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ALMA MATER STUDIORUM
UNIVERSITÀ DI BOLOGNA
CAMPUS DI CESENA

# Health Technology Management

Stefano Severi

University of Bologna

AFYA MOJA
PROJECT

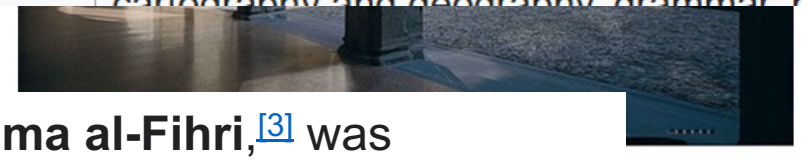
**Stefano Severi**
**Associate Professor of Biomedical Engineering**
**University of Bologna – Cesena Campus**

- MSc (1992) and PhD (1998), University of Bologna
- Teaching:
  - Bioengineering
  - Computational Cardiology
  - Context-sensitive Design of Medical Devices
- Research areas:
  - Computational Cardiology
  - Hemodialysis
  - Bioengineering for Low Resource Settings

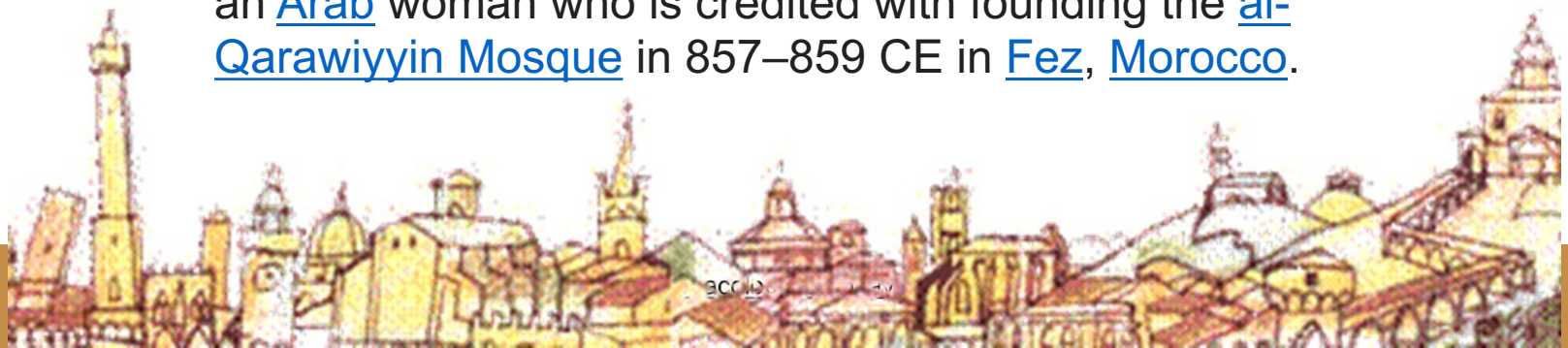
# The University of Bologna

## Still existing [ edit ]

| Year | University | Location | | Notes |
|---|---|---|---|---|
| | | Original | Current | |
| ca. 1040-1147[3][a] | University of al-Qarawiyyin | Almoravid dynasty | Morocco | The university's curriculum included but was not limited to Quranic exegesis (tafsir), Islamic jurisprudence, algebra, astronomy, botany, cartography and geography, grammar, history |



**Fatima al-Fihriya**[2] or **Fatima al-Fihri**,[3] was an Arab woman who is credited with founding the al-Qarawiyyin Mosque in 857–859 CE in Fez, Morocco.



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# Cesena Campus



Biomedical Engineering Courses and Laboratory

# HTM and One Health

- In practice?

St. Luke Hospital
Wolisso – Ethiopia
November 2024

# Disclaimer

- My vision of One Health is quite human-centered
- Humans as 'Caretakers' of the environment

- One Health recognizes that the health of humans, domestic and wild animals, plants, and the wider environment (including ecosystems) are closely linked and interdependent.

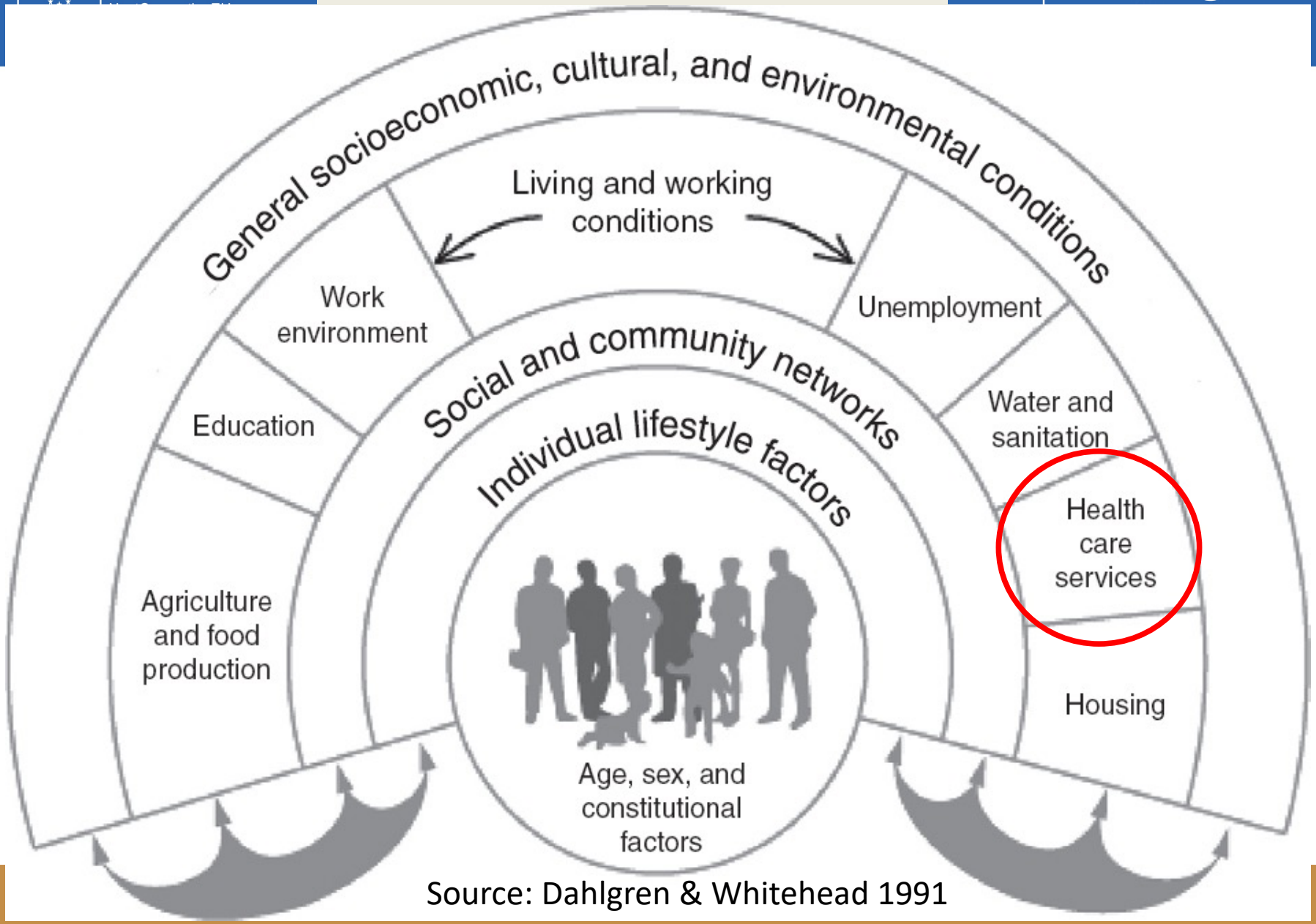
  *Source: https://www.who.int/health-topics/one-health*

# Kibera (1:15 h 'Uber distance')

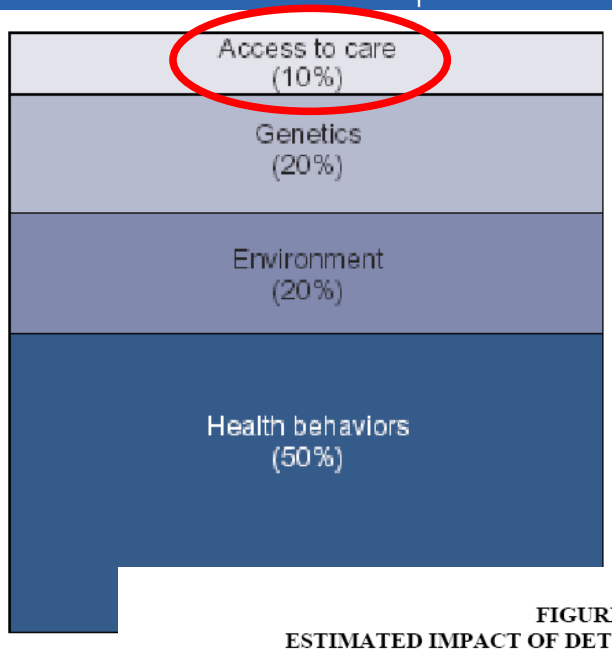
- the largest urban slum in all of Africa.
- the total population may be 500,000 to well over 1,000,000
- the average Kibera slum resident lives in extreme poverty, earning less than US$ 2 per day

# Determinants of Health






Source: Dahlgren & Whitehead 1991




Source: IF
Prevention

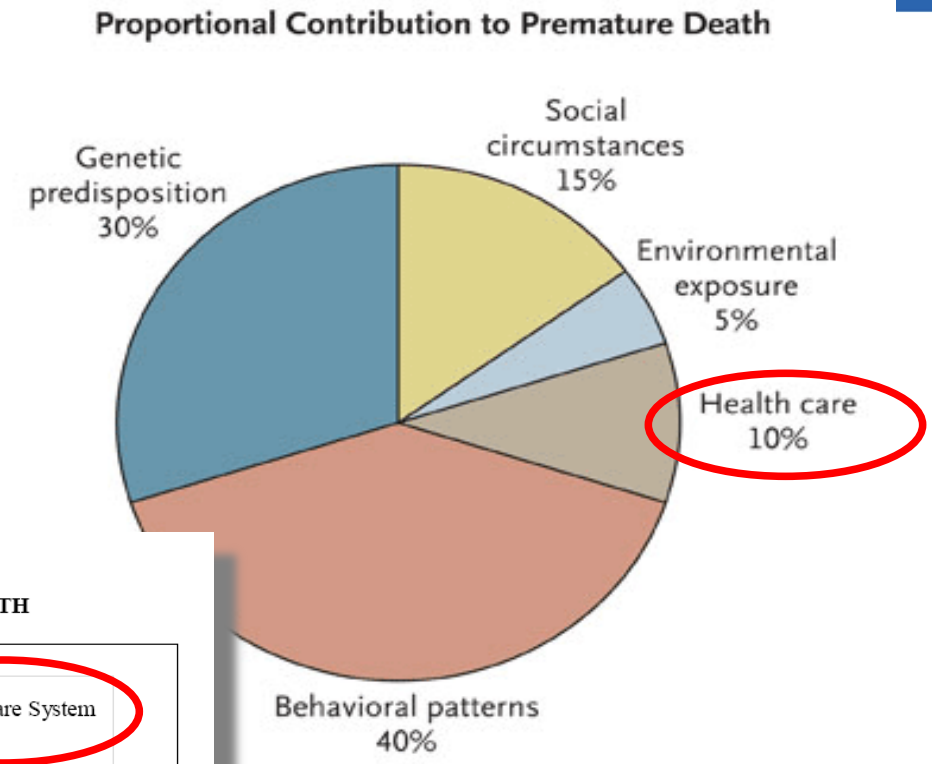
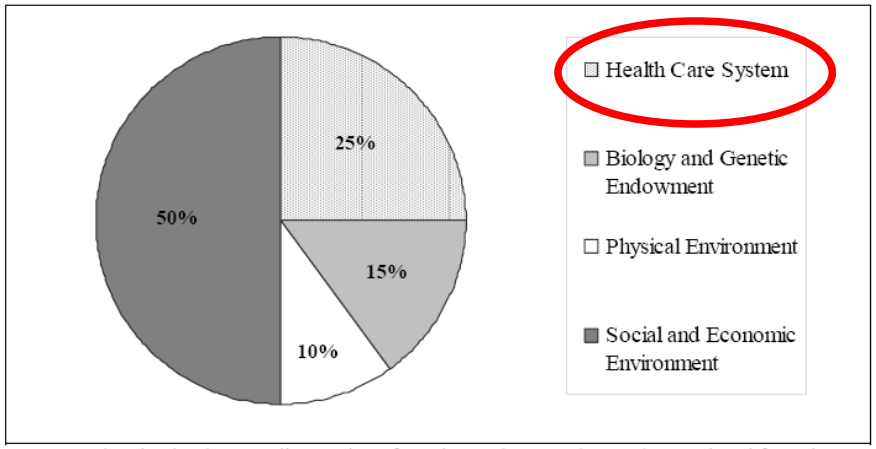
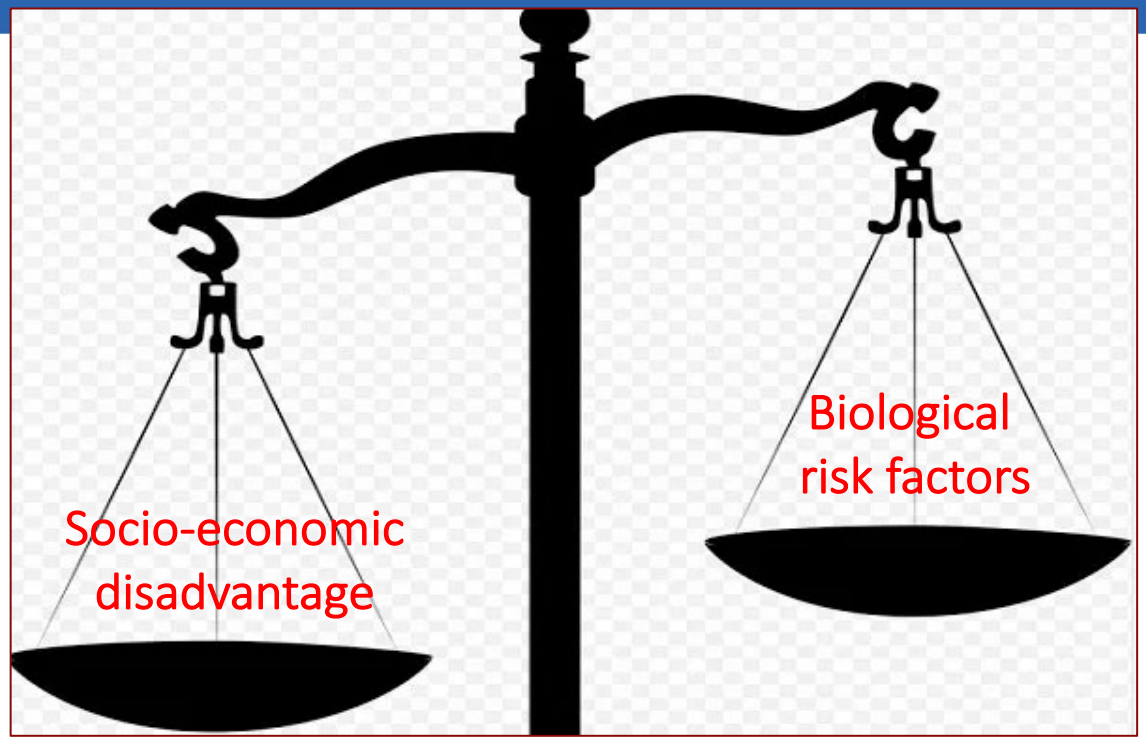



**FIGURE 1**
**ESTIMATED IMPACT OF DETERMINANTS OF HEALTH ON HEALTH OUTCOMES**



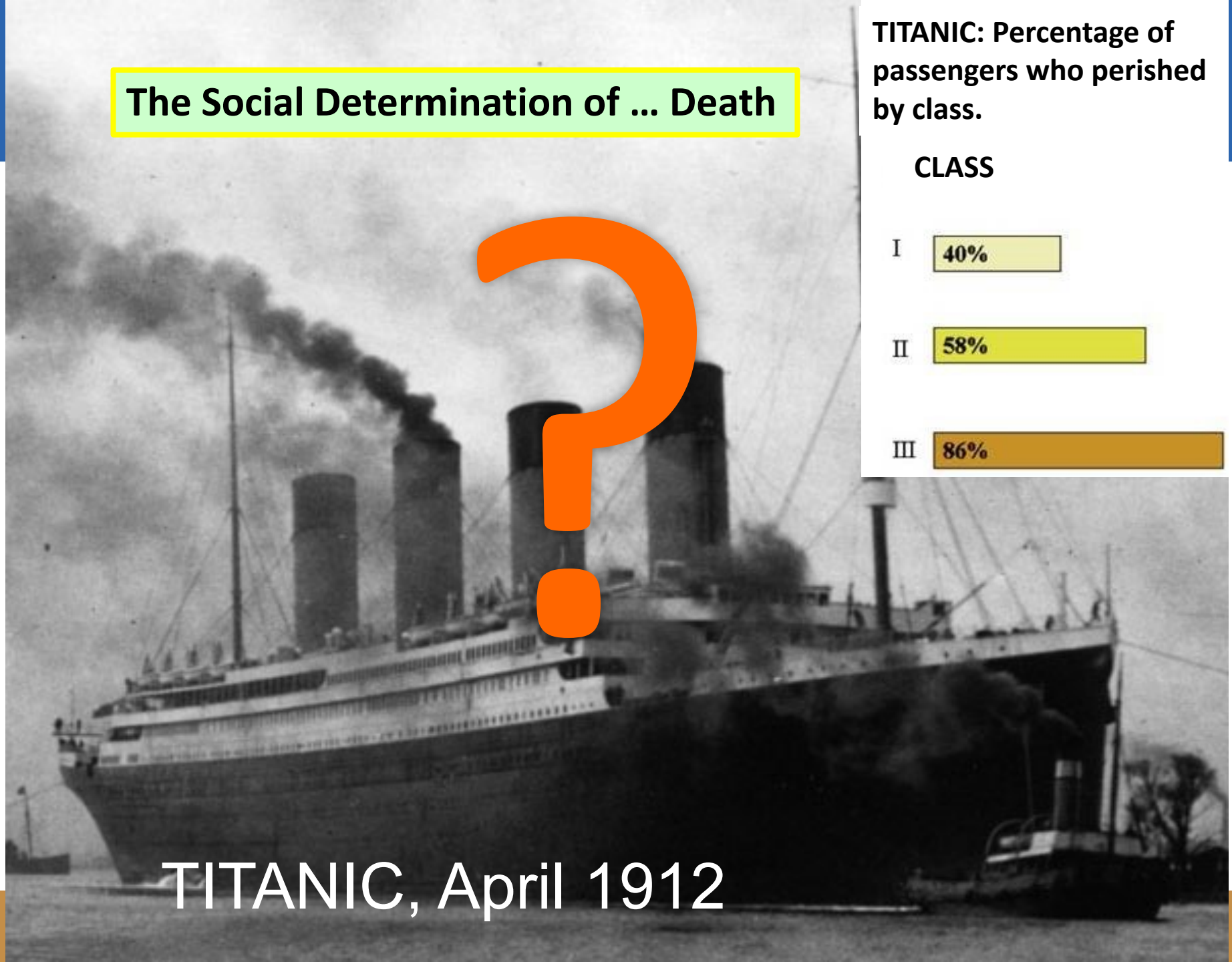

Source: Estimation by the Canadian Institute for Advanced Research. Graph reproduced from the Standing Senate Committee on Social Affairs, Science and Technology, *The Health of Canadians - The Federal Role, Volume One: The Story so Far,* March 2001.

# Influence on Health



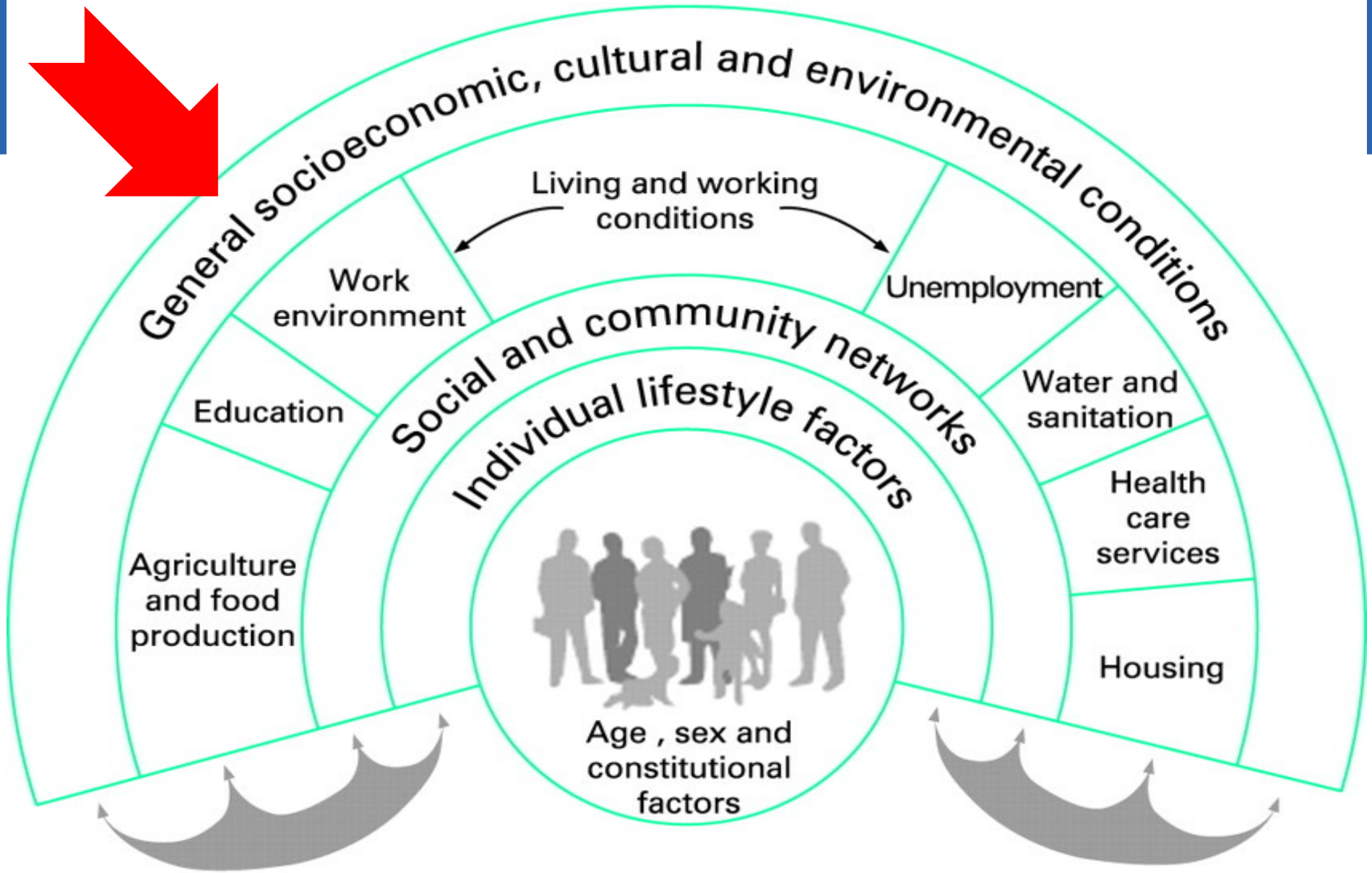

**No biological risk factor**, considered individually, has an influence on health comparable to that of **socio-economic disadvantage.**

# The Social Determination of … Death



TITANIC, April 1912

**TITANIC: Percentage of passengers who perished by class.**


General socioeconomic, cultural and environmental conditions
Living and working conditions
Work environment
Unemployment
Social and community networks
Education
Water and sanitation
Individual lifestyle factors
Health care services
Agriculture and food production
Housing
Age , sex and constitutional factors

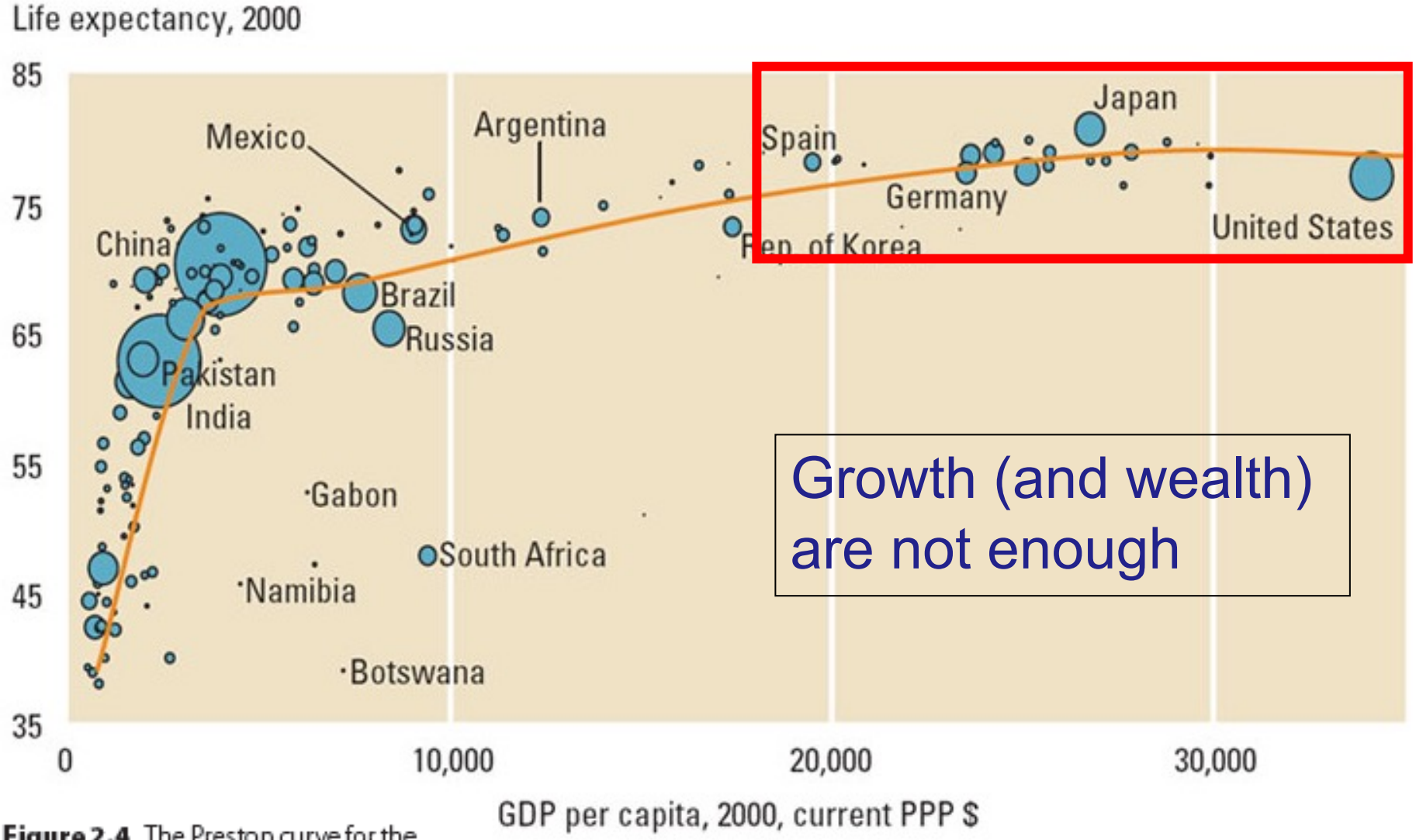
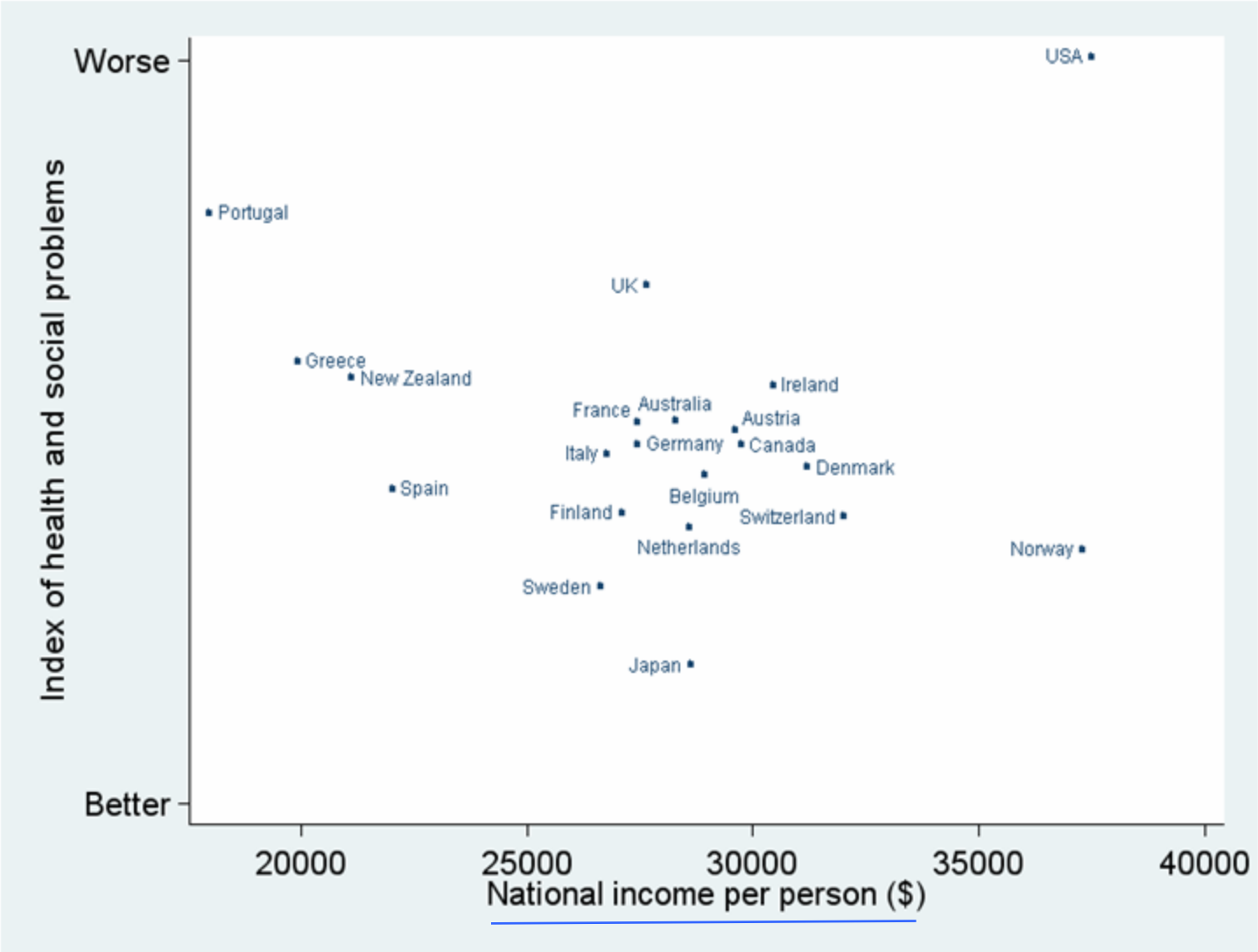



**Figure 2.4** The Preston curve for the year 2000. Reproduced with the permission of the author and the American Economics Association, from Deaton (2003, p. 116).

# Health and Social Problems are not Related to Average Income in Rich Countries

**Index of:**

- Life expectancy
- Math & Literacy
- Infant mortality
- Homicides
- Imprisonment
- Teenage births
- Trust
- Obesity
- Mental illness – incl. drug & alcohol addiction
- Social mobility

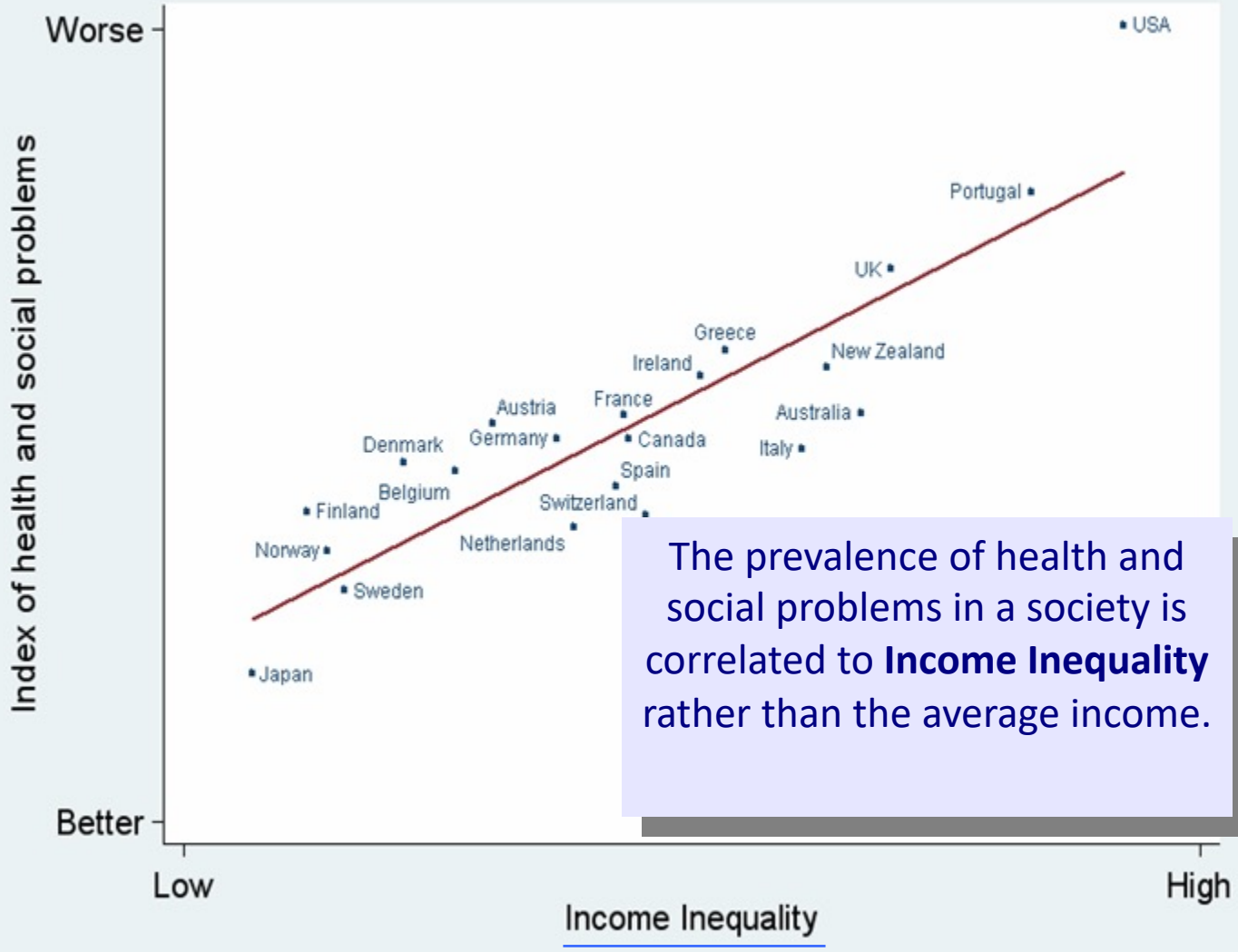



*Source: Wilkinson & Pickett, The Spirit Level (2009)*

# Health and Social Problems are Worse in More Unequal Countries

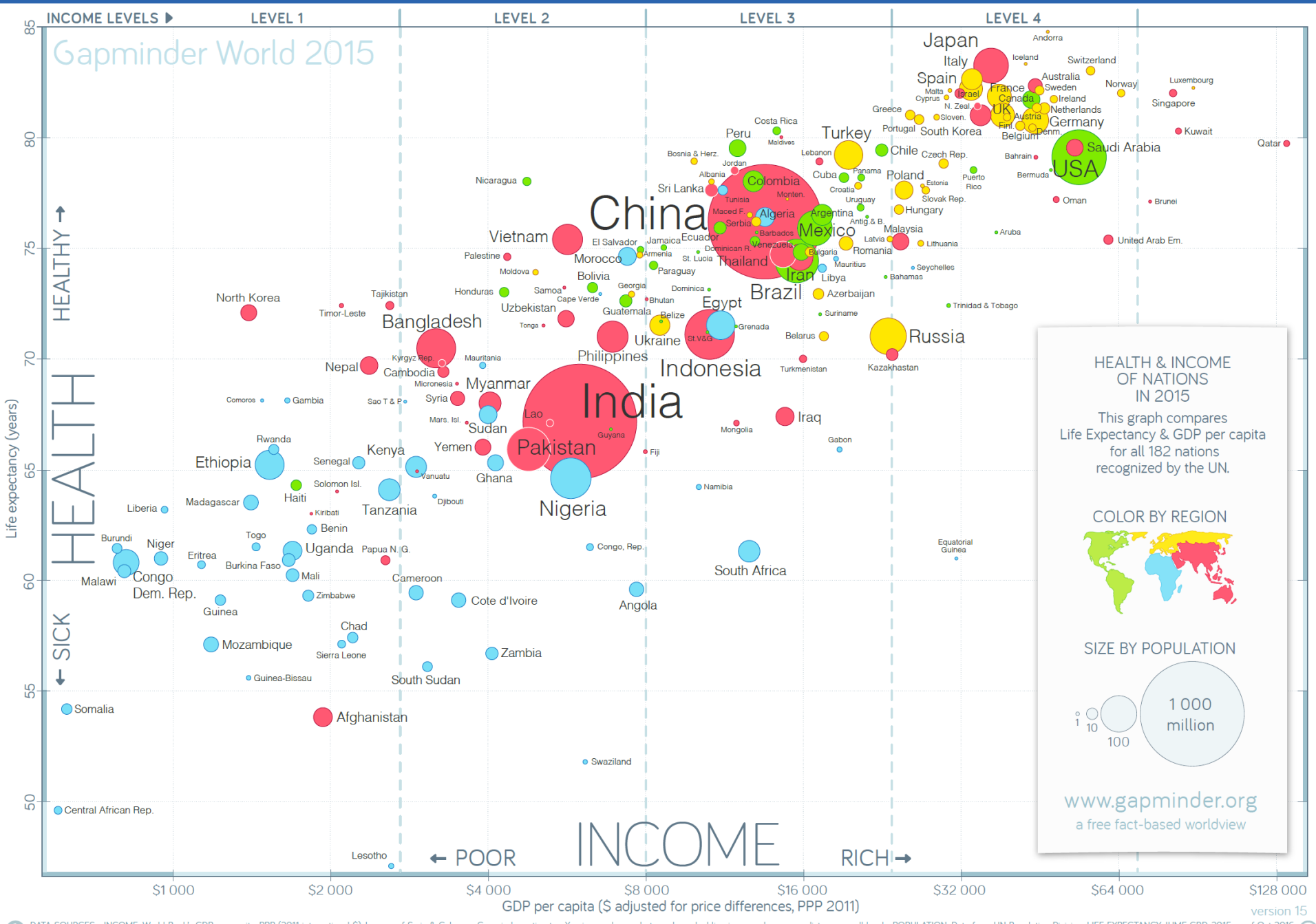
**Index of:**

- Life expectancy
- Math & Literacy
- Infant mortality
- Homicides
- Imprisonment
- Teenage births
- Trust
- Obesity
- Mental illness – incl. drug & alcohol addiction
- Social mobility




The prevalence of health and social problems in a society is correlated to **Income Inequality** rather than the average income.

*Source: Wilkinson & Pickett, The Spirit Level (2009)*




version 15

# Take home messages

- Let's take care of our (real) world!
- Health technologies are important… but not the most important factor
- ➔ please, work against inequalities!

- Look carefully to the data!

- …and now… let's talk about HTM!

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# HTA: A Practical Framework

## For African Clinical Engineers

**Managing Technology in Low-Resource Settings**

Rigorous Methods • Practical Solutions • Sustainable Impact

Courtesy of:
Giovanni Arcuri - *General Manager of Isola Tiberina Hospital, Roma*
Claudio Conti - *Head of HTA and Technology Innovation Unit at Fondazione Policlinico Universitario Agostino Gemelli IRCCS, Roma*

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# The "Graveyard" Reality

We face a stark reality in many of our facilities.

## The Statistic

Up to **40-70%** of medical equipment in low-resource settings is out of service.

**Why?**

- ✓ Lack of spare parts.
- ✓ Incompatible power supply.
- ✓ Missing user manuals.

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# What is HTA? (The Bridge)

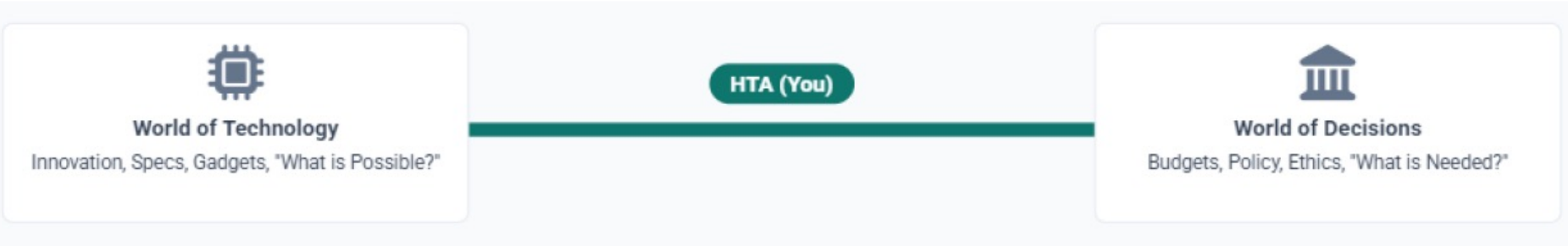
## Definition

Health Technology Assessment (HTA) is the systematic evaluation of properties, effects, and impacts of health technology.

It is a multidisciplinary process to evaluate the social, economic, organizational, and ethical issues of a health intervention or health technology.

> **For Us:** It is the evidence-based process of deciding *"Is this machine right for OUR hospital, right NOW?"*

HTA bridges the gap between **Technical Possibility** and **Policy Reality**.



# The 4 Pillars for Africa

### 1. Clinical Need

Does the epidemiology of our region demand this? Is it a "want" or a "need"?

### 2. Technical Fit

Can it survive our environment? (Heat, Dust, Power Fluctuations, Water).

### 3. Economic (TCO)

Can we afford the *lifecycle*? Consumables, maintenance, disposal?

### 4. Social/Ethical

Is it safe? Is it equitable? Who benefits? How do we dispose of it?

**Total Cost of Ownership**

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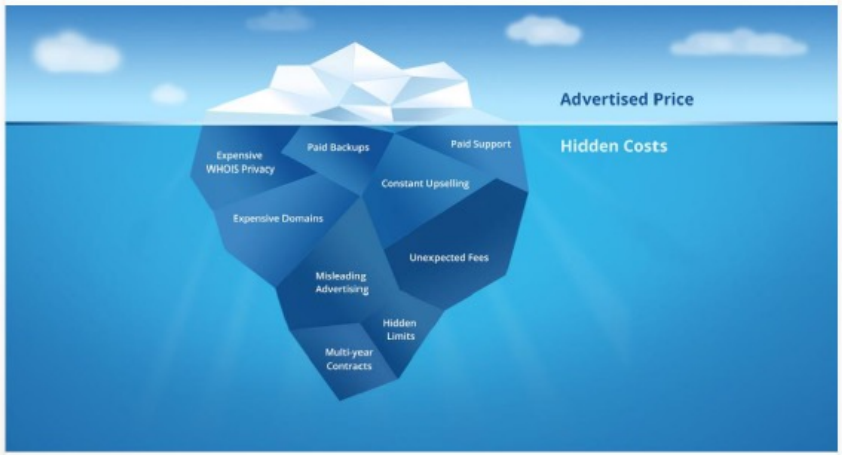
# Technical Feasibility

## The Infrastructure Reality Check

- ✓ **Power Stability:** Is the voltage compatible (220V vs 110V)? Do we need a UPS or stabilizer?
- ✓ **Environment:** Can the device handle 35°C+ heat and 90% humidity? Is it dust-proof?
- ✓ **Utilities:** Does it need medical-grade oxygen, treated water, or compressed air?
- ✓ **Spare Parts:** Is there a local distributor? Or do we have to import a $5 fuse for $100 shipping?

# The Economic Reality (TCO)




## The Iceberg Effect

The **Acquisition Cost** (Purchase Price) is just the tip of the iceberg.

**Hidden Operational Costs (OPEX):**

- Consumables (Reagents, filters, paper)
- Spare parts & Maintenance contracts
- Staff training & retraining
- Electricity & Water consumption
- Decommissioning & Disposal

**In 5 years, OPEX can exceed CAPEX by 3-5 times.**

Capital Expenditures

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# Ethical & Social Responsibility

## E-Waste

Africa is not a dumping ground. Accepting broken equipment harms our environment. We must ensure proper disposal plans are in place.

## Equity

Does this technology serve the majority? Or does it divert resources from basic care (e.g. maternal health) to high-cost elite care?

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# The Donation Dilemma

"There is no such thing as a free lunch."

## The Risks

- Dumping of obsolete technology.
- No manuals or accessories.
- Unknown history (broken on arrival).
- Creates a disposal burden for YOU.

## The HTA Defense

- **Policy:** "We do not accept unsolicited equipment."
- **Standard:** "Equipment must have 50% life remaining."
- **Manuals:** "Must come with technical & user manuals in English/French."

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# Case Study: The Oxygen Concentrators

## The Scenario

A rural hospital receives 10 used oxygen concentrators donated from the USA.

**The Failure:**

- Input: 110V / 60Hz. Local grid: 220V / 50Hz.
- Step-down transformers were bought cheaply.
- Overheating caused compressors to fail within 2 months.
- Filters were clogged with dust (no spares).


**HTA Lesson:** Technical Feasibility Assessment would have flagged voltage and environmental conditions (dust)

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# Case Study: The Imaging Trap

**Scenario:** A teaching hospital is offered a high-end CT Scanner. "Just pay for shipping."

### The Hidden Reality

- **Installation:** Requires lead-lined walls (Cost: $20k).
- **Tube Life:** The X-ray tube was near end-of-life. Replacement cost: $60k.
- **Service:** No engineer in the country trained on this specific model.

# The "Wild West" of Regulation

## The Missing Mark

Weak border enforcement allows uncertified equipment to flood our markets.

**The Risks of Non-Certification:**

- **Electrical Shock:** Devices may lack proper isolation (Type B vs BF vs CF).
- **Inaccuracy:** A cheap BP monitor giving false readings is a "silent killer".
- **No Traceability:** If there is a global recall, you will never know.


**The "China Export" Confusion:** Be aware of deceptive logos that look like the CE mark but simply stand for "China Export".

| Comunidad Europea | China Export |
| --- | --- |
|  |  |
|  |  |

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# Mitigating Regulatory Risk

### 1. Verify Paperwork

Demand a "Declaration of Conformity" (DoC). Do not just look at the sticker. Verify the "Notified Body" number (e.g., CE 0123).

### 2. Trust but TEST

**Mandatory:** Perform Electrical Safety Testing (IEC 62353) on arrival. If it fails leakage tests, reject it immediately.

### 3. Global Research

Use the internet. Is this model sold in Europe or the USA? Check the FDA MAUDE database for recalls.

**"In the absence of a strong regulator, the Clinical Engineering Department IS the regulator."**

"Technology alone does not save lives.

**Managed** technology saves lives."

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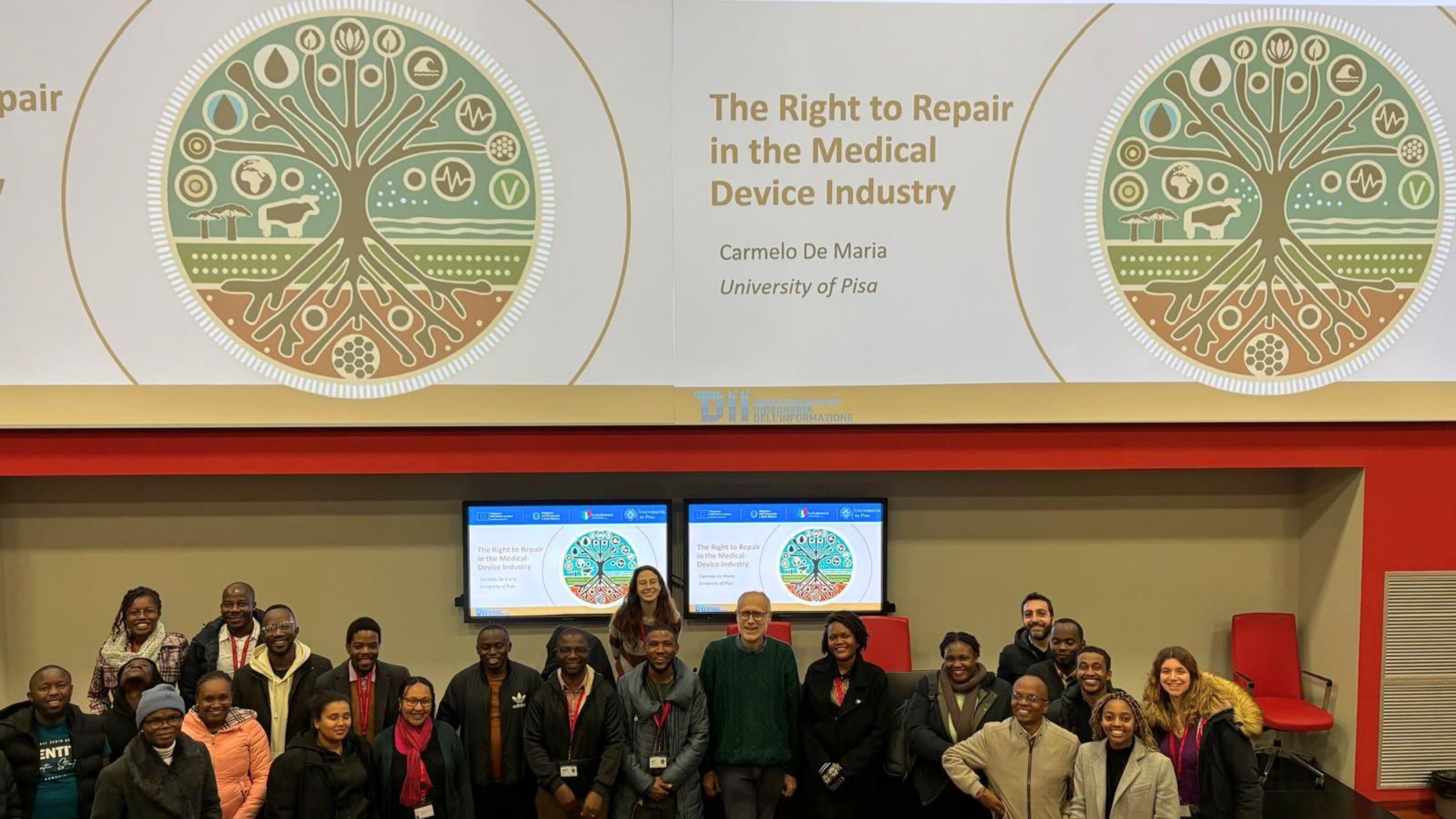
Università di Pisa

# Health Technology Management

Winter School Kenyatta University

Caterina Giuliani - University of Bologna


pair
The Right to Repair in the Medical Device Industry
Carmelo De Maria
University of Pisa
DII
DIPARTIMENTO DI INGEGNERIA DELL'INFORMAZIONE
The Right to Repair in the Medical Device Industry
The Right to Repair in the Medical Device Industry

# Overview

- Fundamentals of Healthcare Technology Management (HTM)
- Health technologies life cycle
- Case study

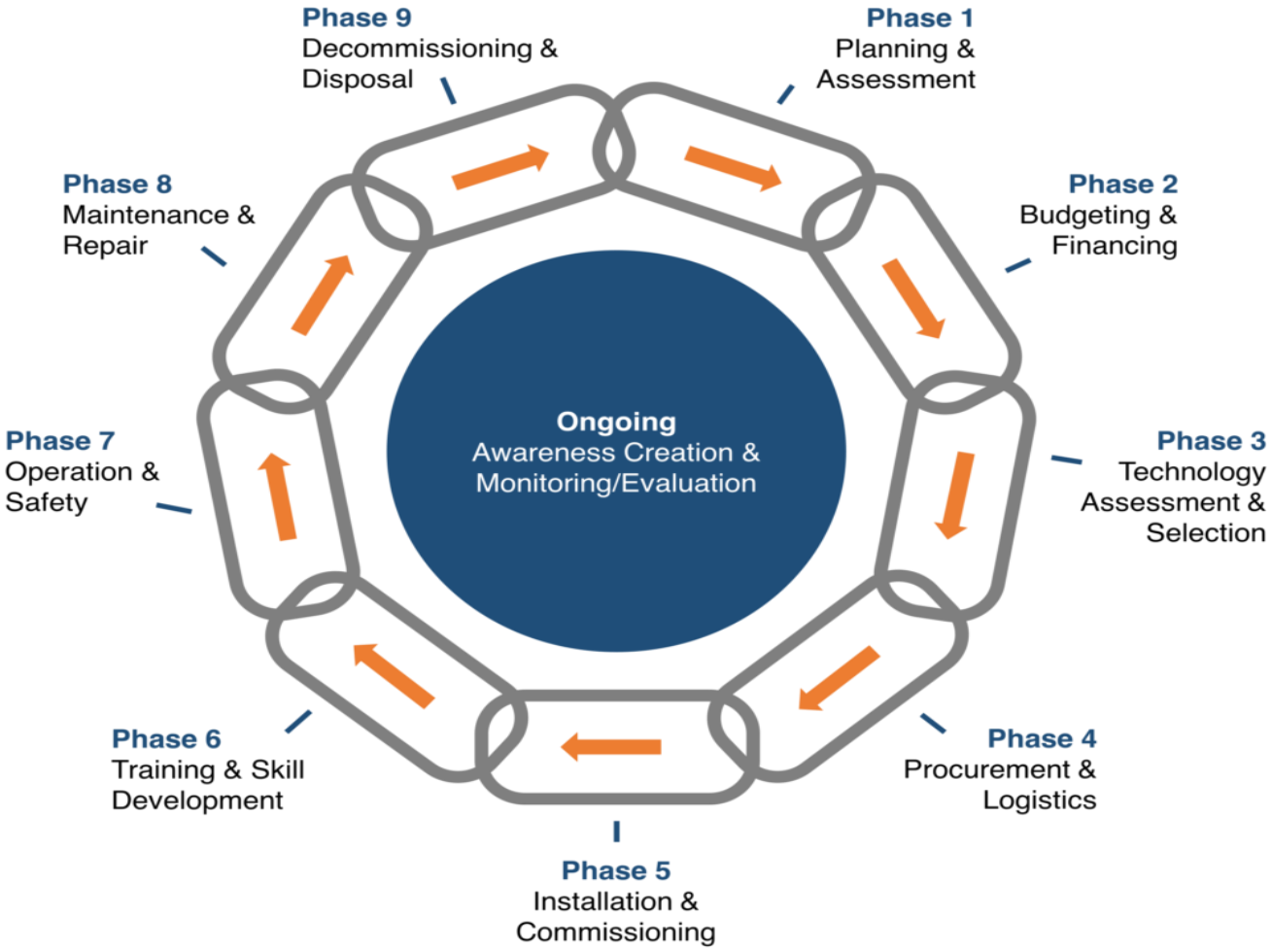
# What is HTM?

**Healthcare Technology Management (HTM) is the set of technical and managerial activities that ensure that health technologies are safe, effective, appropriate, and sustainable during their entire life cycle**

# HTM Benefits

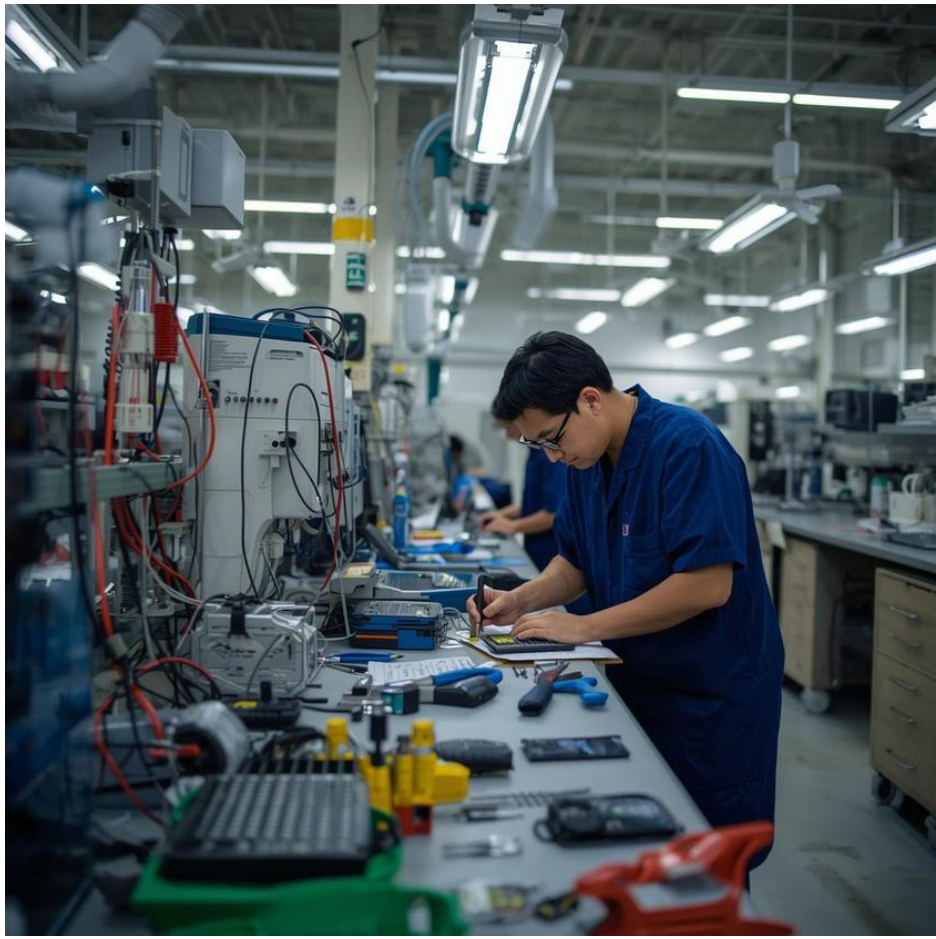
- improved equipment availability,
- patient safety,
- cost efficiency,
- better use of resources,
- improved clinical outcomes,
- data-driven decision making,
- regulatory compliance,
- sustainability

## Health Technology Management Lifecycle



# Availability of resources

- Workshop
- Tools
- Spare parts
- Dedicated personnel



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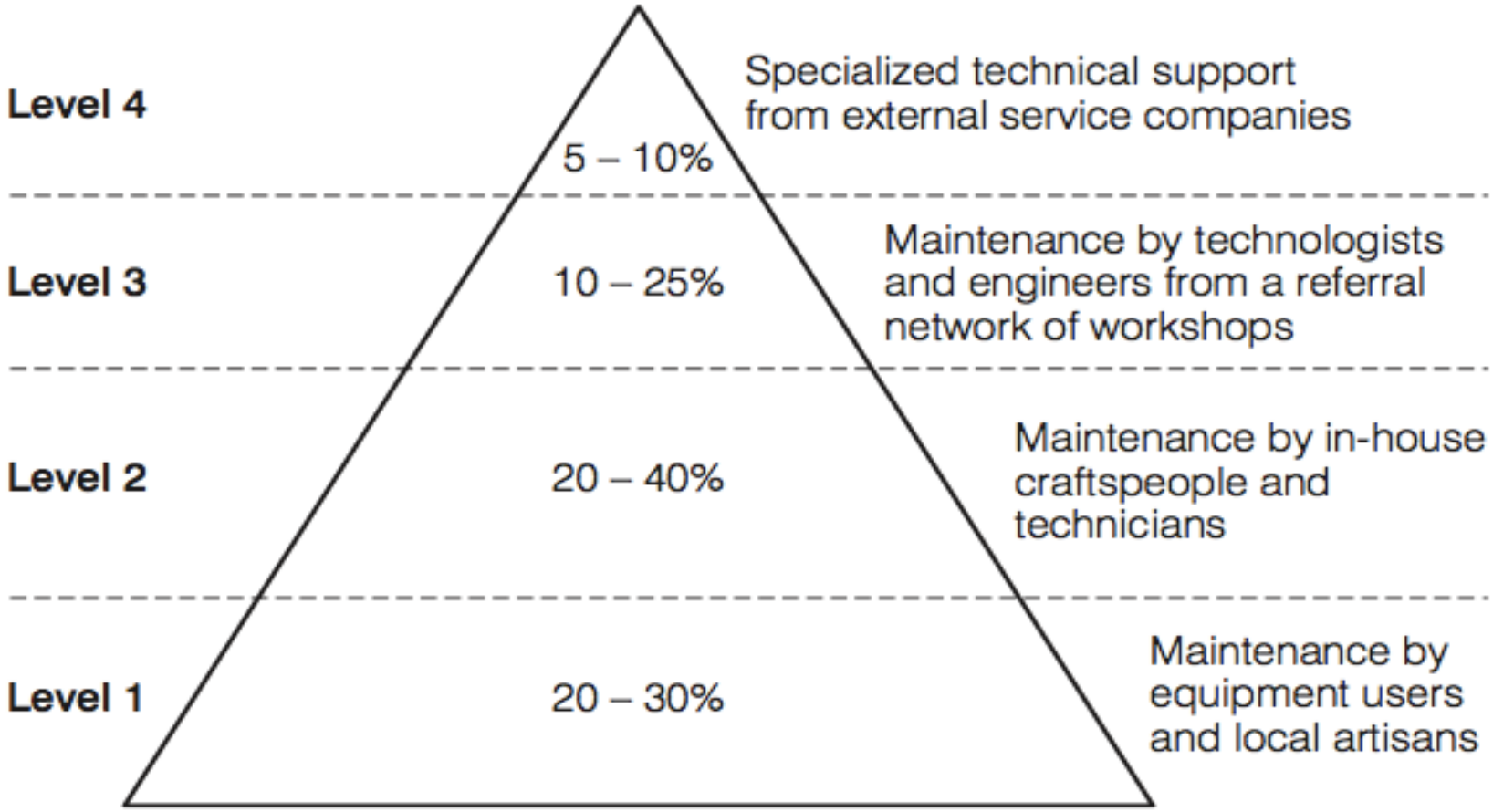
# Types of staff

- Equipment users
- Technicians
- Biomedical engineers
- HTM Managers
- Support staff

Resources


Level 4
5 – 10%
Specialized technical support from external service companies
Level 3
10 – 25%
Maintenance by technologists and engineers from a referral network of workshops
Level 2
20 – 40%
Maintenance by in-house craftspeople and technicians
Level 1
20 – 30%
Maintenance by equipment users and local artisans

Resources

**BOX 29: Suggestions for Staff Development Needs According to Hospital Size from a FAKT International Seminar**

| Label | Level of training | Number of staff per hospital type | | | | |
|---|---|---|---|---|---|---|
| | | 1000 plus beds | 500 plus beds | 200 – 300 beds | 100 plus beds | 30 plus beds |
| Engineer | BSc or HND holder | 2 minimum | 2 | 1 | 0 | 0 |
| Technologist | Diploma holder | 10 | 5 – 7 | 2 – 4 | 2 minimum | 0 |
| Technician | Certificate holder | 20 | 10 | 4 | 2 – 4 | 1 minimum |
| Artisans: | | | | | | |
| electrician | Trade test holder or informal training | 6 plus | 3 – 6 | 2 – 3 | 1 – 2 | |
| plumber | | 6 plus | 3 – 6 | 2 – 3 | 1 – 2 | |
| carpenter | | 5 plus | 3 – 5 | 1 – 3 | 1 | |
| mason | | 3 plus | 2 – 3 | 0 – 1 | 0 | |
| painter | | 2 plus | 1 – 3 | 0 – 1 | 2 | |
| car mechanic | | 3 plus | 2 – 3 | 1 – 2 | 0 | |
| Support staff | Relevant test certificate or informal training | 2 | 1 | 1 | 1 | |

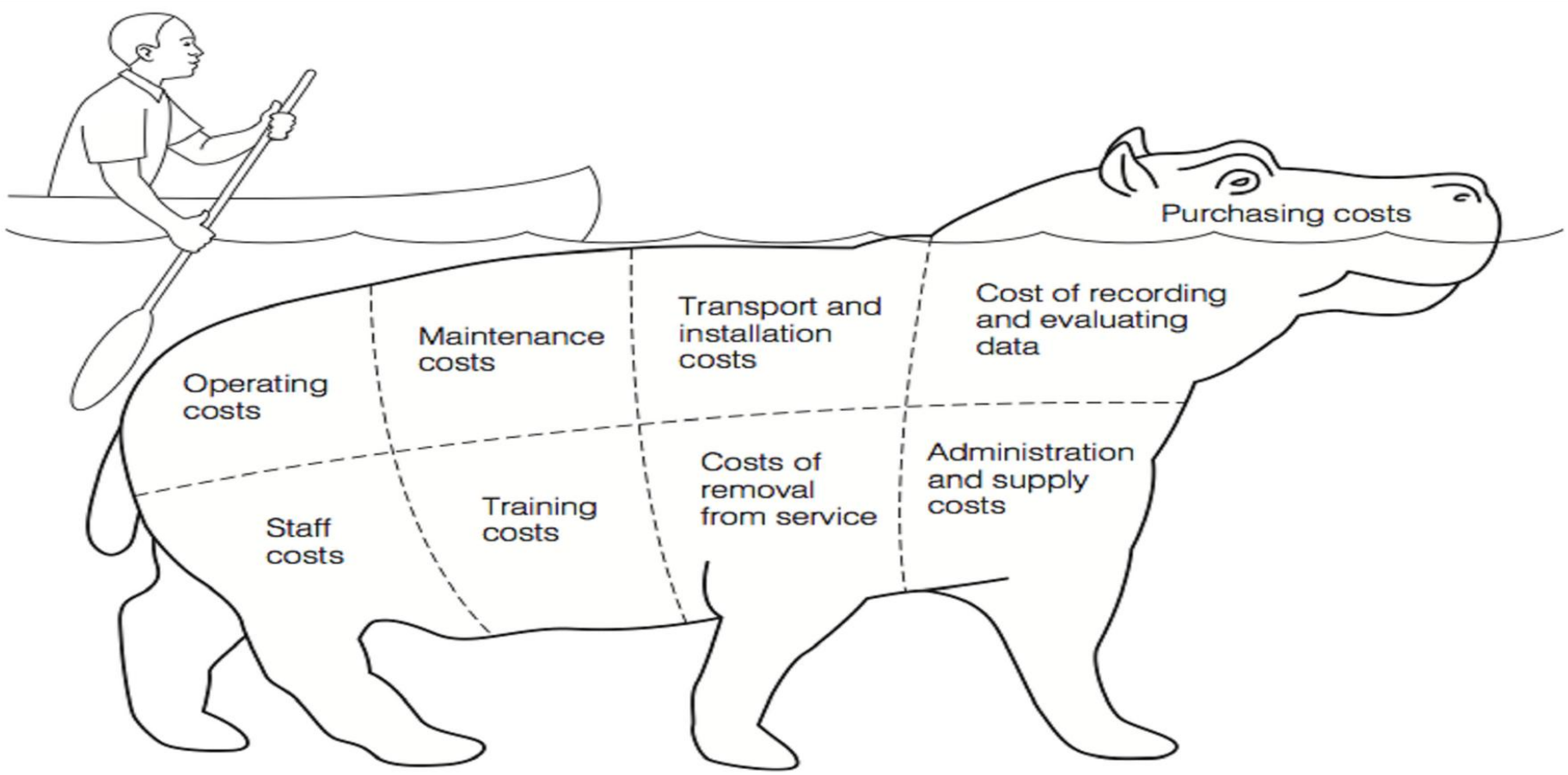
Resources

# Planning and Assessment

- Clinical evaluation
- Economic evaluation
- Health Technology Assessment (HTA)

# Planning tools

- keeping an update **Equipment inventory**
- knowing the **value of stock** of equipment
- consumable use estimations
- **budget lines** for equipment expenditure


Purchasing costs
Cost of recording and evaluating data
Transport and installation costs
Maintenance costs
Operating costs
Administration and supply costs
Costs of removal from service
Training costs
Staff costs

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# Consumable cost

Some equipment use many and expensive consumables. Up to 120% of purchasing cost per year!

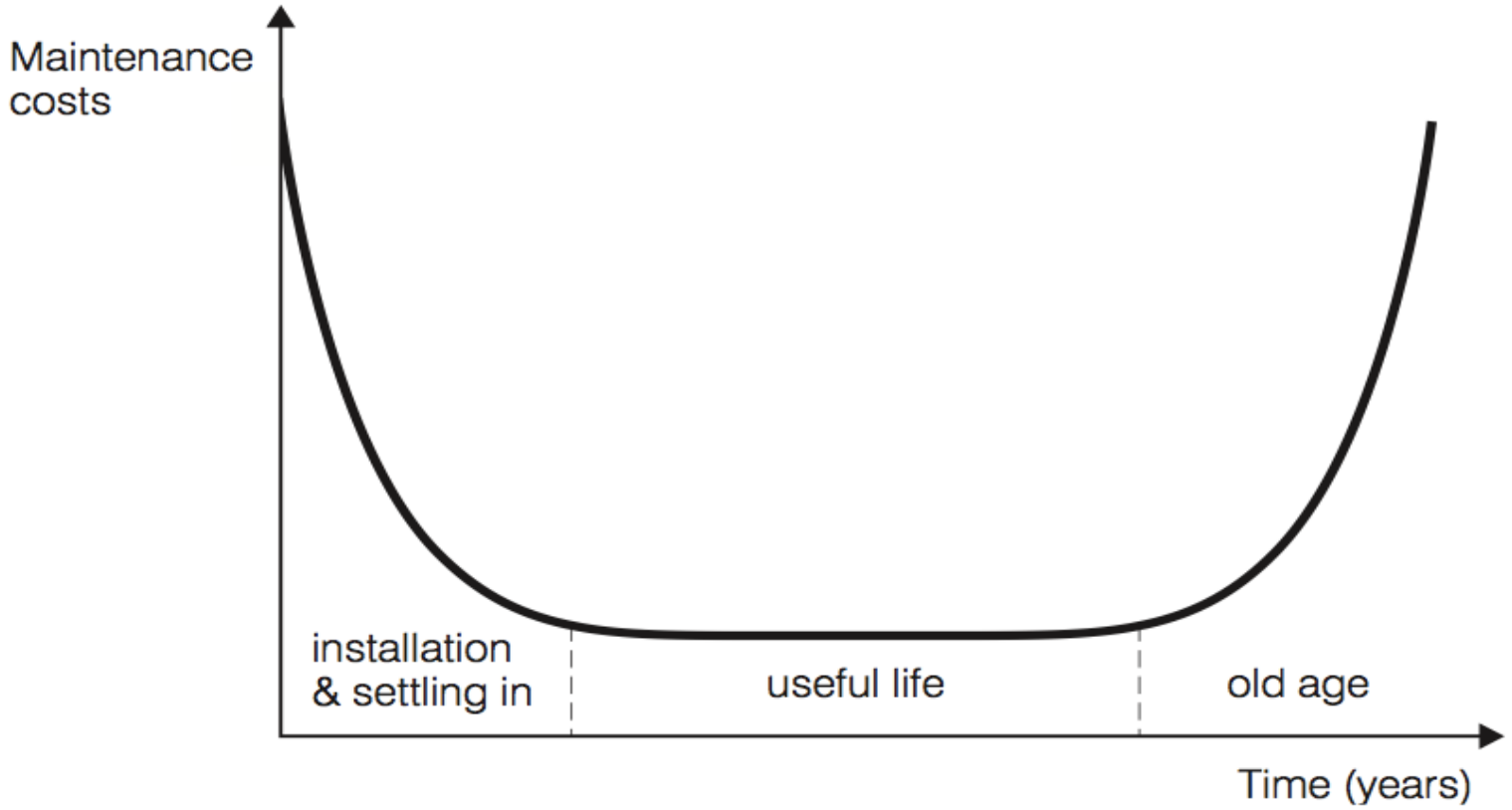
**BOX 30: Suggestions for Rough Estimations of Consumable Operating Costs for Forward Planning (continued)**

| Description | Consumable cost per year relative to original purchase cost |
|---|---|
| **Equipment with high consumable operating costs, such as:** | |
| Haemodialysis machine | |
| Automatic biochemical analyser | |
| Automatic haematology analyser | 70–120 per cent |
| Electrolyte analyser | |
| Blood gas analyser | |
| **Equipment with medium consumable operating costs, such as:** | |
| Conventional X-ray machine | 30 per cent |
| Anaesthesia machine | 20 per cent |
| ECG recorder, three channel | |
| Ultrasound, medical/obstetric | |
| Ventilator, ICU | 15–25 per cent |
| Physiological monitor | |
| EEG machine | |
| Autoclave, steam | 10–15 per cent |
| Incubator, baby, ICU | 5–15 per cent |
| **Equipment with low consumable operating costs, such as:** | |
| Centrifuge, electrical | 5 per cent |
| Suction pump | 2–5 per cent |
| Delivery bed | |
| Operating theatre lamp | |
| Slit lamp | 1–2 per cent |
| Operating microscope | |
| Water bath | |

# Maintenance cost

Many calculations make use of a percentage of “equipment stock value” e.g. for calculating maintenance cost for equipment, you take an internationally recognized percentage of you equipment stock value (5-6%)

**Figure 19: Traditional 'Bath-tub' Curve of Maintenance Costs over the Lifetime of Equipment**



# Model Equipment List

a standardised list of equipment required for a specific level of healthcare facility, based on an analysis of needs and available resources.

The model equipment list should then be compared with the current inventory to identify gaps or surpluses

# What should we purchase?

## THE BEST TECHNOLOGY

- appropriate
- sustainable
- safe
- ethical

**BOX 3: Savings Derived from Effective Procurement and Commissioning of Healthcare Technology**

| Problems that could be avoided | Resulting waste you could save |
|---|---|
| ◆ lack of standardization | ◆ 30–50% additional cost for extra spare parts and extra maintenance workload |
| ◆ purchase of sophisticated equipment for which operating and maintenance staff have no skills | ◆ 20–40% of equipment remains under-utilized or unused |
| ◆ impact on equipment and buildings during installation, unforeseen at the initial tender stage | ◆ extra modifications or additions required for 10–30% of equipment |
| ◆ inability to correctly specify and foresee total needs when ordering equipment | ◆ 10–30% additional unplanned costs |
| ◆ improper use of equipment by operating and maintenance staff who lack the necessary training | ◆ loss of 30–80% of the potential lifetime of equipment |
| ◆ excessive equipment down-time due to absence of preventive maintenance, inability to repair, and lack of spare parts | ◆ 25–35% of equipment out of service |

# Installation and Acceptance Testing

- Technical compliance verification
- Electrical and functional safety
- Formal acceptance
- Technical documentation

# Clinical Use

- User training
- Operating procedures
- Appropriate use
- Performance monitoring

# Preventive Maintenance

PPM is a series of actions carried out on equipment to prevent breakdowns and ensure the equipment is operational and safe.

PPM enables the HTM to:

- detect problems before they become crises
- save money
- make sure that the equipment is fully operational
- guarantee accuracy
- reduce downtime
- extend the life-span of equipment

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# Good Preventive Maintenance saves costs!

| Equipment type | Lifetime in years | | | |
|---|---|---|---|---|
| | Poor quality makes | | Good quality makes | |
| | Poorly maintained | Well maintained | Poorly maintained | Well maintained |
| Air-conditioner (window type) | 3 | 5 – 7 | 5 – 6 | 10 – 12 |
| Anaesthetic machine (Boyles) | 2 – 5 | 5 – 10 | 5 – 10 | 10 – 15 |
| Centrifuge | 3 – 4 | 7 – 8 | 6 – 9 | 10 – 12 |
| Generator (diesel) | 3 – 6 | 9 – 10 | 10 – 12 | 18 – 20 |
| Generator (petrol) | 2 – 5 | 5 – 10 | 6 – 15 | 10 – 20 |
| Microscope | 3 – 6 | 5 – 10 | 6 – 10 | 10 – 20 |
| Oven, hot air (laboratory) | 2 – 6 | 5 – 8 | 6 – 10 | 10 – 15 |
| Refrigerator (electrical) | 3 – 5 | 5 – 8 | 5 – 8 | 10 – 15 |
| Refrigerator (kerosene) | 4 | 4 – 8 | 5 – 10 | 10 – 17 |
| Sphygmomanometer (aneroid) | 1 – 3 | 2 – 3 | 2 – 5 | 5 – 10 |
| Sphygmomanometer (mercury) | 1 – 2 | 3 – 5 | 3 - 5 | 8 – 10 |
| Sterilizer, bench-top (horizontal) | 3 – 5 | 5 – 8 | 6 – 10 | 10 – 14 |
| Sterilizer, floor-standing (vertical) | 3 – 6 | 5 – 12 | 8 | 14 – 15 |
| Suction pump (electrical) | 1 – 3 | 5 – 7 | 5 – 8 | 10 – 15 |
| Truck, pick-up | 2 – 4 | 3 – 6 | 4 – 8 | 7 – 12 |
| Washing machine (electrical) | 2 – 4 | 5 | 6 | 8 – 11 |

# Corrective maintenance

All maintenance actions performed after a failure has occurred, to restore medical equipment to a safe and functional operating condition.

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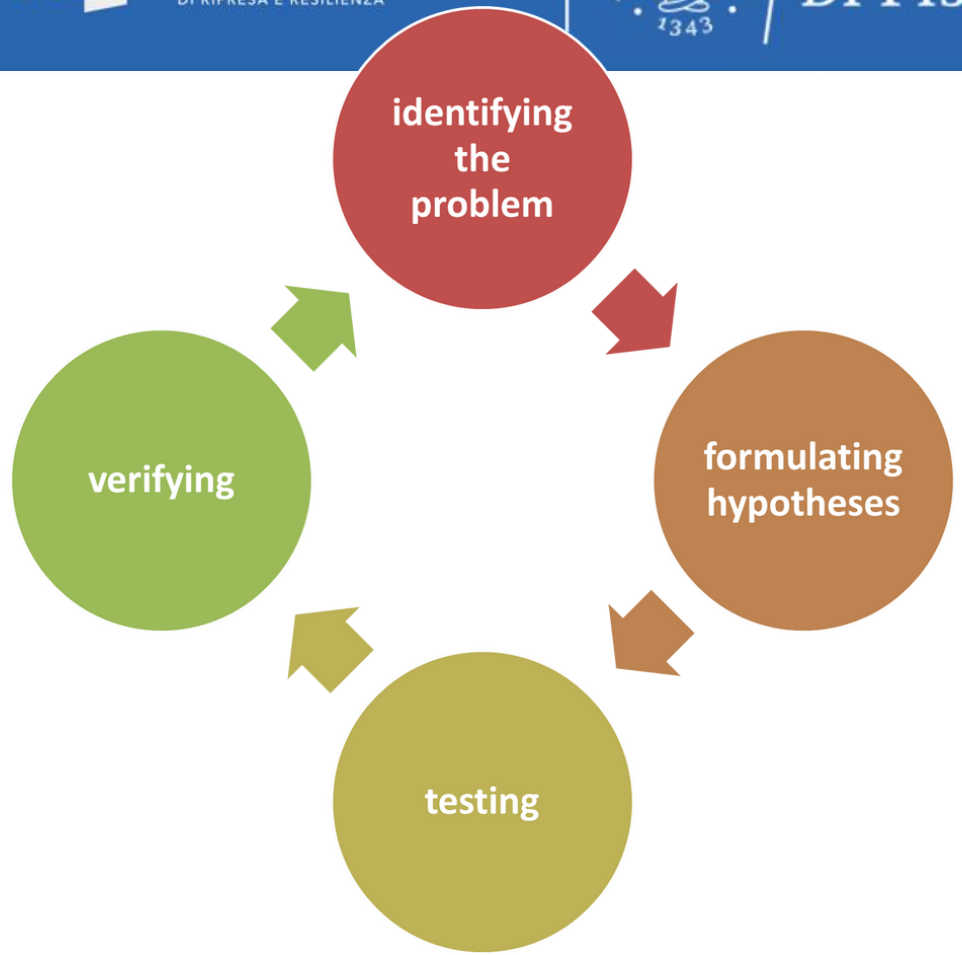
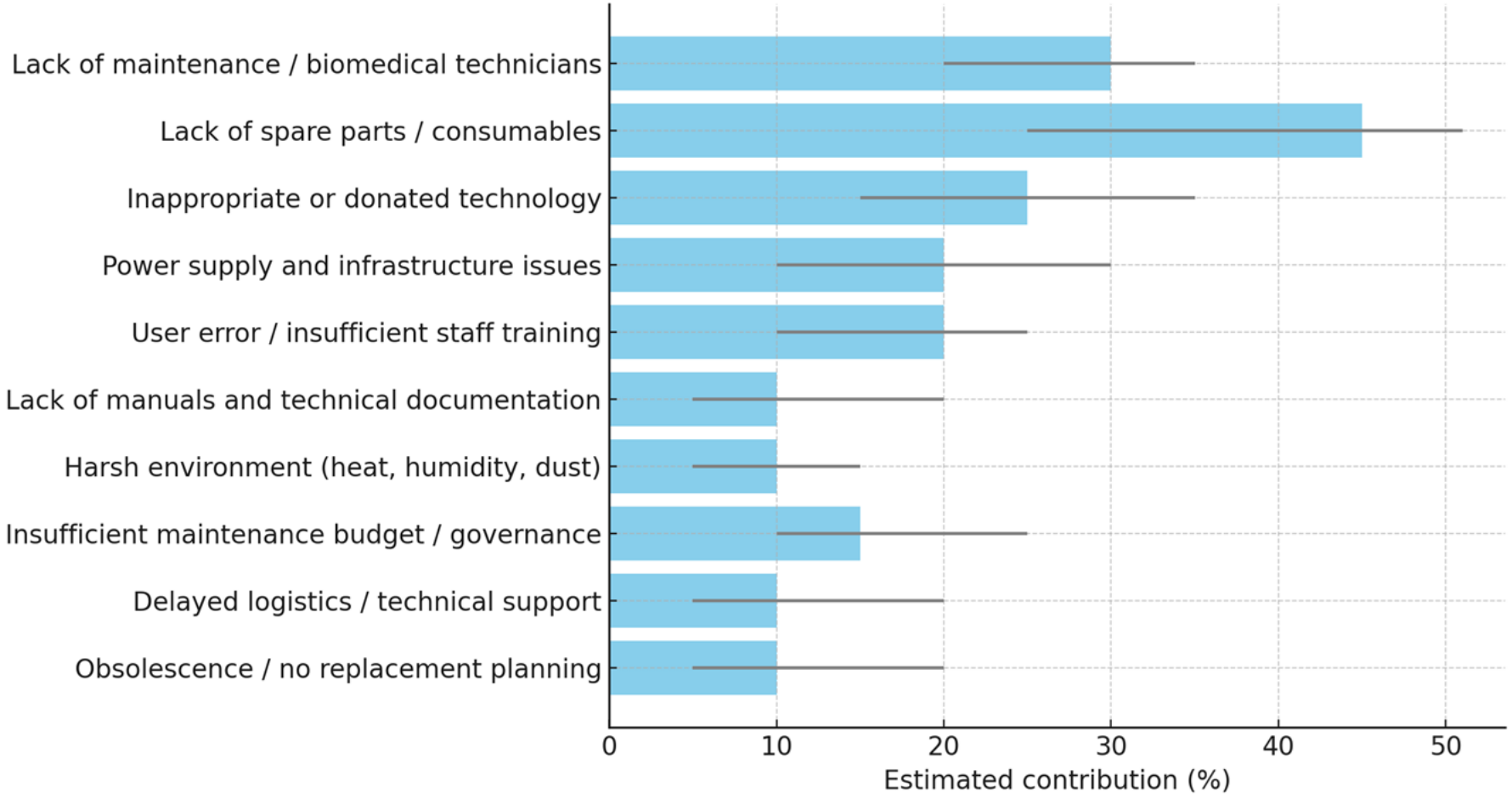
# Troubleshooting

- Know the principles of operation of equipment
- Know the equipment history from the user and maintenance records
- Use service manuals, test equipment and correct tools
- Use correct troubleshooting techniques
- Record equipment details in workshop receiving book.



# Main Causes of Non-Functional equipment



# Records

- the work done on the equipment
- spares used on equipment
- consumables used on equipment
- when the equipment came to the workshop
- the maintenance staff who worked on the equipment
- the time taken to repair/doing the work

# Decommissioning and Replacement

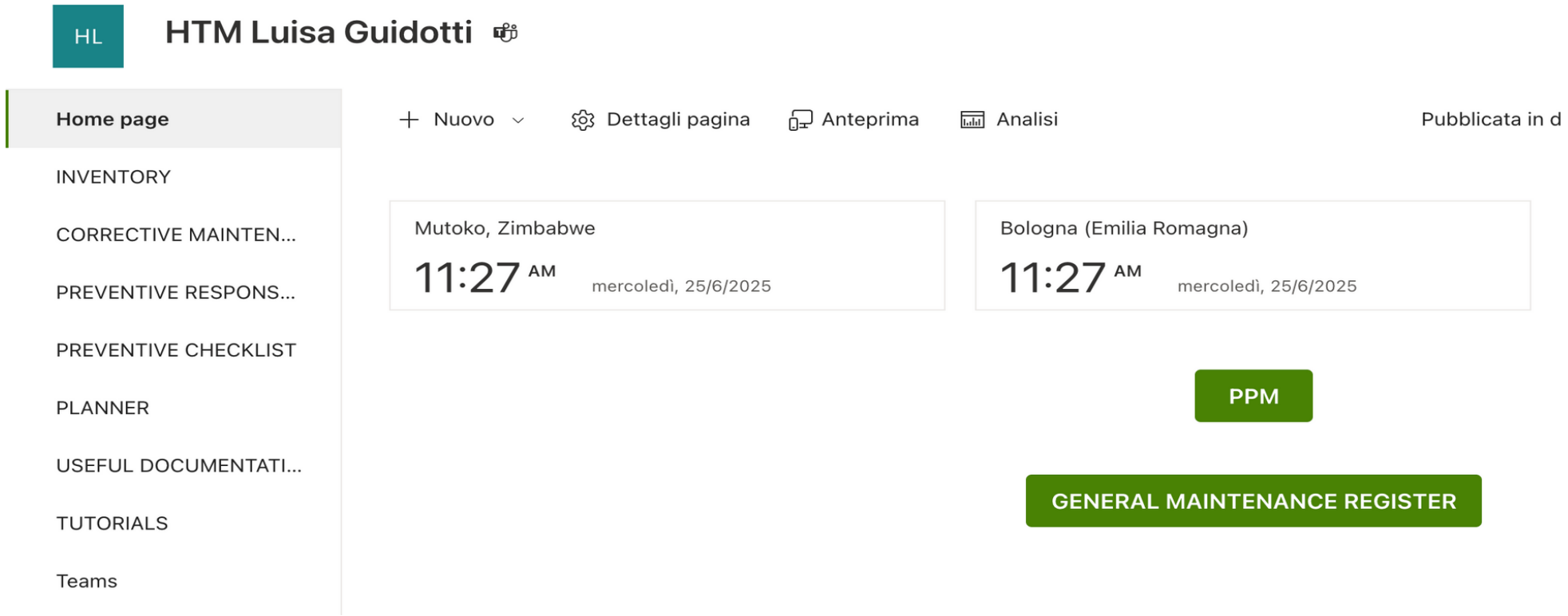
Every technology has an end of life!

The disposal phase must be managed safely and responsibly, taking into account environmental and regulatory aspects.

# Physically disposing of the equipment

- Destroy memory containing patient data
- Remove useful components and parts
- hazardous components are disposed safely: radioactive sources, asbestos, mercury, etc.

# CMMS - example



Logo qui

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# HTM Luisa Guidotti

- Home page
- INVENTORY
- CORRECTIVE MAINTEN...
- PREVENTIVE RESPONS...
- PREVENTIVE CHECKLIST
- PLANNER
- USEFUL DOCUMENTATI...
- TUTORIALS
- Teams
- Cestino
- Modifica

Nuovo

| A | B | C | D | E | F | G | H | I |
|---|---|---|---|---|---|---|---|---|
| Inventory Code Numl | Departeme | Type of equipment | Stat | Comments & different location | Name of Manufacturer | Model Name | Serial Number | Operation Manua |
| FCHHBD001 | FCH | Height Board | OK | | ADE | MZ10042 | | |
| FCHHBD002 | FCH | Height Board | OK | | FAZZINI | | | |
| FCHSCA001 | FCH | Scale | OK | | SECA | 7001021008 | 5700055148140 | |
| FCHSCA002 | FCH | Scale | OK | | SALTER | 2356S | | |
| FCHHBD003 | FCH | Height Board | OK | | ADE | MZ10040 | 165240005556 | |
| FCHSAT001 | FCH | Saturimeter | OK | | Hunan | | | |
| FCHUSS001 | FCH | Ultrasound Scan | OK | | Fukuda Denshi | UF-750XT | 37061665 | |
| FCHGLC001 | FCH | Glucometer | OK | | CareSens | GM01WAA | F066210L0971 | |
| FCHBED001 | FCH | Bed | OK | | Surgimed | | | |
| FCHIVP001 | FCH | IV Pole | NP | Wheels are not working | | | | |
| FCHBED002 | FCH | Bed | OK | | | | | |
| FCHCRD001 | FCH | Cradle | OK | | SNELL | | | |
| FCHSUC001 | FCH | Suction Machine | OK | | Ca-mi | NEW ASKIR 30 | 2399 | |
| FCHMON001 | FCH | Patient Monitor | OK | | MASmed | MAS-V900 | 21090712040238 | |
| FCHTHR001 | FCH | Thermometer | OK | | UEBE Medical GmbH | 0816 | | |
| MATRTE001 | MAT | Resuscitre | OK | | Drager | Babytherm8004 | | |
| MATRTE002 | MAT | Resuscitre | NO | Not working at all | OHMEDA | IWS3300 | | |
| MATMON001 | MAT | Patient Monitor | NP | SpO2 and temperature not working | MASmed | MAS-V900 | 21090712040233 | |
| MATSAT001 | MAT | Saturimeter | OK | Batteries have to be changed | ROHS | | | |
| MATSAT002 | MAT | Saturimeter | OK | Charging system to check | ACARE | AH-M1 | | |

HL **HTM Luisa Guidotti**

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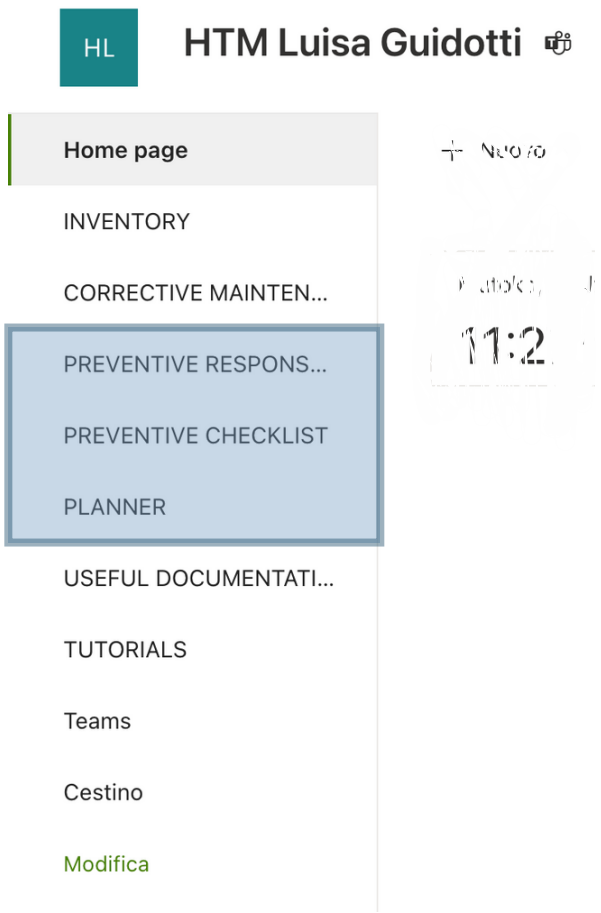
+ Nuovo

**GENERAL MAINTENANCE REGISTER**

| Technician | Date of request | Equipment | Inventory | Department | Person making request | Problem |
|---|---|---|---|---|---|---|
| Gracious | 12/19/2024 | oxygen concentrator | | Adult | | concentrator servicing |
| Gracious | 12/19/2024 | oxygen concentrator | | Pediatric | | concentrator servicing |
| Gracious | 12/19/2024 | oxygen concentrator | | Out patient department | | concentrator servicing |
| Gracious | 24/19/2024 | heater | | Pediatric | | heater |

| URGENCY: 1 = as soon as possible; 2 = in a week; 3 = in a month; 4 = >1 month | What was done/is needed | Status of the request | Complition date |
|---|---|---|---|
| 2 | service | Completed | 19/12/24 |
| 2 | service | Completed | 19/12/24 |
| 2 | service | Completed | 19/12/24 |
| 2 | gluing the parts | Pending | |




20 STANDARD QUESTIONS TO SUPPORT TECHNICIANS IN THE MAINTENANCE:

- **Basic identification**: technician's name, date, department, and inventory code
- **Visual inspection** of the device and accessories
- **Functionality checks** specific to the device
- **Electrical safety**
- **Cleaning and disinfection status**
- **Additional observations**

# Thank You

AFYA MOJA
PROJECT