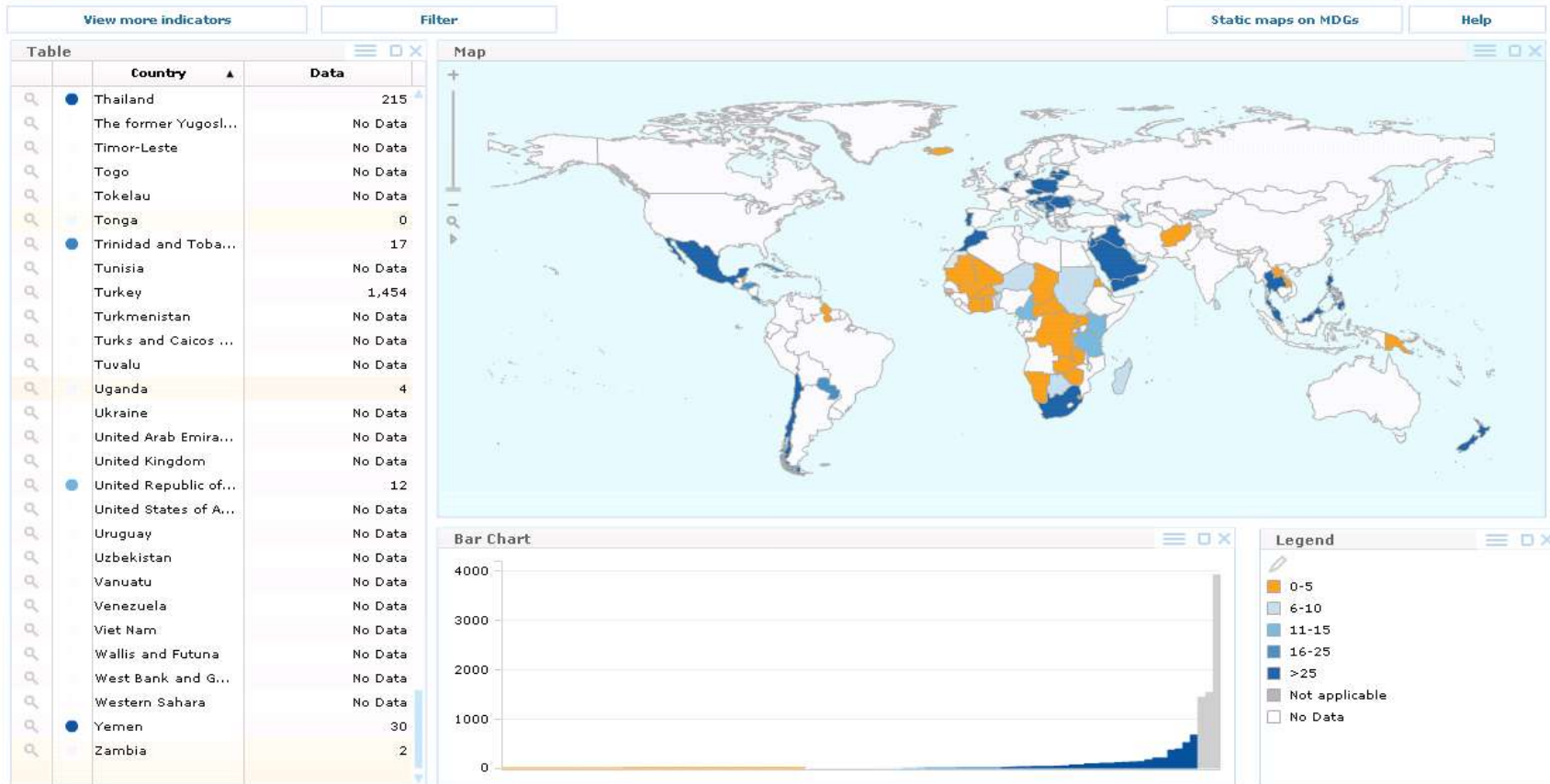
Global



Mammography Equipment: Geographical Distribution



BCMD 2010 survey: Number of medical devices/equipment
Medical Equipment – Total density* per 1 000 000 population: Mammograph (Total)a



Use your mouse to select data. Use Ctrl-key to make multiple selections. Click on the right mouse button to clear selections.

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Background: Health Gaps

Year	Life expectancy at birth		Maternal mortality rate / 100000 live births	Under 5 mortality rate / 1000 live births		Per capita total expenditure on health ^a
	1990	2007	2005	1990	2007	2006
Low income	53	57	650	162	126	57
Lower middle income	63	68	180	81	50	181
Upper middle income	68	70	91	44	22	707
High income	76	80	9	12	7	3848
Global	64	68	400	91	67	790

a Purchasing Power Parity, international dollars

Source: World Health Statistics 2009. Geneva, World Health Organization, 2009



Decentralization of Care Delivery

Implications for medical devices	Implications for public health
<p>Greater reliance on portable devices.</p> <p>Increased reliance on developments in nonmedical technology (e.g. communication networks for telemedicine, long-life batteries, and alternate power sources).</p> <p>Remote-use technology could accommodate needs of end-users (e.g. patients, family caregivers, and other non-clinicians) with safeguards to protect against inadequate user training.</p> <p>Remote devices may vary in complexity depending on which patient data are required.</p> <p>Portable devices are likely to require greater durability than stationary (i.e. hospital-based) devices.</p>	<p>More patient care can be delivered outside the traditional hospital setting.</p> <p>Quality of care can be improved. It may allow clinicians to monitor patients more closely and deliver more timely care, potentially improving outcomes.</p> <p>Increase ability of rural health-care professionals to perform highly specialized procedures through remote supervision.</p>

Medical Devices: Managing the Mismatch

An outcome of the Priority Medical Devices project

Trends in medical technology and expected impact on public health

Background Paper 7

WHO/HSS/EHT/DIM/10.7, August 2010



Decentralization of Care Delivery

1. Remote Clinical Monitoring of Patients Heading



2. Portable Technology

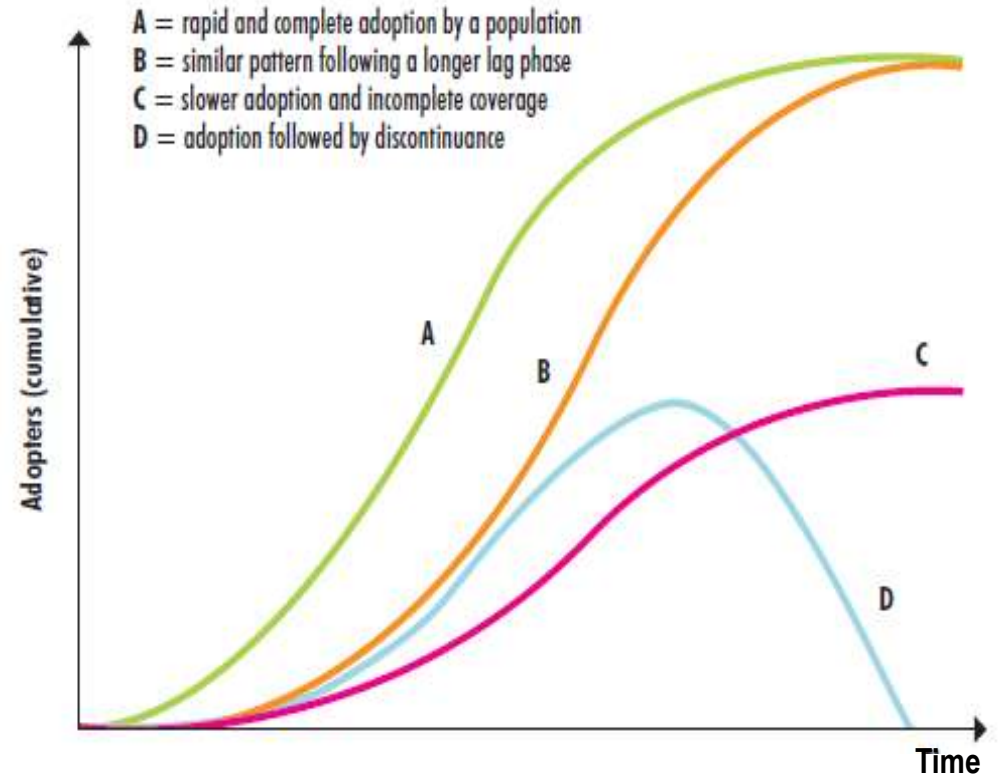
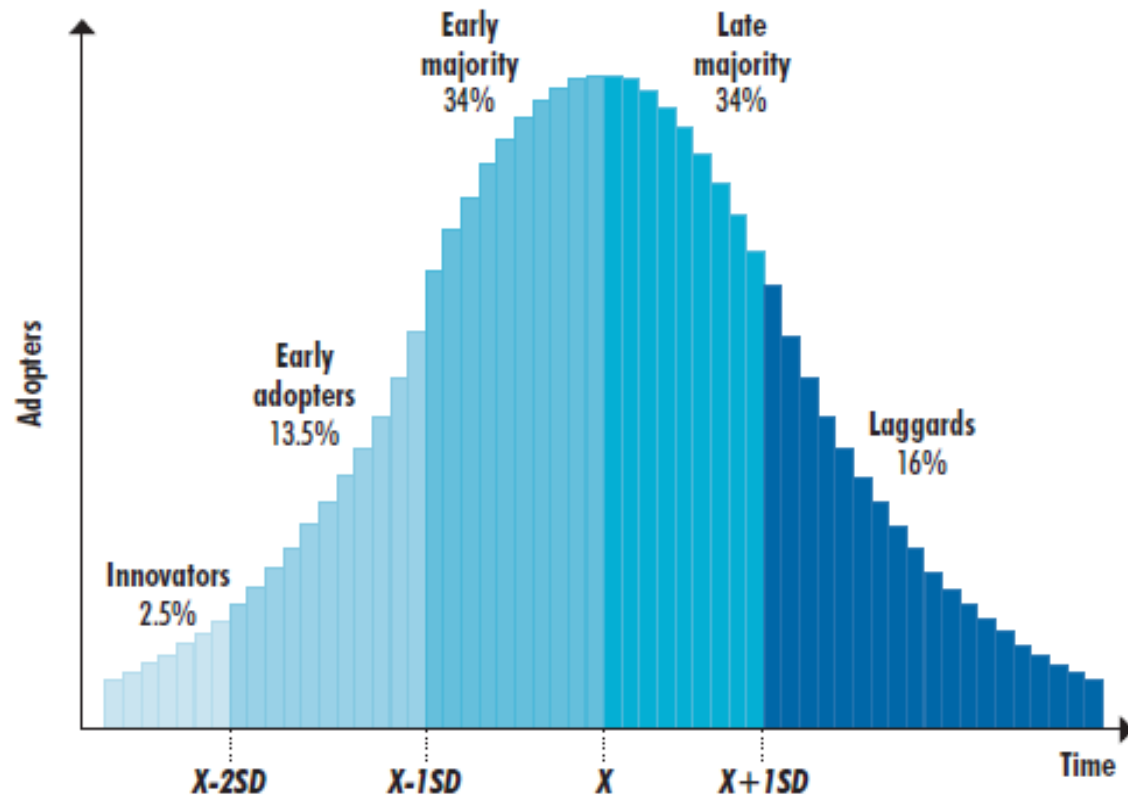


3. Telemedicine



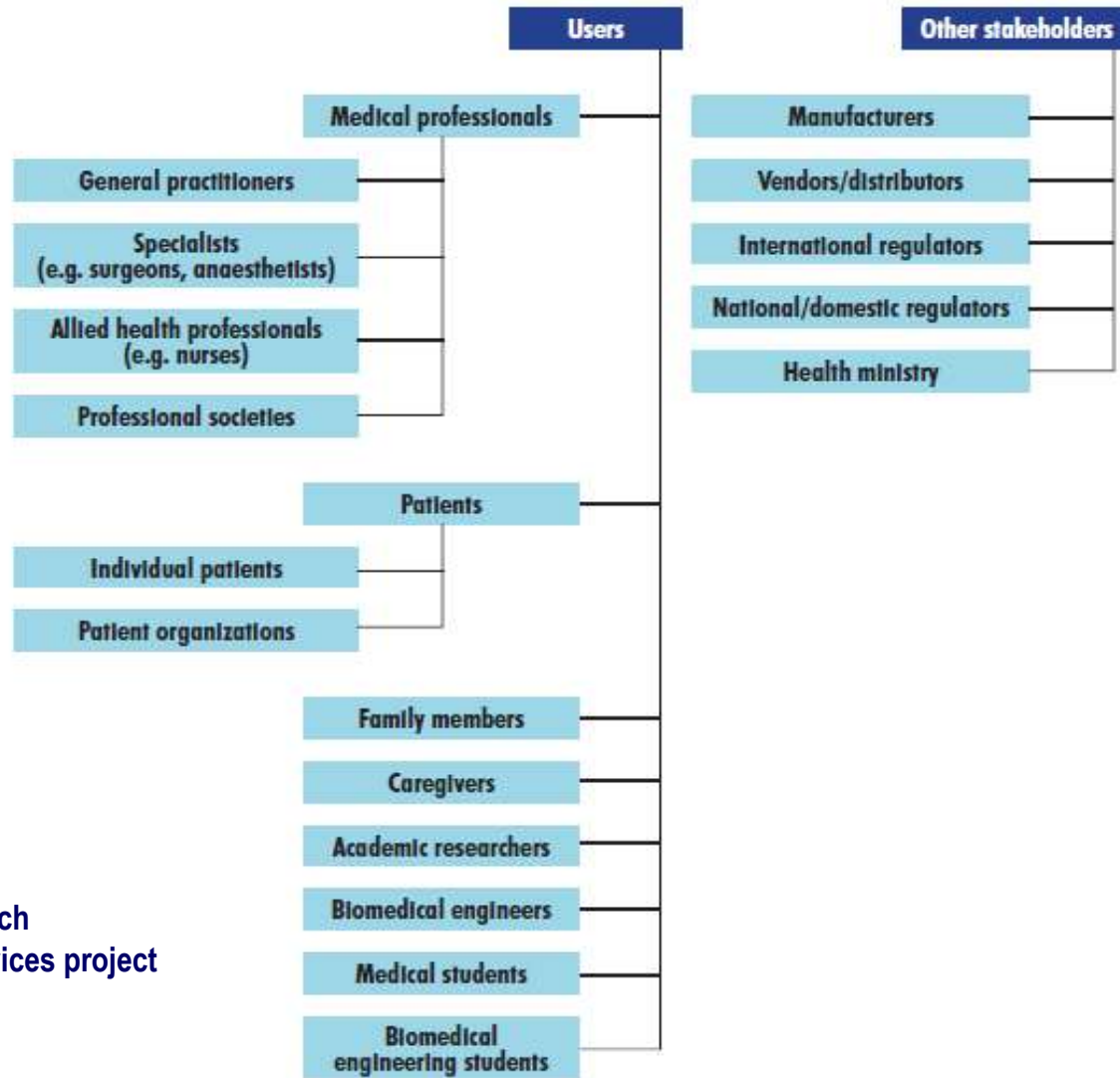
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WH0/HSS/EHT/DIM/10.7, August 2010

Diffusion of New Technology



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 WHO/HSS/EHT/DIM/10.7, August 2010

Stakeholders Involved in the Innovative Process

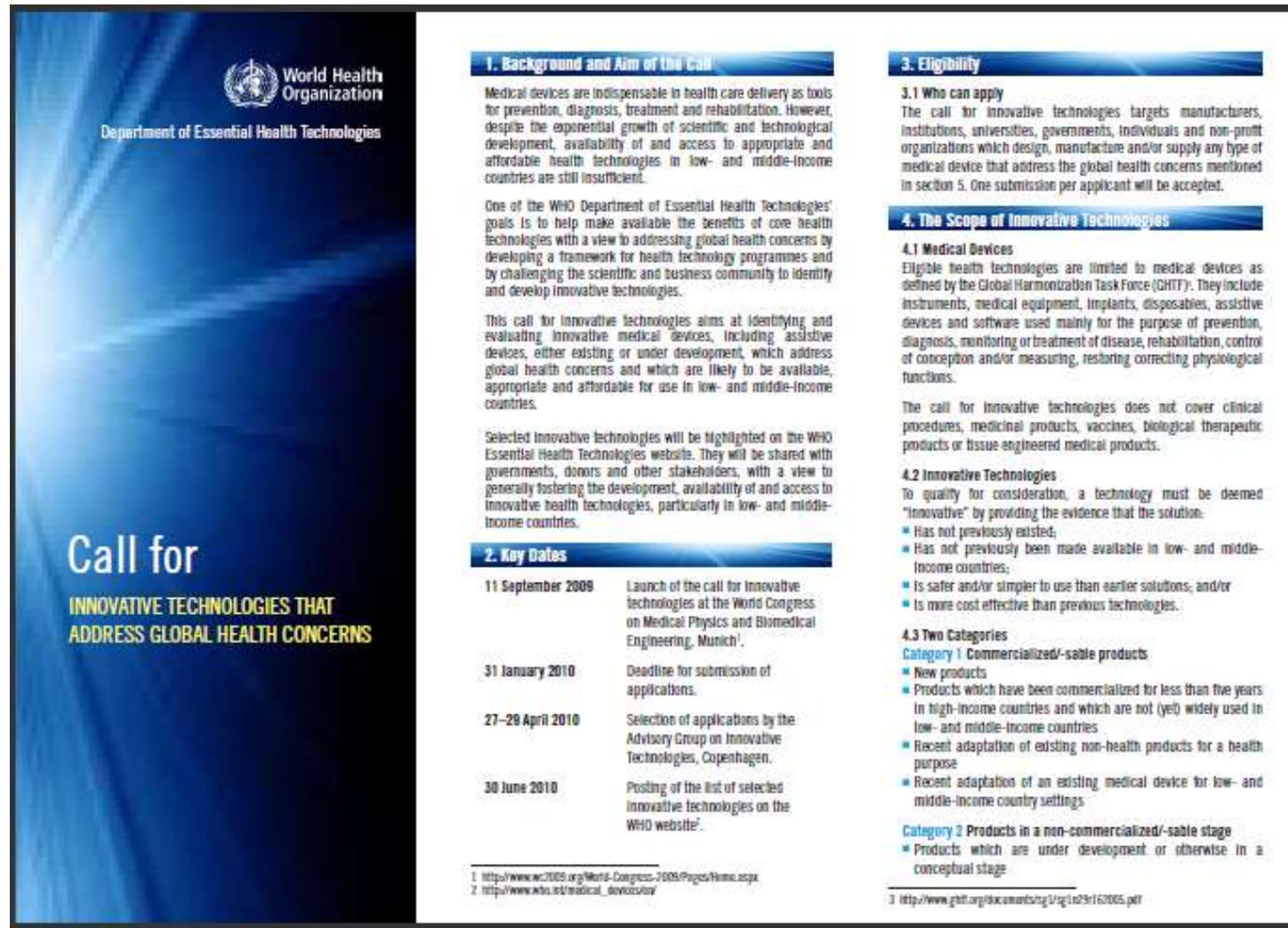


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An outcome of the Priority Medical Devices project
Background Paper 6
WH0/HSS/EHT/DIM/10.7, August 2010



WHO Call for Innovative Technologies

- Selection Criteria
- Health Problems
- Eligibility



The poster features the WHO logo and the text 'World Health Organization Department of Essential Health Technologies' at the top. The main title is 'Call for INNOVATIVE TECHNOLOGIES THAT ADDRESS GLOBAL HEALTH CONCERNS'. The content is organized into sections: 1. Background and Aim of the Call, 2. Key Dates, 3. Eligibility, and 4. The Scope of Innovative Technologies. It includes detailed text about the call's purpose, a timeline of key events from 2009 to 2010, and specific criteria for who can apply and what technologies are eligible.

World Health Organization
Department of Essential Health Technologies

Call for INNOVATIVE TECHNOLOGIES THAT ADDRESS GLOBAL HEALTH CONCERNS

1. Background and Aim of the Call

Medical devices are indispensable in health care delivery as tools for prevention, diagnosis, treatment and rehabilitation. However, despite the exponential growth of scientific and technological development, availability of and access to appropriate and affordable health technologies in low- and middle-income countries are still insufficient.

One of the WHO Department of Essential Health Technologies' goals is to help make available the benefits of core health technologies with a view to addressing global health concerns by developing a framework for health technology programmes and by challenging the scientific and business community to identify and develop innovative technologies.

This call for innovative technologies aims at identifying and evaluating innovative medical devices, including assistive devices, either existing or under development, which address global health concerns and which are likely to be available, appropriate and affordable for use in low- and middle-income countries.

Selected innovative technologies will be highlighted on the WHO Essential Health Technologies website. They will be shared with governments, donors and other stakeholders, with a view to generally fostering the development, availability of and access to innovative health technologies, particularly in low- and middle-income countries.

2. Key Dates

11 September 2009	Launch of the call for innovative technologies at the World Congress on Medical Physics and Biomedical Engineering, Munich ¹ .
31 January 2010	Deadline for submission of applications.
27–29 April 2010	Selection of applications by the Advisory Group on Innovative Technologies, Copenhagen.
30 June 2010	Posting of the list of selected innovative technologies on the WHO website ² .

3. Eligibility

3.1 Who can apply

The call for innovative technologies targets manufacturers, institutions, universities, governments, individuals and non-profit organizations which design, manufacture and/or supply any type of medical device that address the global health concerns mentioned in section 5. One submission per applicant will be accepted.

4. The Scope of Innovative Technologies

4.1 Medical Devices

Eligible health technologies are limited to medical devices as defined by the Global Harmonization Task Force (GHTF). They include instruments, medical equipment, implants, disposables, assistive devices and software used mainly for the purpose of prevention, diagnosis, monitoring or treatment of disease, rehabilitation, control of conception and/or measuring, restoring correcting physiological functions.

The call for innovative technologies does not cover clinical procedures, medicinal products, vaccines, biological therapeutic products or tissue engineered medical products.

4.2 Innovative Technologies

To qualify for consideration, a technology must be deemed "innovative" by providing the evidence that the solution:

- Has not previously existed;
- Has not previously been made available in low- and middle-income countries;
- Is safer and/or simpler to use than earlier solutions; and/or
- Is more cost effective than previous technologies.

4.3 Two Categories

Category 1 Commercialized/-stable products

- New products
- Products which have been commercialized for less than five years in high-income countries and which are not (yet) widely used in low- and middle-income countries
- Recent adaptation of existing non-health products for a health purpose
- Recent adaptation of an existing medical device for low- and middle-income country settings

Category 2 Products in a non-commercialized/-stable stage

- Products which are under development or otherwise in a conceptual stage

1 <http://www.wc2009.org/World-Congress-2009/Pages/Home.aspx>
2 http://www.who.int/medical_devices/en/
3 <http://www.ghtf.org/docman/whg/Usg1129162005.pdf>

e-Documentation Centre

- Searchable database of WHO documentation
- Available on www.who.int/medical_devices
- More than 300 documents currently available in 15 languages



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