

The 3rd International Conference ON Biomedical & Clinical Engineering

#### Innovation and Investments in Health Technology: Overcoming Barriers to Successful Uptake

Adham R Ismail, MS, MBA, PhD Regional Adviser, Health Technology and Biomedical Devices (HMD) Eastern Mediterranean Regional Office (EMRO) World Health Organization (WHO)



## Presentation Outline

• Part 1:

Introduction

• Part 2:

Barriers to Innovative Ideas: The Death Valley

• Part 3:

**Barriers to Innovation Uptake** 

• Part 4:

**Overcoming Innovation Barriers** 

• Part 5:

Creative & Innovative Examples



#### Part 1 Introduction





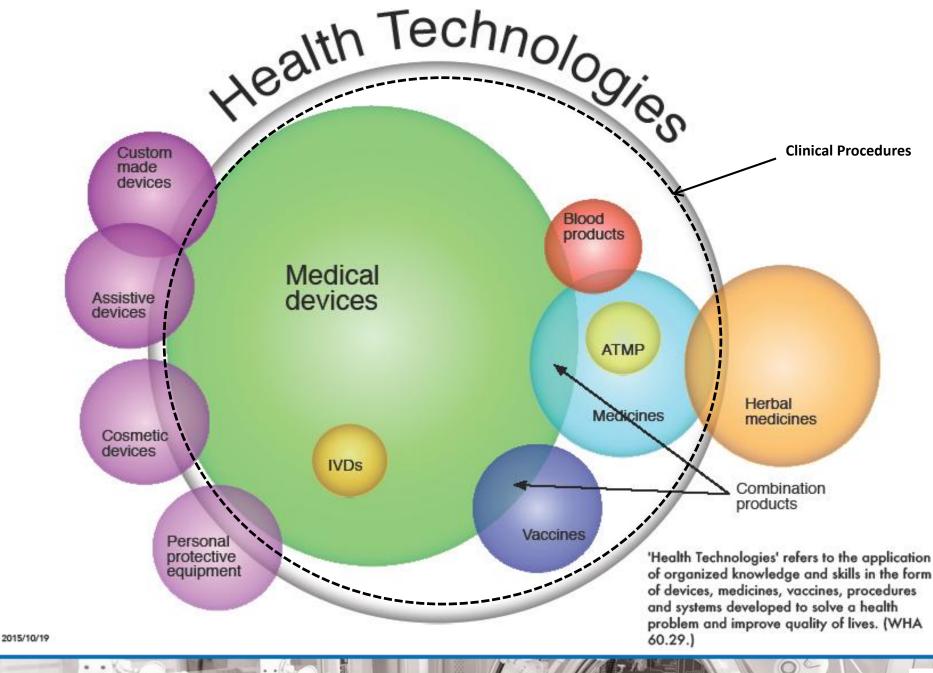
# What is a Health Technology (HT)?

• WHO experts define HT as;

"The application of organized knowledge and skills in the form of devices, medicines, vaccines, procedures and systems developed to solve a health problem and improve quality of lives".

 This definition also encompasses traditional medicine, health promotion & prevention activities and information systems.





#### **HT** Policies

#### Health technology Innovation

#### Medical Processes (R&D)

Business Processes (Marketing, Financing, IT &/or Operating) Health technology regulation

Safety Performance (devices) Efficacy (drugs) Health technology assessment

Health technology management

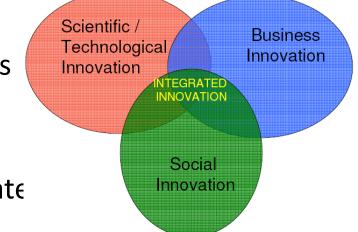
Clinical effectiveness Ethics Social issues Organizational Procurement Selection Training Use

Valley of Death

6

# **HT Innovation: Introduction**

- Public health needs are not often main drivers of innovation, especially in high-resource settings.
- WHO defines innovation as "process cycle of 3 major phases that feed into each other: *discovery*, *development* and *delivery*".
- People often decide whether or not to adopt an innovation based on:
  - Utility of invention
  - Disruptive effects on existing habits
  - Personal values
  - Social status
  - How keen individuals are to innovate



# Willingness to adopt new HT

- Within any population, people have different abilities & willingness to adopt new HT.
- They can be categorized as:
  - "Innovators" constituting 2.5% of pop;
  - "Early adopters" constituting 13.5% of pop;
  - "Early majority" and "Late majority", respectively constituting 34% each of pop;
  - "Laggards" constituting 16% of the pop.
- When considering barriers to innovation, it is important to differentiate between obstacles to innovative ideas and obstacles to the uptake of medical innovation.



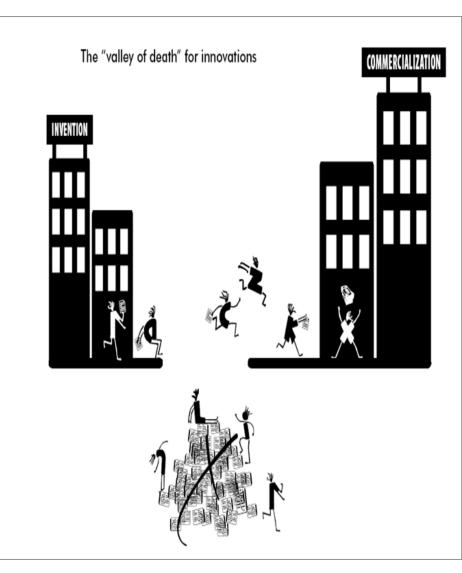
#### **Part 2** Barriers to Innovative Ideas





# The Valley of Death

- Lack of funding can kill good ideas before hitting the market.
- At this stage, risk for innovators is high & profit is uncertain.
- Private sector stay away and prefer to fund more mature projects.



19

# **Out-of-Context Situation**

- Health professionals, especially in low-resource settings, often develop ideas for improving medical devices.
- Difficulties faced in moving innovative ideas forward can be due to:
  - Lack of local research infrastructure
  - Little encouragement for local innovations
  - Lack of marketing mechanisms
- This leads to an out-of context situation where:
  "Medical Devices for low-resource settings are

developed in high-resource settings".



### **Regulatory Requirements**

- Regulations ensure safety but can also be a financial burden on designers and manufacturers, especially in low-resource settings.
- For ex., Immunodiagnostic tests incur low development costs; however, costs are doubled or tripled when they are submitted to regulatory process for licensing.
- High regulatory costs can prompt companies to elude regulatory oversight and market their products in unregulated markets, thereby compromising patient safety.

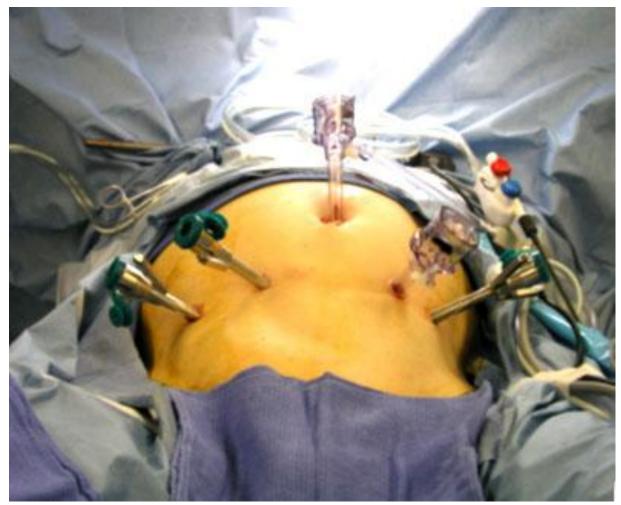


# The need for NRAs

- International standards vary from one local conditions to the other.
  - For ex., standards require batteries of portable defibrillators to function at temp as low as (-10) °C. This might not be applicable to tropical settings.
- Manufacturers are usually asking perplexing questions :
  - Should the same standards be applied everywhere?
  - Could standards be adapted to local conditions?
  - Could lowering standards lead to lowering overall HC standards?
  - What body could authorize such exceptions?
  - Would compliant manufacturers suffer a comparative disadvantage with respect to those who bend the rules?
  - Could compliant manufacturers be permitted to market their products at lower safety, quality, and/or performance than those necessary for other devices?
- National Regulatory Authorities (NRAs) at national, regional and global levels are requied.



#### Part 3 Barriers to Innovative Uptake





# Reluctance, Resistance, Rejection

- Obstacles to the introduction of any new method, procedure or piece of equipment exist in both industrialized and developing countries.
- Common barriers between high- and low-resource settings include:
  - Reluctance to alter existing practices or be trained to develop new skills
  - Resistance can be based on reluctance of the medical community to adopt new technologies.
  - Rejection by traditional communities proud of their culture <u>or</u> of local brands in favor of international brands.



### Inappropriate Design

- Sometimes it is difficult to strike a balance between solving problems & creating new needs.
  - Disposable batteries may solve electricity shortage, but may require a supply chain and waste management.
- An ex. of inappropriate design could be the failure of <u>affordable wooden-seat wheelchairs</u> to achieve widespread use among users in Nicaragua.
  - Though appropriate to local conditions (narrow doorways, high pavements and lack of access to buildings for wheelchair users), it required a cushion to prevent ulcers in people with spinal cord injuries.
  - Although cushions were provided during the first year of use, most people in Nicaragua could not afford a replacement once the cushions wore out.

25

# Cost of Innovative devices

- Though their main purpose is to improve health, in many times innovations lead to escalation in HC expenditures.
- Efforts to reduce costs mean that some innovations will diffuse, while others will not.
- Conversely, inappropriate uptake can lead to overuse of innovative, expensive devices that may not meet urgent clinical needs.
  - The frequent implantation of defibrillators.
  - The inappropriate use of diagnostic imaging devices.



#### Part 4 Overcoming Innovation Barriers





# Identifying local design priorities

- The need and potential for identifying local design priorities is overwhelming.
- Since HT developed in high-resource settings rarely function efficiently in low-resource settings and thus R&D in appropriate local context is urgently needed.
- There are some successful examples of how local innovation based on local design can be widely implemented, such as the Jaipur foot assistive device produced in India.

### The Jaipur Foot Device

• The Jaipur foot is a lower-limb replacement device.



- Imported prosthetics were out-of context as they didn't meet local requirements, such as: <u>need to walk on uneven surfaces</u>, or <u>to sit on the floor squatting or cross-legged</u>.
- The Jaipur foot had special a special design :
  - Made of waterproof, durable material that is locally available,
  - Allows rotation of the foot to facilitate walking on uneven surfaces
  - Cosmetically acceptable so that it can be worn without a shoe
- Price is affordable (US\$ 30), and assembled in 1 hour.
- It was not-patented to facilitate its spread at a low cost.
- Currently used in India, South-East Asia and Africa.

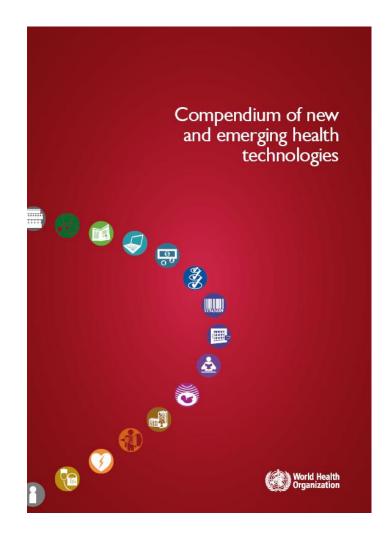


# Networking for Innovation

- Community networks can help with
  - Free exchange of knowledge and experience of imaginative ideas.
  - Support innovation from proof of concept to proof of added value.
- Innovation institutes can help to bridge the gap between research & commercial applications:
  - University of Exeter Innovation Centre in UK,
  - Innovation Center Denmark in Munich, Germany
  - University of Cape Town Centre for Innovation in South Africa
  - Center for Medicine & Innovative Technology in USA
- A call for innovative HT, launched by WHO in 2009, urged inventors to provide solutions to existing health problems. Solutions should be:
  - In the form of existing concepts of technology or those that are still in development.
  - Appropriate for, accessible to, and affordable by lowresource countries.



#### WHO Call for Innovative HT: Commercialized & Under-developed



# **Overcoming the Cost Barrier**

- Financing mechanisms influence the rate at which innovations emerge and gain acceptance.
  - <u>When coronary angioplasty</u> was reimbursed at a level significantly greater than its cost, the procedure was widely adopted.
  - <u>When cochlear hearing implants</u> were reimbursed at a fraction of their cost, their uptake was low.
- Cost barrier could be partly overcome by creating locallyowned companies manufacturing for local markets.
- Governments of some emerging economies subsidize R&D for domestic products to be used in rural areas.
- These companies can soon develop the capability to design and produce HT that compete directly with products patented in Europe, Japan, and the US.

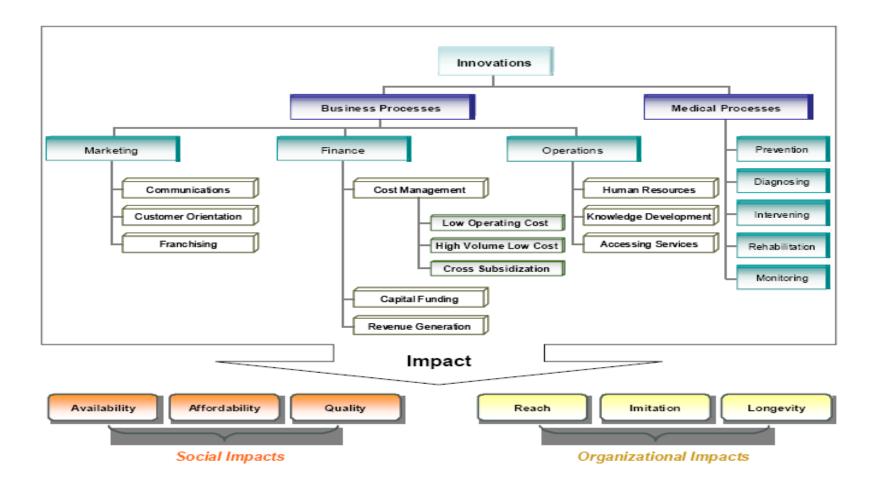


# Inexpensive Innovation in action

- A non-profit hospital in India, teamed up with industry to manufacture high-quality intraocular lenses, suture needles, pharmaceuticals, surgical blades, & hearing aids.
- This resulted in overcoming cost barrier of many products
  - Hearing aids sell for about US\$ 50 a piece, versus around US\$ 1500 in US.
- A sliding scale charging model was adopted such that:
  - Poorest people pay nothing
  - Moderately poor pay a price that roughly covers the manufacturing costs (between US\$ 20 and US\$ 60)
  - Well-off people pay higher prices to generate profit and offset losses on below-cost sales.
- In this way, sufficient revenue is gained for the company to be profitable and grow while serving the poorest.



#### Part 5 Creative & Innovative Examples



Innovation in Medical Processes, Prevention Stage:

- A non-profit social enterprise in India developed a kit that allows lay health workers to screen for problems with visual acuity.
- The treatment can be made with inexpensive reading glasses (less than \$4).
- This new process makes it possible for staff with limited training to screen people door-to-door, thus greatly facilitating access to this service.
- Now they are operating in 13 countries, including: El Salvador, Guatemala, Bangladesh, Mexico, Ghana, and Sub-Saharan Africa.



Innovation in Medical Processes, Treatment Stage:

- Another vision company innovated a surgical procedure for cataracts that does not require sutures and that makes use of a mobile microscope.
- Accordingly, one surgeon can operate at two tables, side by side.
- This results in great reduction of costs (no expensive sutures and less space required) and increase in service volume (reducing time needed for a surgery).

39

39

• From April 2007 to March 2008, about 285,000 have undergone eye surgeries using this innovation.

Innovation in Medical Processes, Rehabilitation Stage:

- A company specialized in manufacturing prosthetics innovated a new affordable, hand-made prosthesis that is fitted using a one-time intervention procedure that minimizes the need for follow-up.
- The prosthetic limb costs approximately \$35 with materials that can be locally found in any developing country (normally costs \$4,000 to \$8,000 in USA).
- Outreach camps to promote the product are present in many countries, including: Afghanistan, Bangladesh, Dominican Republic, Honduras, India, Indonesia, Malawi, Nigeria, Nepal, Kenya, Panama, Philippines, Papua New Guinea, Rwanda, Somalia, Trinidad, Vietnam, Zimbabwe, and Sudan.



Innovation in Business Processes, Financing Strategies

- A non-profit hospital in India, have teamed up with industry to manufacture high-quality intraocular lenses, suture needles, pharmaceuticals, surgical blades, and hearing aids.
- Hearing aids sell for about US\$ 50 a piece vs. approx. US\$ 1500 in USA.
- Price reduction stems from a sliding scale charging model adopted by company:
  - Poorest people pay nothing
  - Moderately poor pay a price that roughly covers the manufacturing costs (between US\$ 20 and US\$ 60)
  - Well-off people pay higher prices to generate profit and offset losses on below-cost sales.
- In this way, sufficient revenue is gained for the company to be profitable and grow while serving the poorest.



Information and Communication Technologies (ICT)

- ICT can provide important solutions to many existing health problems.
  - For ex., handheld computers equipped with various sensors could provide remote consultation, diagnosis and treatment.
- A Local hospital in Gambia provide remote health services to residents in a Ginnack (a remote island village) as follows:
  - Nurses visit the island twice a week and take digital pictures of the patient's visible symptoms.
  - Pictures are taken to local hospital physicians examine them.
  - If further consultation is required, the physician can send the pictures over the internet to a medical institute in the UK.
- Success of ICT methods relies on presence of strong power infrastructure, internet connectivity, trained staff, and supporting government regulations.



#### 됩 3 듣 D C F **\_** ADVA SC CE NCE **RKS REA** E $\overline{\mathbf{V}}$

Albert Einstein, 1921

