

Medical Devices Management Workshop

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First
Global Forum
on **Medical Devices**

Bangkok, Thailand | September 9-11 2010

What is a Clinical Engineer?

"A Clinical Engineer is a professional who supports and advances patient care by applying engineering and managerial skills to healthcare technology."
ACCE Definition, 1992

Workshop Objectives

- Briefly introduce basic HTM concepts and framework
- Briefly introduce available tools and resources for managing HT/MD
- Learn from countries about their successes and challenges in managing HT/MD
- Provide specific recommendations to:
 - WHO
 - Medical Device Industry
 - NGOs and Donors

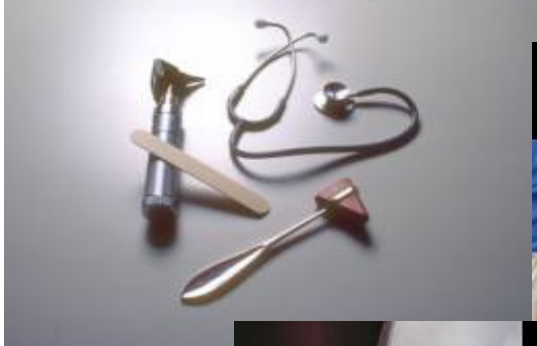
Agenda/Schedule

Time	Title	Speaker
14:00	Introduction	Ismael Cordero
14:05	Presentation of Basic HTM concepts and Available Tools and Resources	Ismael Cordero & Others
14:20	Presentation on Country Experiences	Country Representatives
15:00	Group Discussions	Groups of no more than 10 people each
15:40	Presentations on Group Discussions	Group Representative

Healthcare Technology

Providing healthcare effectively and efficiently involves putting together a great variety of resource inputs, commonly described as healthcare technology

Medical Device



Intervention



Drugs



Human Resource



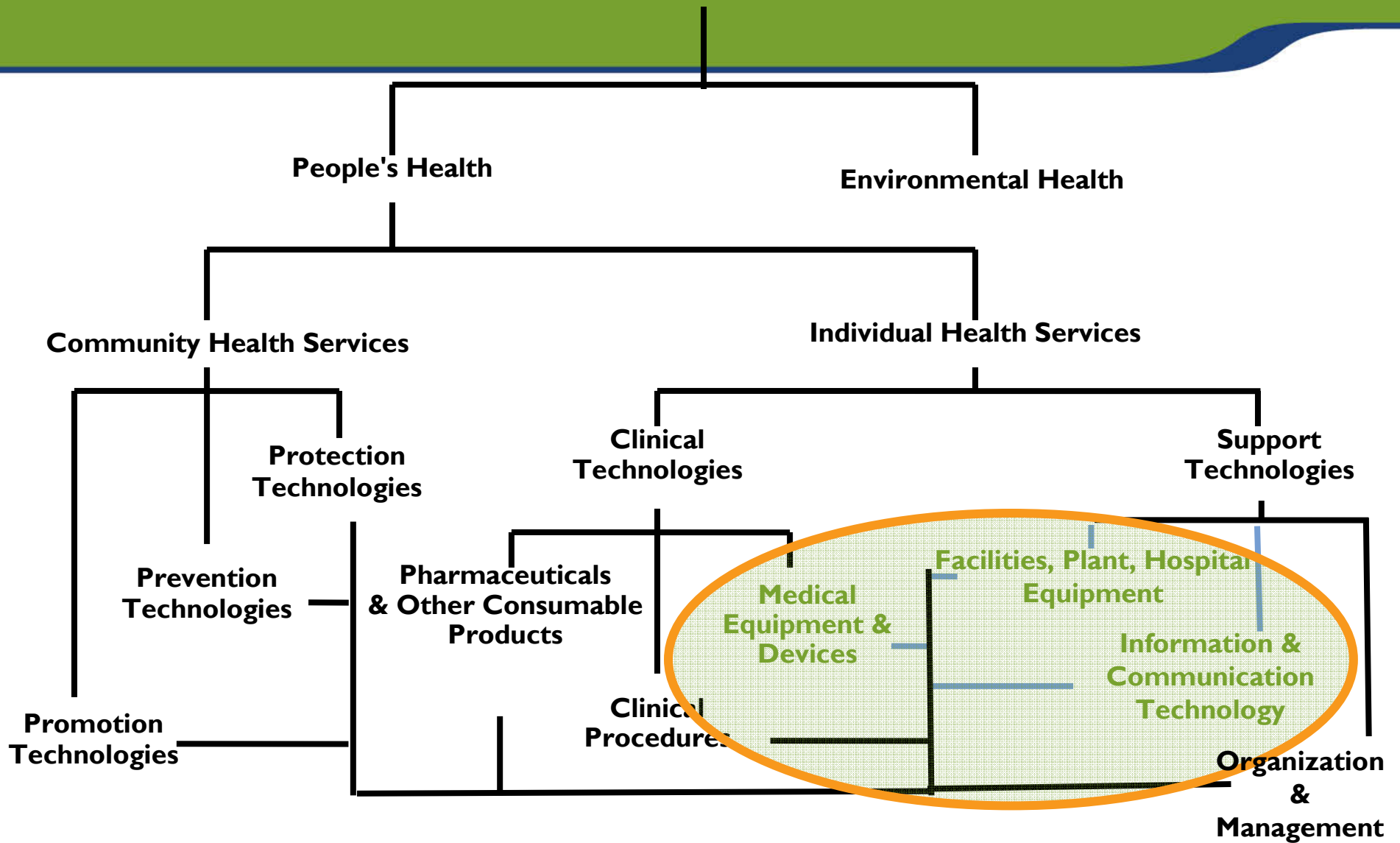
Facilities



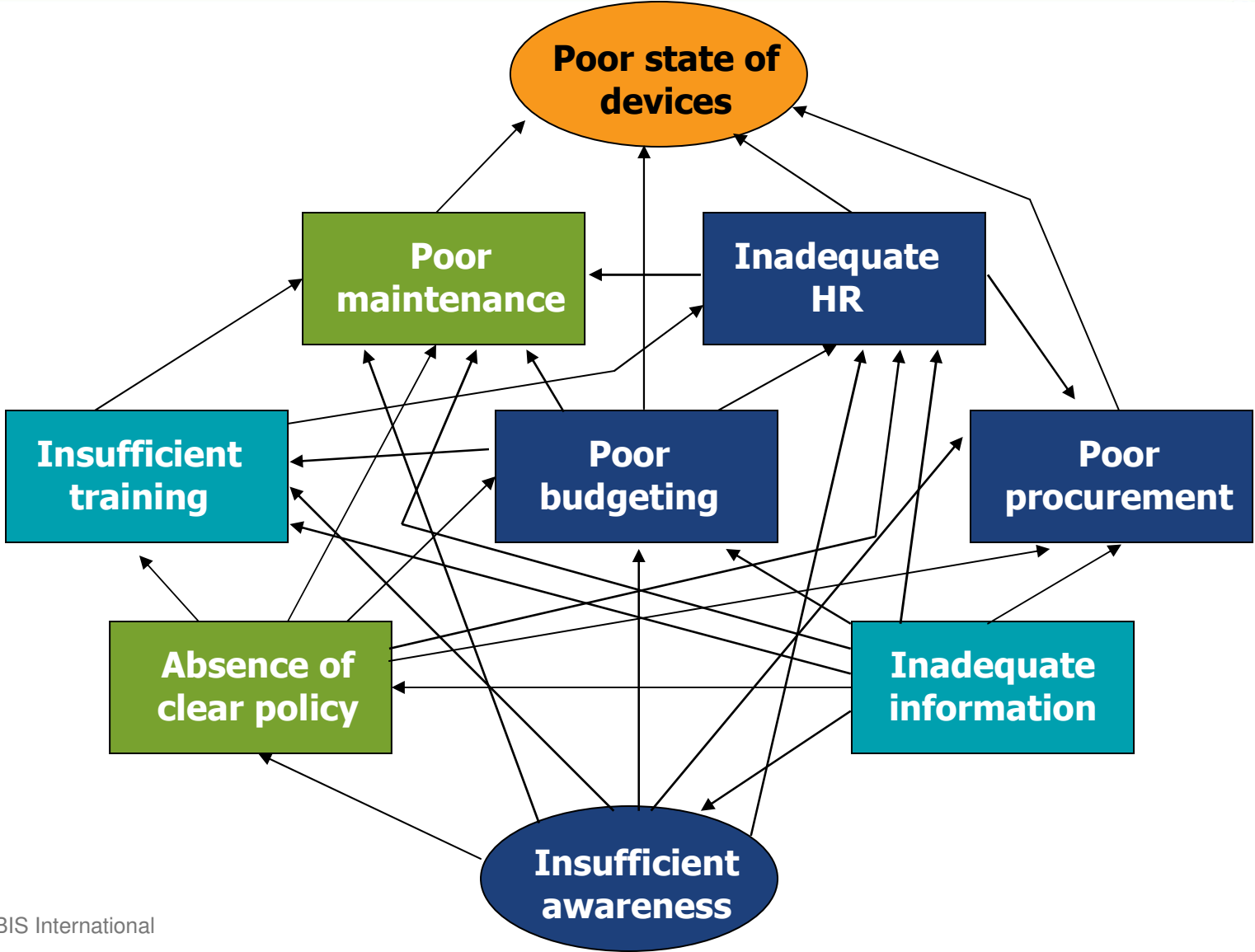
Healthcare Technology

The devices, equipment, systems, software, facilities, supplies, pharmaceuticals, biotechnologies, and medical and surgical procedures used in the intervention, diagnosis, rehabilitation and treatment of disease in humans

Health Technologies



Problem Tree

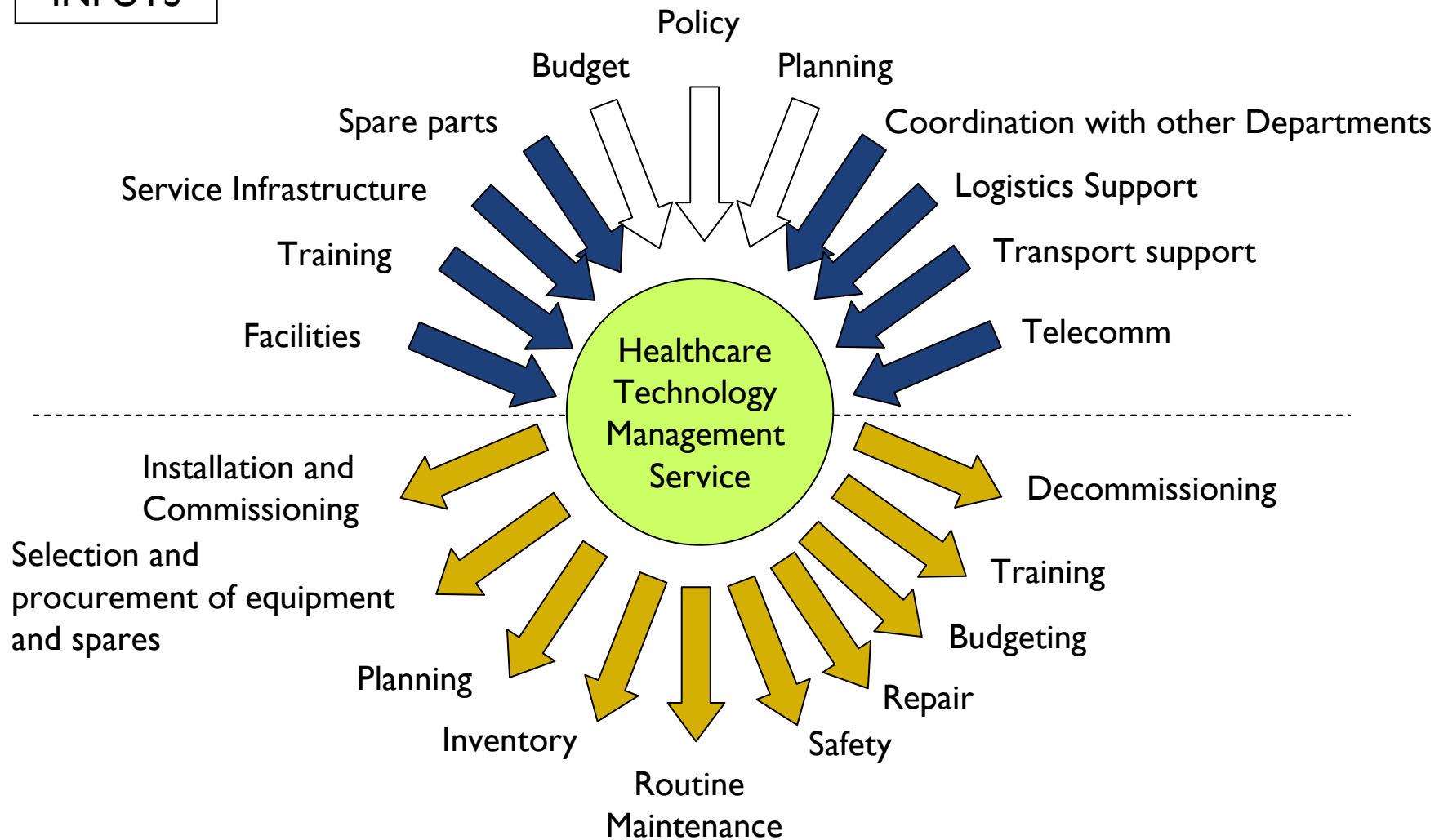


Healthcare Technology Management

An accountable and systematic approach to ensure that cost-effective, efficacious, appropriate and safe equipment is available to meet the demands of quality patient care

HTM Inputs and Outputs

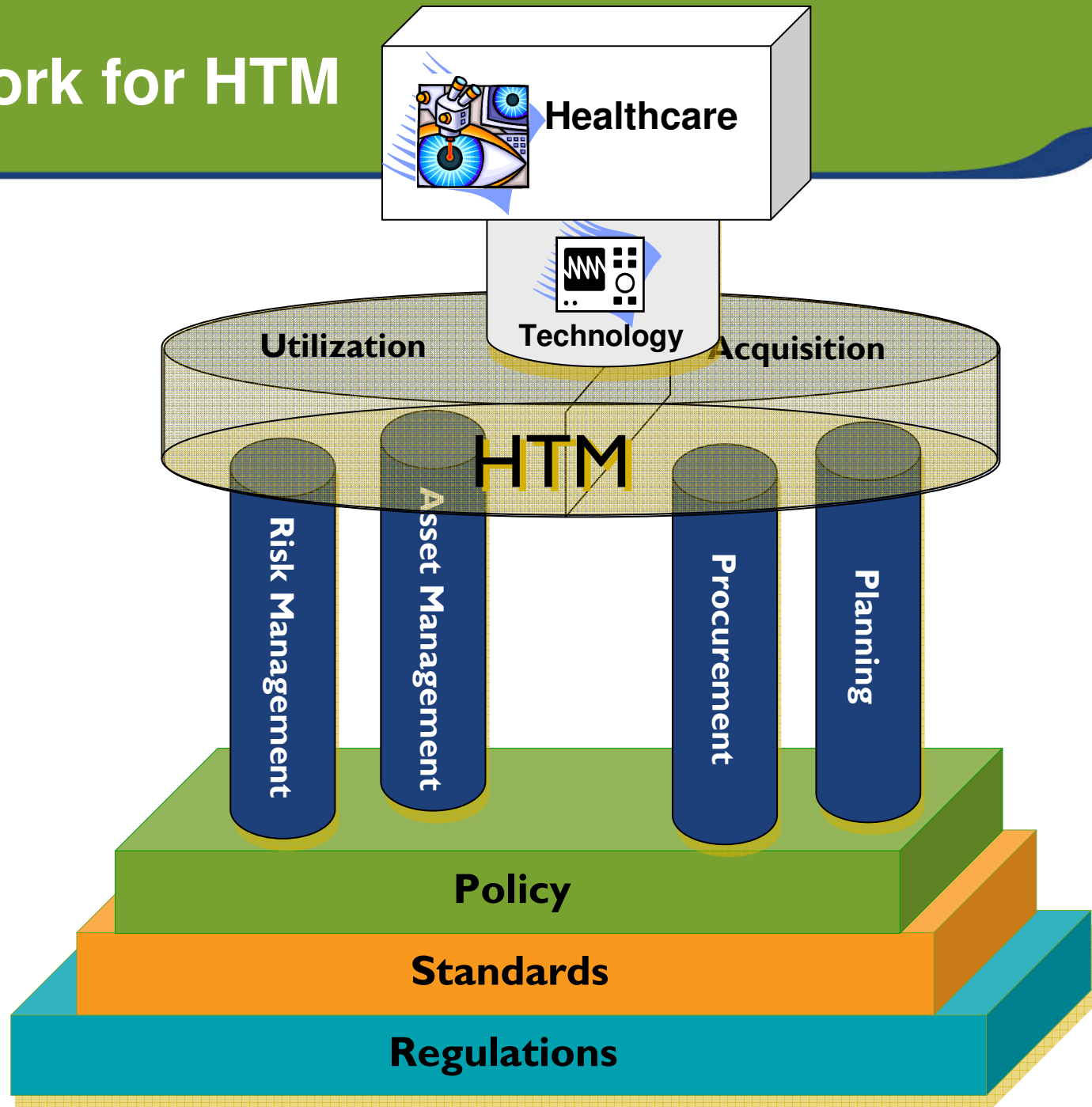
INPUTS



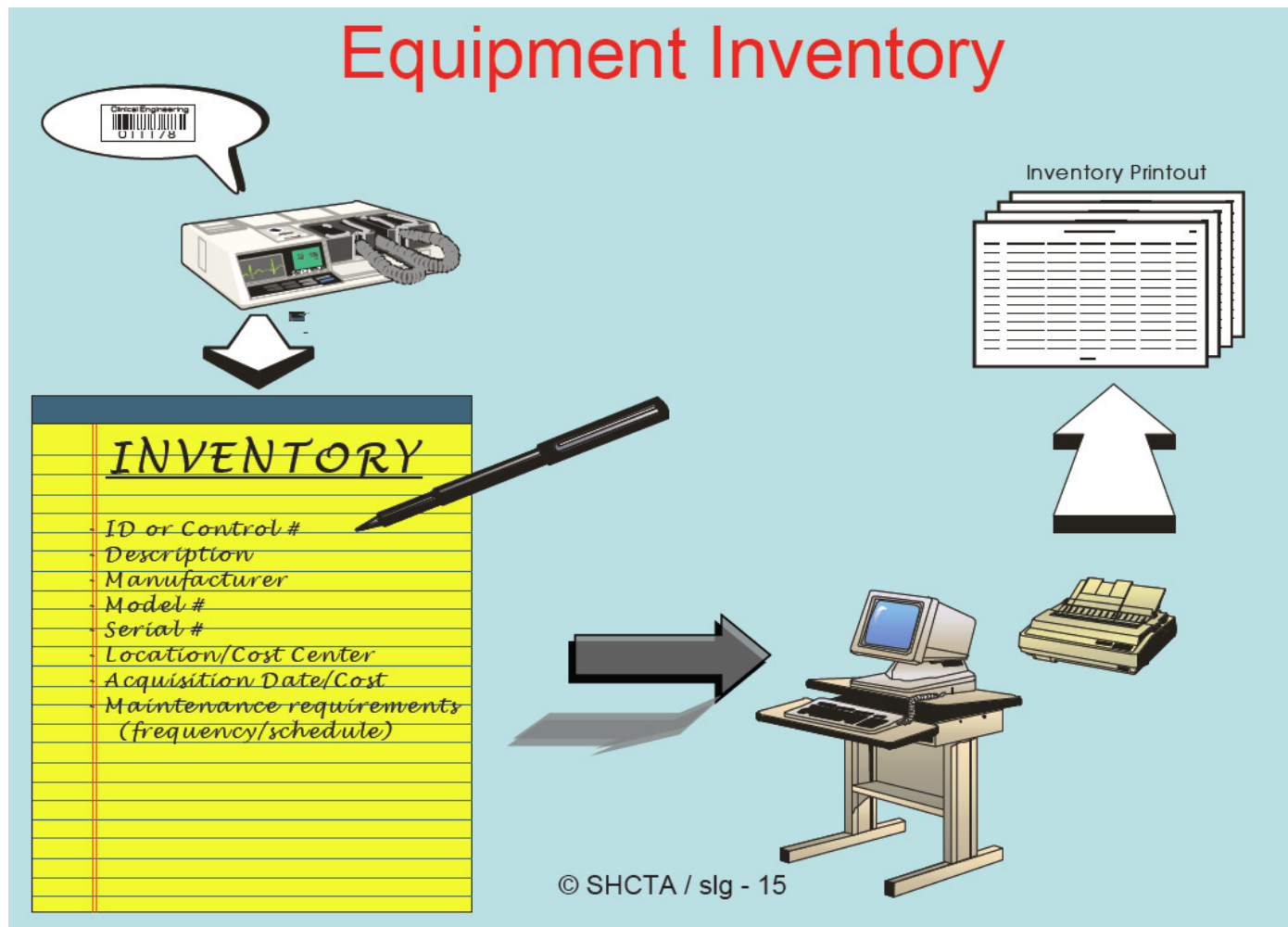
Framework for HTM

Phase	Process	Activities
A C Q U I S I T I O N	Planning	<ul style="list-style-type: none"> • Strategic Planning & Programming • Budgeting & Resource Allocation • Requirements Planning / Needs Assessment • Feasibility & Option Appraisal / Prioritization • Technology Scanning / HTA
	Procurement	<ul style="list-style-type: none"> • Requisition / Specification / Evaluation • Provisioning (tender/purchase/lease/hire) • Delivery / Installation • Commissioning / Acceptance • Training (users & maintainers, initial)
U T I L I S A T I O N	Asset Management	<ul style="list-style-type: none"> • Inventory / Asset Registers / Audit Checks • Utilization & Performance Monitoring • Maintenance & Spare Parts Management • Training (users & maintainers, ongoing) • Replacement Planning & Decommissioning
	Risk Management	<ul style="list-style-type: none"> • Risk Profiling & Assessment • Post-Market Surveillance / Hazard Notification • Inspection / Calibration / Safety Checks • Training (users & maintainers, ongoing) • Adverse Event Monitoring & Analysis

Framework for HTM

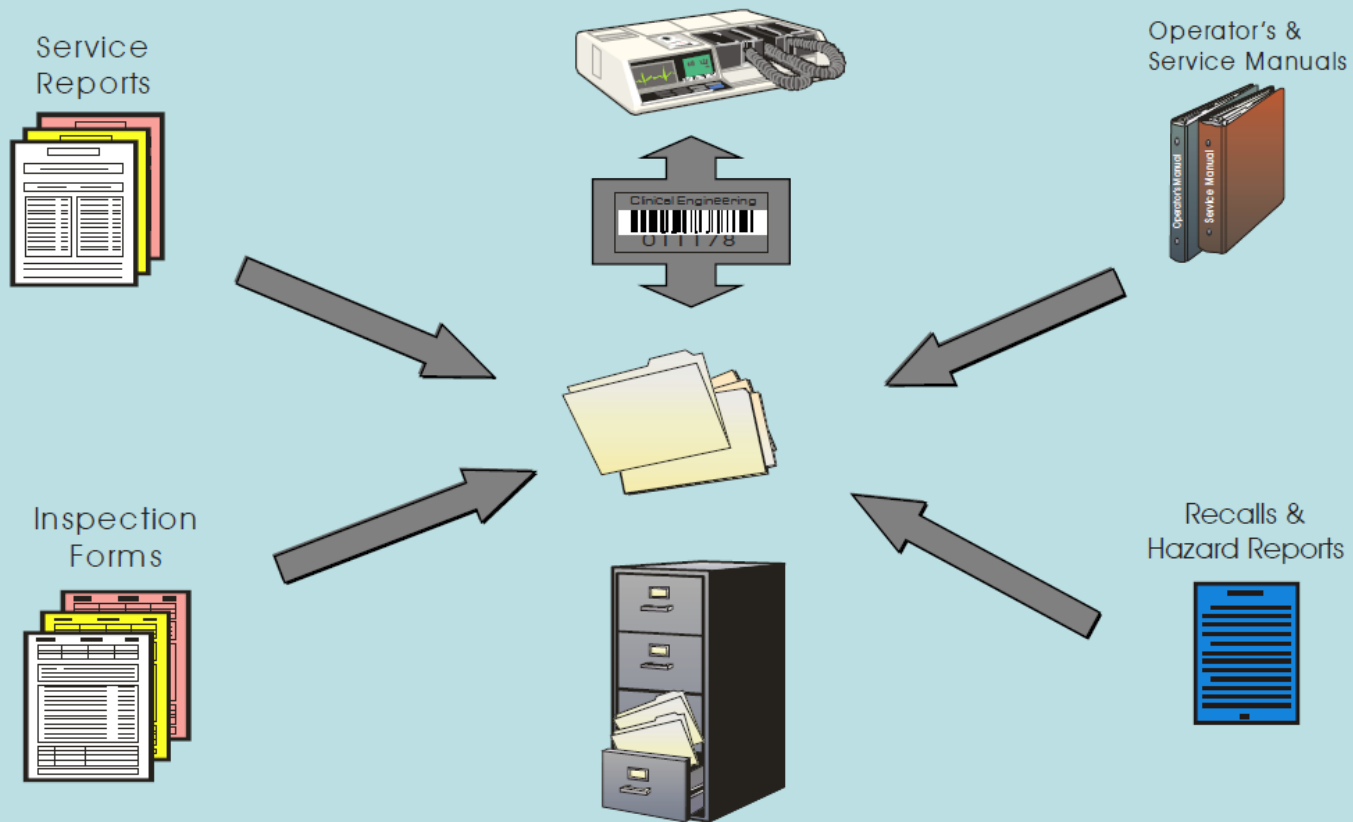


You cannot manage what you don't understand



You cannot manage what you don't understand

Centralized Documentation System




© SHCTA / slg - 16


Available Tools and Resources

- WHO tools
- “How to Manage” Series
- ACCE- ACEWs
- IFMBE CED
- INFRATECH
- Biomedtalk
- AAMI
- ECRI Institute


Forum CD- Technical Advisory Group on Health Technology Documents




Medical Device Lists




DRAFT - Guidelines for Health Care Equipment Donations (2010)




DRAFT - Introduction to Medical Device Procurement



DRAFT - The Advancement of Health Technology Assessment in D

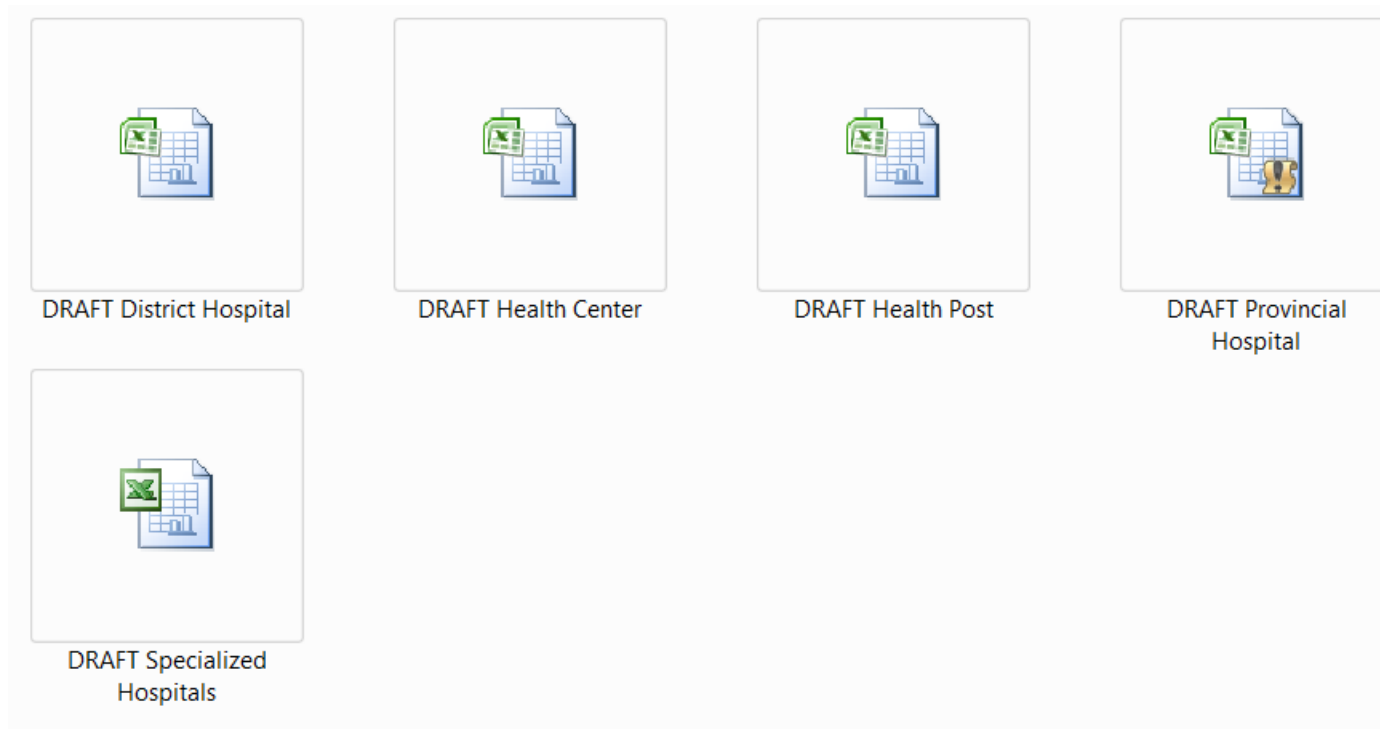


PUBLISHED - Guidelines for Health Care Equipment Donations (



PUBLISHED - Medical Device Regulations Global Overview and G

Forum CD- Medical Devices Lists



These spreadsheets will be consolidated into a searchable database

Medical Device Lists

Equipment List of District Hospital - Inpatient

	A	B	C	D	E	F	G	H	I	J	K	L	M		
1															
2	Equipment List of District Hospital - Inpatient														
3															
4	Equipment localization					Equipment identification									
5	Area	Unit	Subunit	Type		Equipment name	GMDN				UMNDS				
6				ME	MF		IN	AC	Generic Device Group		Specific Type		Code	Code	Te
7									Code 1	TermName 1	Code 2	TermName 2			
8	Inpatient	General Attention	Stretchers Station	ME		Wheelchair	14449	Wheelchair, <specify>	41630	Wheelchair, attendant driven, collapsible	14-449	14449	Wheelchair		
9	Inpatient	General Attention	Stretchers Station	MF		Stretcher	13814	Stretcher, <specify>	32204	Stretcher, general-purpose	13-814	13814	Stretchers		
10															
11	Inpatient	General Attention	Wards	ME		Clinical electronic thermometer	14028	Thermometer, <specify>	14032	Thermometer, electronic	14-032	14032	Thermomet Electronic		
12	Inpatient	General Attention	Wards	ME		Patient-Nurse Communication System		NA		NA	15-614	15614	Hospital Communic Systems, N		
13	Inpatient	General Attention	Wards	MF		Bed mattress	12475	Mattress, bed, <specify>	35183	Mattress, bed, general-purpose	12-475	12475	Mattresses,		
14	Inpatient	General Attention	Wards	MF		Bedrail	15852	Rail, <specify>	34868	Rail, side-support, bed	10-341	10431	Bedrails		
15	Inpatient	General Attention	Wards	MF		Bedside cabinet	10526	Cabinet, <specify>	10531	Cabinet, bedside	10-531	10531	Cabinets, St Bedside		
16	Inpatient	General Attention	Wards	MF		Electric bed	41436	Bed, general-purpose, <specify>	34870	Bed, general-purpose, electrically-powered	10-347	10347	Beds, Electr		
17	Inpatient	General Attention	Wards	MF		Footstool	11771	Footstool, <specify>	11772	Footstool, conductive	11-621	11621	Footstools, Step		
18	Inpatient	General Attention	Wards	MF		Intravenous stand	40509	Fluid delivery mount, <specify>	36069	Fluid delivery mount, general-purpose	12-177	12177	Intravenous		
19	Inpatient	General Attention	Wards	MF		Kick bucket	41111	Kick bucket	14427	Bucket, swab	14-427	14427	Kick Bucket		
20	Inpatient	General Attention	Wards	MF		Overbed light	12347	Light, <specify>	15660	Light, overbed	15-660	15660	Lights, Over		
21	Inpatient	General Attention	Wards	MF		Overbed table	13949	Table, <specify>	35395	Table, over-bed	13-963	13963	Tables, Ove		
22	Inpatient	General Attention	Wards	MF		Patient record	15567	Chart, <specify>	15962	Chart, patient record	15-962	15962	Charts, Bed		
23	Inpatient	General Attention	Wards	MF		Screen for examination table	13513	Screen, <specify>	13514	Screen, bedside	13-514	13514	Screens, be		

WHO Health Technologies e-Documentation Centre

The screenshot shows a Windows Internet Explorer browser window displaying the WHO Medical Devices website. The address bar shows the URL http://www.who.int/medical_devices/en/index.html. The browser's toolbar includes various icons for navigation and utility. The website header features the WHO logo and the text "World Health Organization" in multiple languages: العربية, 中文, English, Français, Русский, and Español. A search bar is located to the right of the logo. Below the header, a navigation menu on the left lists various sections: Home, About WHO, Countries, Health topics, Publications, Data and statistics, Programmes and projects, Medical devices (highlighted), Policies and resolutions, Quality and safety regulations, Access, Management and use, Innovative technologies, and Global collaborations. The main content area is titled "Medical devices" and includes a sub-header "Medical devices" with a search bar. Below this, there are three columns of content: a large image showing a medical professional in a surgical setting, a text block describing the importance of medical devices, and a section titled "EVENTS" featuring "The First Global Forum on Medical Devices" held in Bangkok, Thailand, in September 2010. To the right, there is a "HIGHLIGHTS" section with a grid of images and text, including "Improving access to safe, effective, and innovative quality diagnostics" and "First Global Forum on Medical Devices, 9-11 September 2010". Below this, there is a "KEY INITIATIVES" section with "Outcome of the call for innovative technologies" and "Baseline country survey on". The browser's status bar at the bottom shows "Internet | Protected Mode: Off" and a zoom level of 125%.

WHO | Medical devices - Windows Internet Explorer
http://www.who.int/medical_devices/en/index.html
who essential technologies

File Edit View Favorites Tools Help

WHO | Medical devices

World Health Organization

العربية | 中文 | English | Français | Русский | Español

Search

All WHO This site only

Home **Medical devices**

About WHO [WHO > Programmes and projects > Medical devices](#)

Countries

Health topics

Publications

Data and statistics

Programmes and projects

Medical devices

Policies and resolutions

Quality and safety regulations

Access

Management and use

Innovative technologies

Global collaborations

Medical devices

Medical devices are essential for safe and effective prevention, diagnosis, treatment and rehabilitation of illness and disease. The achievement of health-related development goals, including the Millennium Development Goals depends upon proper manufacturing, regulation, planning, assessment, acquisition, management and use of medical devices which are of good quality, safe and compatible with the settings in which they are used.

As outlined in the World Health Assembly resolution WHA60.29, the WHO Department of Essential Health Technologies (EHT), Diagnostics Imaging and Medical Devices Team (DIM) aims to ensure improved access, quality and use of safe and appropriate medical devices in line with Primary Health Care Reform.

EVENTS

The First Global Forum on Medical Devices
The World Health Organization is pleased to announce the First Global Forum on Medical Devices to be held 9-11 September, 2010 in Bangkok, Thailand. A webcast is available to view the sessions.
[Overview and registration](#)

KEY INITIATIVES

Outcome of the call for innovative technologies
WHO is pleased to announce the outcome of the call for innovative technologies that address global health concerns.
[More](#)

Baseline country survey on

HIGHLIGHTS

Improving access to safe, effective, and innovative quality diagnostics

First Global Forum on Medical Devices, 9-11 September 2010
[Overview](#)
[Live webcast](#)

WHO Health Technologies e-Documentation Centre

Call for INNOVATIVE TECHNOLOGIES THAT ADDRESS GLOBAL HEALTH CONCERNS

http://www.who.int/en/ Internet | Protected Mode: Off 125%


“How to Manage” Series for Healthcare Technology

<http://www.healthpartners-int.co.uk>

'HOW TO MANAGE' SERIES FOR HEALTHCARE TECHNOLOGY

Guide 1
How to Organize a System of Healthcare Technology Management

Management Procedures for Health Facilities and Health Authorities




Logos: ZI, FAKT, ECHO, Disability ICF, TALC

'HOW TO MANAGE' SERIES FOR HEALTHCARE TECHNOLOGY

Guide 2
How to Plan and Budget for Your Healthcare Technology

Management Procedures for Health Facilities and District Authorities




Logos: ZI, FAKT, ECHO, Disability ICF, TALC

'HOW TO MANAGE' SERIES FOR HEALTHCARE TECHNOLOGY

Guide 3
How to Procure and Commission Your Healthcare Technology

Management Procedures for Health Facilities and Health Authorities




Logos: ZI, FAKT, ECHO, Disability ICF, TALC, HealthPartners

'HOW TO MANAGE' SERIES FOR HEALTHCARE TECHNOLOGY

Guide 4
How to Operate Your Healthcare Technology Effectively and Safely

Management Procedures for Health Facilities and District Authorities




Logos: ZI, FAKT, ECHO, Disability ICF, TALC

'HOW TO MANAGE' SERIES FOR HEALTHCARE TECHNOLOGY

Guide 5
How to Organize the Maintenance of Your Healthcare Technology

Management Procedures for Health Facilities and District Authorities




Logos: ZI, FAKT, ECHO, Disability ICF, TALC

'HOW TO MANAGE' SERIES FOR HEALTHCARE TECHNOLOGY

Guide 6
How to Manage the Finances of Your Healthcare Technology Management Teams

Management Procedures for Health Facilities and District Authorities



Logos: ZI, FAKT, ECHO, Disability ICF, TALC

American College of Clinical Engineering (ACCE) <http://accenet.org>

The screenshot shows the ACCE website in a Windows Internet Explorer browser window. The address bar displays <http://accenet.org/>. The browser's menu bar includes File, Edit, View, Favorites, Tools, and Help. The toolbar shows various icons for navigation and utility. The website header features the ACCE logo, the text "American College of Clinical Engineering", and a "Membership Renewals!" banner. Below the header is a navigation menu with links for ABOUT ACCE, MEMBERSHIP, PUBLICATIONS & REFERENCES, ACCE MALL, NEWS & EVENTS, GOVERNANCE, and MEMBERS AREA. The main content area begins with a welcome message: "Welcome to the World Wide Web home of the American College of Clinical Engineering (ACCE). Founded in 1991, ACCE is committed to enhancing the profession of clinical engineering. With members in the United States and abroad, the ACCE is the only internationally recognized professional society for clinical engineers." Below this is a featured announcement for the "AAMI and FDA SUMMIT ON INFUSION DEVICES" held from October 5-6, 2010, in Silver Spring, MD. The announcement includes the AAMI and FDA logos and a link to the AAMI Website and Press Release. To the right of the main content is a sidebar with a "What's New" section listing recent news items: "ACEW covered in El Salvador Press", "The first CE-IT Community webinar held in June 2010", "Student Papers from the 2010 ACCE Awards competition", and "JOB OPPORTUNITIES in the Clinical Engineering field". At the bottom of the sidebar is an "ADVERTISE WITH ACCE!" section. The browser's status bar at the bottom indicates "Internet | Protected Mode: Off" and a zoom level of "125%".

ACCE- Advanced Clinical Engineering Workshops (ACEWs)

- Three Levels of ACEW
- Main Topics:
 - Healthcare Technology Management
 - Health Technology Assessment
 - Human Resources Development
 - Patient Safety, Risk Management & Use Error
 - Maintenance Service Management
 - Technology Management Shared Services
 - Utility Systems in Healthcare Facilities
- New Issues:
 - Electro Magnetic Interference (EMI/EMC)
 - Medical Telemetric Systems/ Wireless Communications
 - Patient Care Device Interoperability
 - Norms and Standards: ISO, IEC, ITU, IEEE
 - PACS, RIS, HL7, DICOM
 - Medical Devices Regulation
 - Medical Device Incident Investigation
 - Donated/Refurbished Medical Equipment
 - Reuse of Single-Use Medical Devices
 - Integrated Health Technology Package - IHTP

ACEW- Statistics

- 21 Years
- 46 ACEW
- 29 Countries Hosted ACEW
- 16 from Latin America and the Caribbean (LA&C)
- 63 Countries have Participated in ACEW
- 32 from LA&C
- 4,075 Attendees
- 3,350 from LA&C
- 72 Faculty Members of ACCE- 20 Former ACEW Attendees
- 1,850 Hours of Lecture
- 2 Certification Boards on CE (Brazil & Mexico)

ACEW- Contact

Frank R. Painter, MS, CCE

frpainter@earthlink.net

INFRATECH Discussion Group

<http://infratechonline.net>

The screenshot shows a Windows Internet Explorer browser window displaying the INFRATECH Web Archive website. The address bar shows the URL http://infratechonline.net/?page_id=3. The website has a dark header with the title "INFRATECH Web Archive" and the subtitle "Online archive for the INFRATECH discussion group". Below the header is a navigation menu with links for "About INFRATECH", "How to join INFRATECH", "Glossary of Terms", and "Equipment Donation Disasters". The main content area is divided into two columns. The left column is titled "About INFRATECH" and contains a paragraph describing the forum's purpose and a list of specific objectives. The right column contains "RSS Links" for "All posts" and "All comments", a search box, and a section for "Most used keywords" listing terms like "50% Out Of Service", "alternative energy", "anaesthesia", "appropriate technologies", "Brazil conferences", "corruption", "Equipment donations", "freezers", "grants", "Health outcomes", and "Hospital". The browser's status bar at the bottom indicates "Internet | Protected Mode: Off" and a zoom level of 125%.

About INFRATECH | INFRATECH Web Archive - Windows Internet Explorer

http://infratechonline.net/?page_id=3

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Apple Gall... iDisk Mobi... iGoo... CNN CNN msnbc NYT Huff... ECRI ORBL... ORBL... FedEx PFFCU ACCE

About INFRATECH | INFRATECH Web ...

INFRATECH Web Archive

Online archive for the INFRATECH discussion group

[About INFRATECH](#) [How to join INFRATECH](#) [Glossary of Terms](#) [Equipment Donation Disasters](#)

About INFRATECH

INFRATECH is an international discussion forum for global exchange of information regarding infrastructure and technology for health services with emphasis on developing countries.

Specific objectives of Infratech are:

- Exchange of information between practitioners in different countries
- Provide information support for INFRATECH members.
- Advocacy and promotion of technology management.
- Information provided on upcoming events, publications and other resources.
- Development of a knowledge base
- Development of a searchable archive of previous postings indexed by subject

RSS Links

- All posts
- All comments

Search for:

Most used keywords

50% Out Of Service
alternative energy anaesthesia
appropriate technologies
Brazil conferences corruption
Equipment donations
freezers grants Health outcomes Hospital

Internet | Protected Mode: Off 125%

Thank You



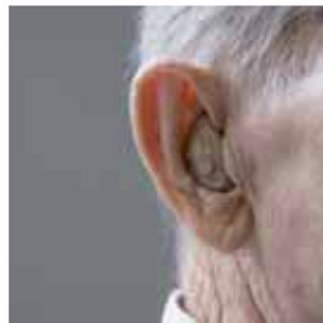
Innovation
Affordability
Safety
Equity
Effective



Improving access
to safe, effective
and innovative
quality medical
devices



Research
Assessment
Training
Maintenance



Group Discussions

Group	Topic
1	Procurement
2	Donations
3	Inventory and Maintenance Management
4	HR development for HT managers and equipment maintainers
5	Patient and User Safety
6	Monitoring and Evaluation (indicators)
7	National HT Policy/ National HT Institutions

3 Recommendations for: - WHO
- Medical Device Industry
- NGOs and Donors