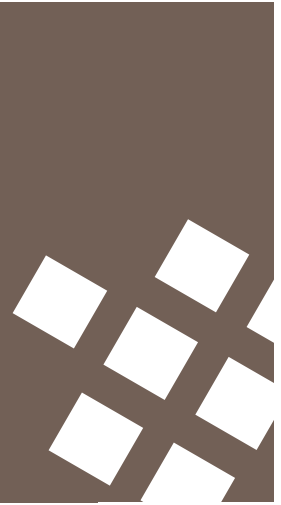


Health technology assessment of medical devices

PRESENTED BY

DR JOSIP CAR

16TH JANUARY 2013



How do we fix diabetes?

Pocket-size answers for
population-size problems

Josip Car, José Marcano and Kit Huckvale
Global eHealth Unit



Overview

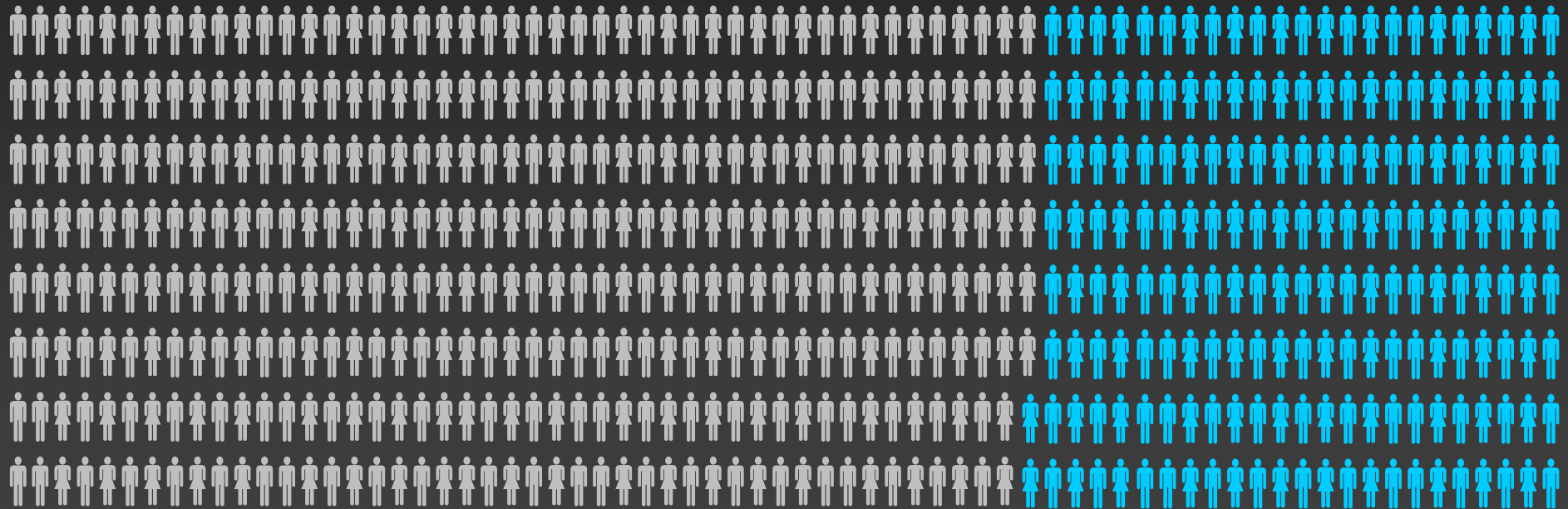
The future for diabetes

Smartphones and apps

Pocket-size potential: case studies

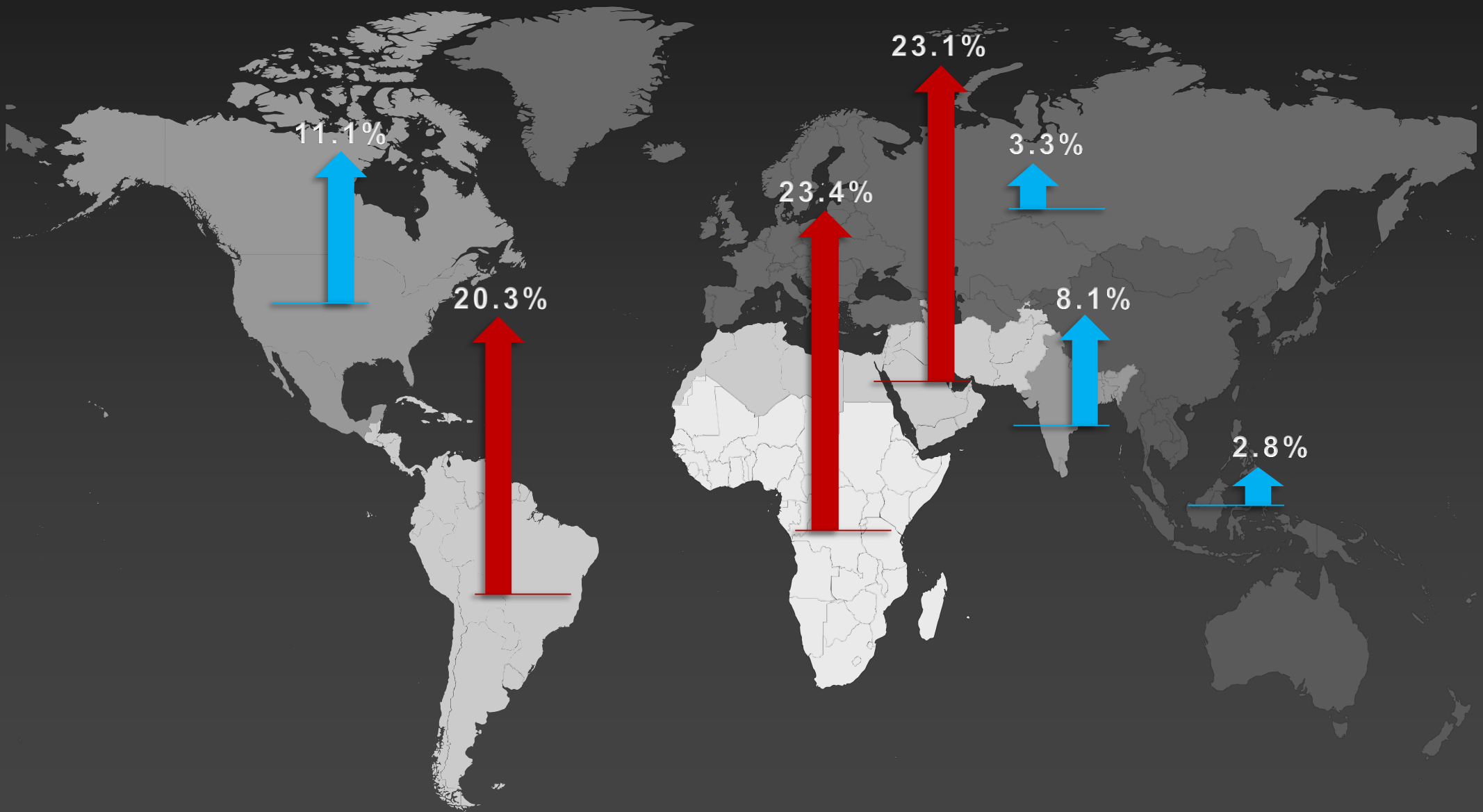
Benefits for patients, clinicians and providers

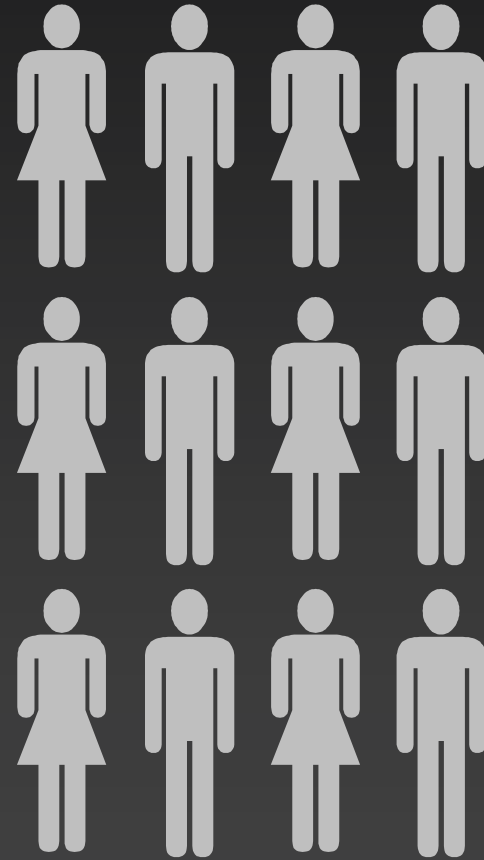
2011 2012 2013 2014 2015 2016



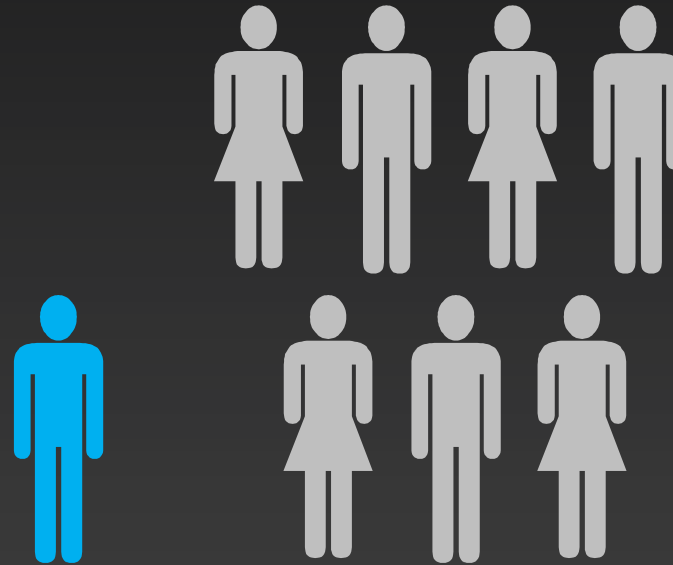
50% more

546,100,000 people
900,000,000 people





1 in 13 people



1 in 3 people

\$1040m
\$2000m

2022
5050

From prevalence to impact

Cost to patients

Mortality

↓ 10yr Type 2 diabetes

10% of all deaths

Comorbidity

↓ 10%
x2 Risk of CVD

1 in 3 Renal disease

Challenges for patients



Understanding the condition

Making informed treatment choices

Sustaining diet, exercise and self-care
Behaviours over years

Balancing current control against
risk of future complications

Coping with evolving disease

Accessing timely care

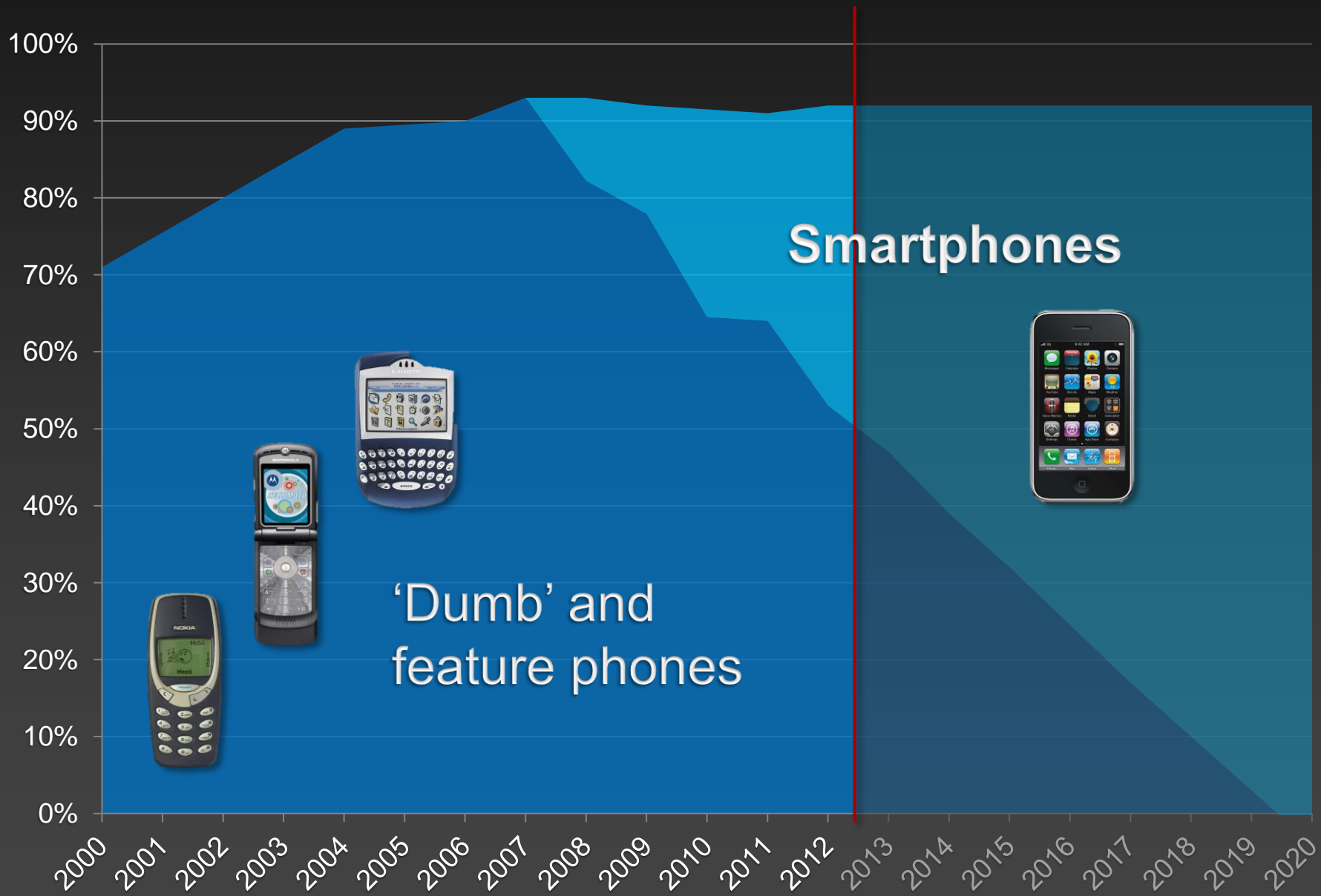
Navigating complex health systems

Challenges for clinicians and providers



Only 7% of US patients meet targets for blood sugar, lipid and blood pressure control

Saydah, Fradkin and
Cowie 2004



Mobile uptake

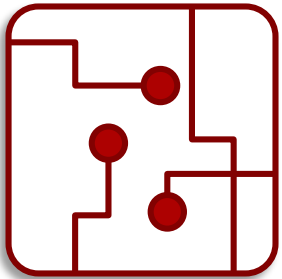
Mobile uptake



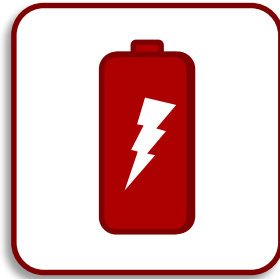
- 46%** Email
- 41%** Browsing
- 40%** Social networking
- 32%** Music
- 20%** Games
- 18%** Shopping
- 13%** Banking

Routine smartphone use

Smartphone features...



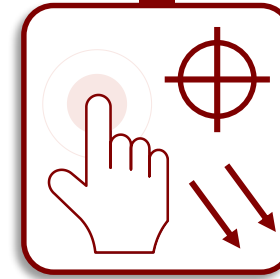
Powerful
handheld
computers



All-day
batteries



Ubiquitous
wireless
connectivity



Integrated
sensors



Apps

Sensors



Touch



Geolocation



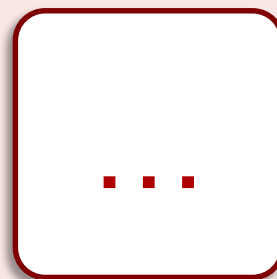
Sound



Imaging



Accelerometry



External
sensors



Sensing for health

Barcode scanning
Drug provenance verification
Camera



- Tremor analysis (Archimedes spiral)
Parkinson's disease
Touch
- Activity logging
Rehabilitation
Accelerometry and geolocation
- Pulse and respiration
Diagnostics
Imaging
Spirometry
COPD/Asthma
Microphone
- Falls detection
Elderly care
Accelerometry
- Blood glucose
Diabetes
Plug-in sensor

Complex sensor and data integration

Current location

Geolocation

Appointment schedule

Calendar

Historical walking speeds "Leave now to be on time"

Geolocation and accelerometry

Imperial Presentation

Sherfield Building, Exhibition Road, Kensington SW7 2AZ

Piccadilly Line departs in 10 min (walk 6 min to Barons Court)

Distance to travel
Geospatial data

Train routes

Public datasets (TFL)

Behavioural traffic status

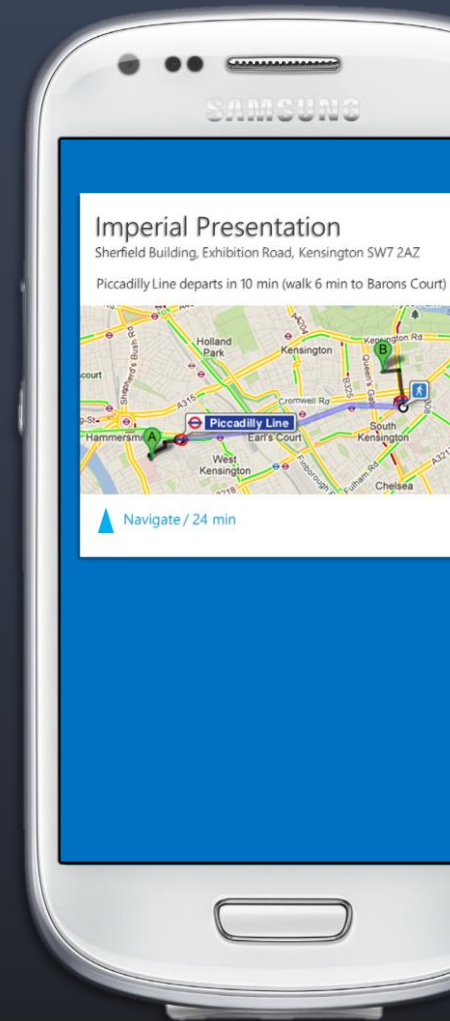
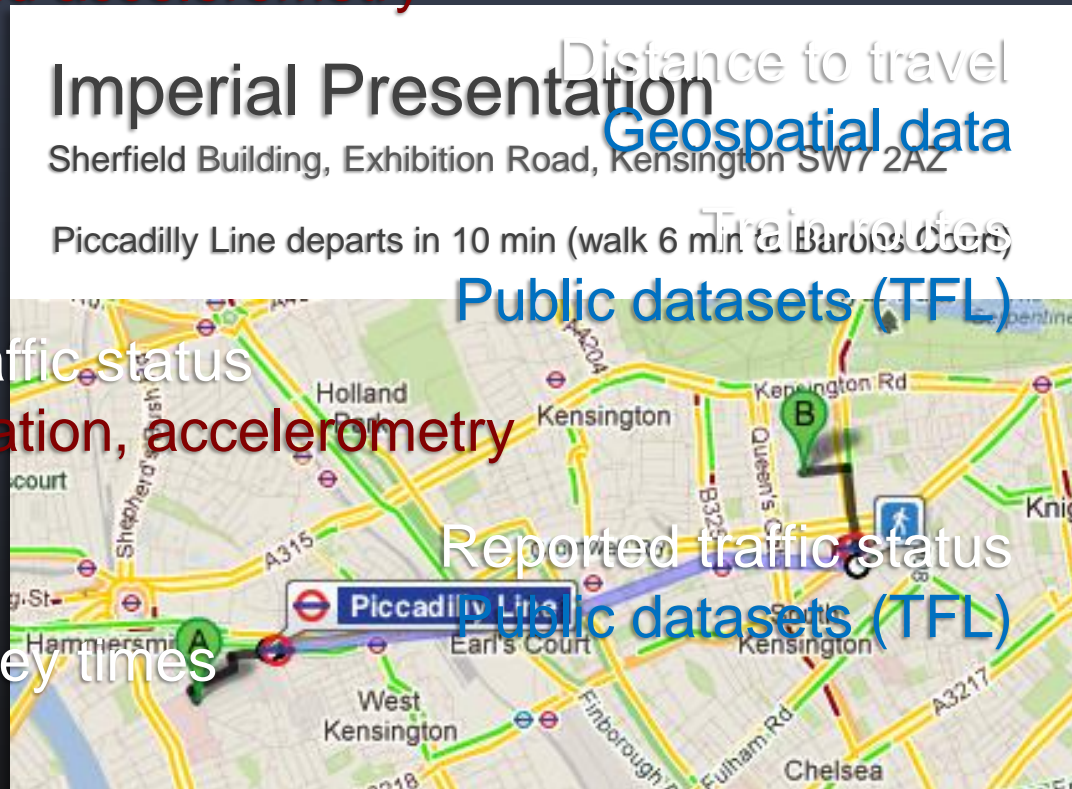
Sound, geolocation, accelerometry

Reported traffic status

Public datasets (TFL)

Historical journey times

Geolocation



Sensors



Touch



Geolocation



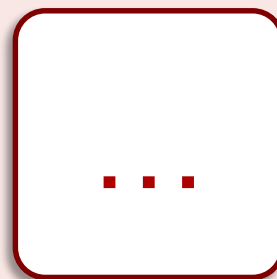
Sound



Imaging



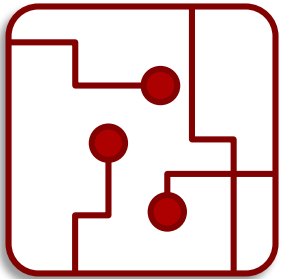
Accelerometry



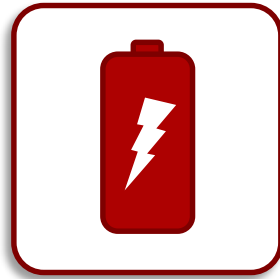
External
sensors



Smartphone features...



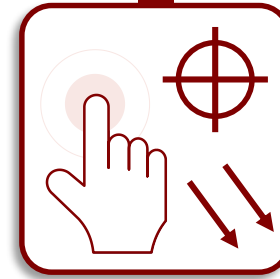
Powerful
handheld
computers



All-day
batteries



Ubiquitous
wireless
connectivity



Integrated
sensors



Apps

... and how people use them



Always On



Always Carried



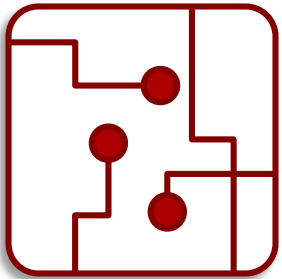
Private



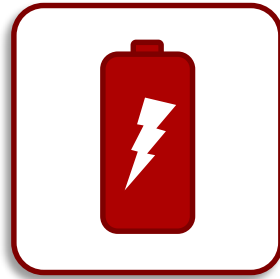
Task-oriented



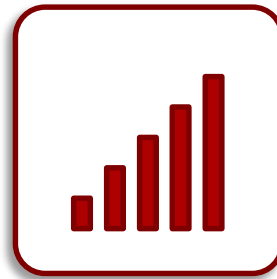
Smartphone features...



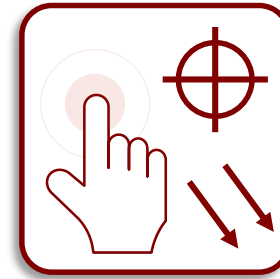
Powerful
Handheld
computers



All-day
batteries



Ubiquitous
wireless
connectivity



Integrated
sensors



Apps

Small software packages that extend smartphone functions

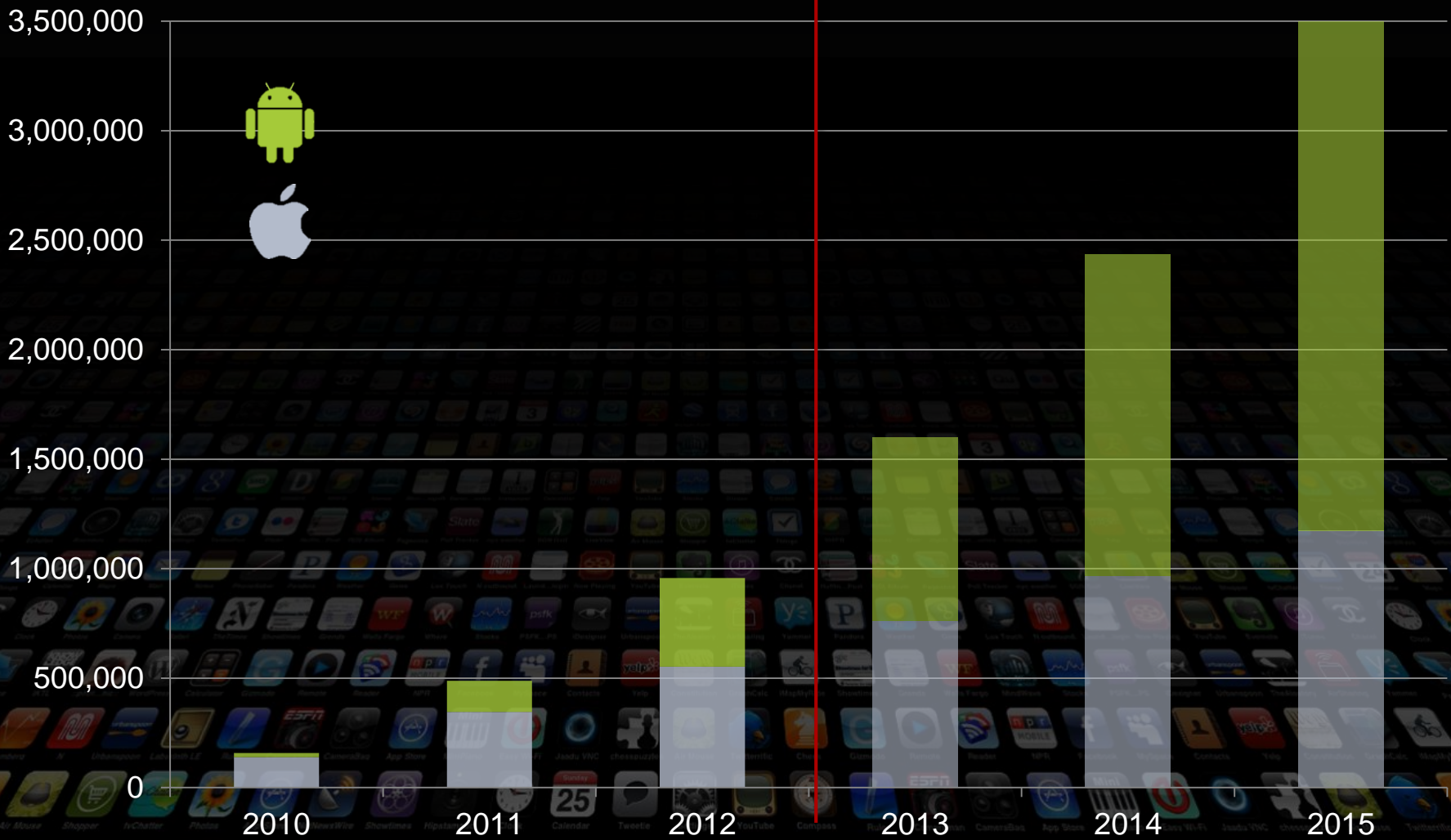
Optimised for touch and user experience

Able to use full range of device sensors, network connectivity and multimedia graphics

No-cost distribution and update through online app stores

Free, paid and 'freemium' models





Published apps

Source: Multiple



Pocket-size potential

How could apps for diabetes help?



Getting the best start

Optimal management **at the time of diagnosis**

- A frightening and uncertain time
- Frequently inconsistent
- Rushed *or* delegated and therefore delayed

Lead time for DESMOND: XXXX

- Does not recognise health literacy issues

Significant association with diabetes control

e.g. Tang et al., 2008

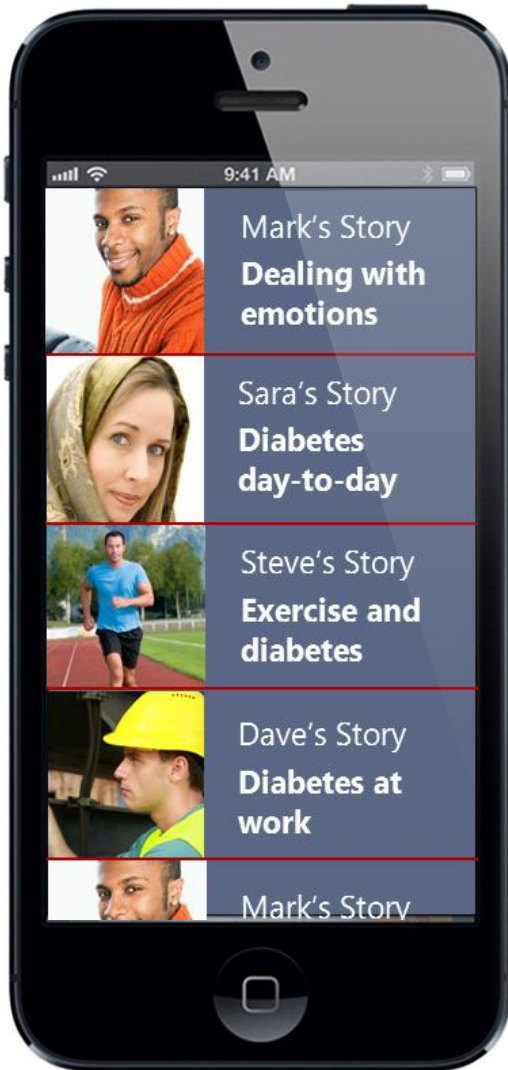


but also...

- Opportunity to build partnership and set goals
- Potential driver for changes in behaviour
- Time to establish self-care routines that will need to last a lifetime
- Opportunity for support from patients with same lived experiences

Getting the best start

App potential



'Diabetes Stories' App

No delays

- Prescribed at the time of diagnosis

Consistent but tailored:

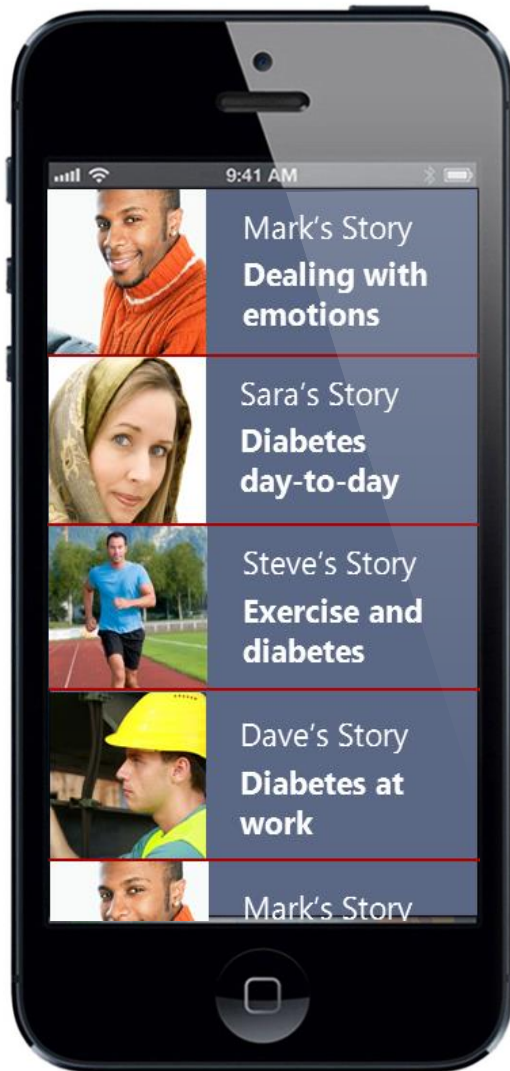
- Simple setup questions
- 'Recommended for you' content

Literacy needs taken into account

- Screening questions
- Accessible content in a range of formats
- User sets pace

Getting the best start

App potential



'Diabetes Stories' App

Shared experience

- Emphasis on narrative and lived experiences, e.g. talking heads
- Links to third party support

Better than the web

- Personal and private
- Set it up in the moment
- Pick up where you left off
- No login prompts
- Bridge to self-monitoring, reminders, etc.



Care for all

The potential of smartphones as medical devices

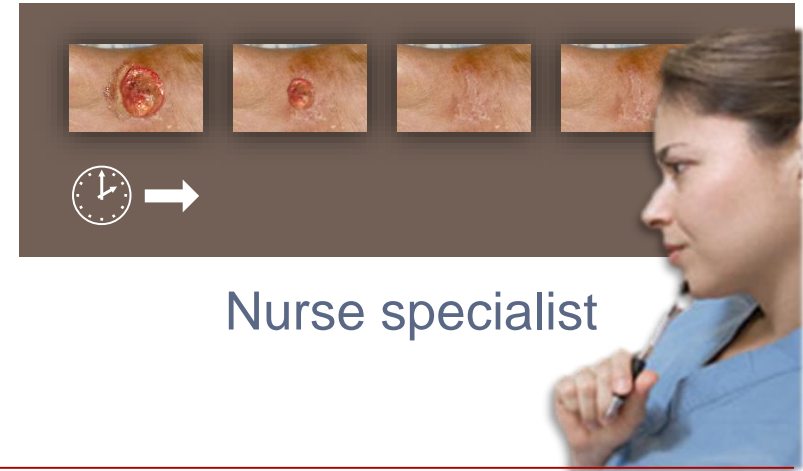
Availability and cost of medical devices is a barrier in developing settings

Untapped power of device sensors

Care for all

App potential

Patient or clinician



Wound Tracker

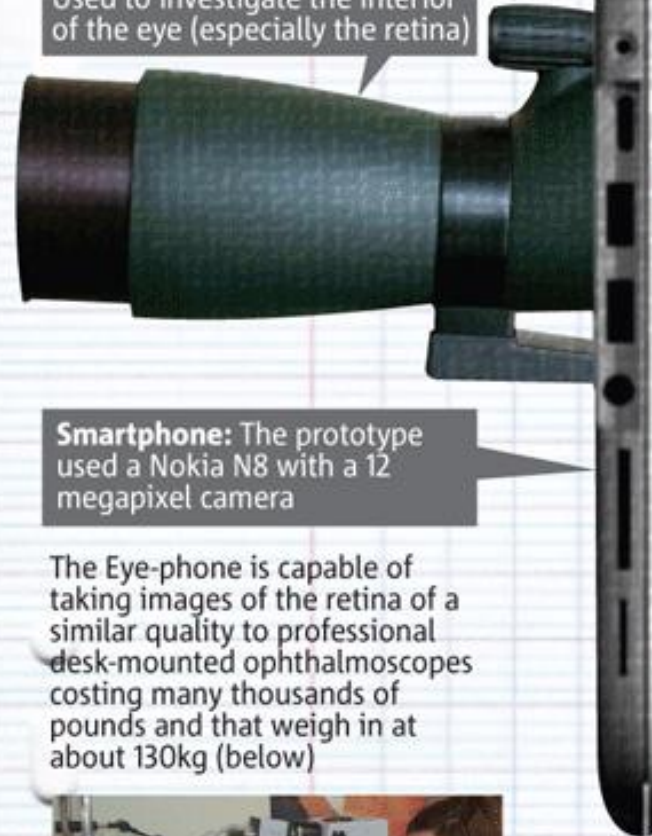
Native device camera and network

Track progress of slowly healing wounds over time

Access expertise remotely

The Eye-Phone

Modified ophthalmoscope:
Used to investigate the interior of the eye (especially the retina)



Smartphone: The prototype used a Nokia N8 with a 12 megapixel camera

The Eye-phone is capable of taking images of the retina of a similar quality to professional desk-mounted ophthalmoscopes costing many thousands of pounds and that weigh in at about 130kg (below)



The phone is designed to measure vision and the causes of blindness such as cataract or glaucoma



By contrast the Eye-phone only weighs 625g and costs less than a thousand pounds



Information can be shared with experts anywhere in the world in real-time or can be stored on Google Maps for location at a later date



Eye-Phone
Bastawrous 2012

Getting the best start

App potential

Medical Sensing Apps

Advantages

- Cheap
- Portable
- Integrated technologies
 - Decision support
 - Data sharing

Work in progress

- Performance and reliability
- Regulation and safety



Breadth of applications

- Day-to-day management of long-term conditions
- Patient self-monitoring and record keeping
- Communicating health behaviour risks
- Communicating condition-specific information
- Health promotion
- Social interaction and support
- Time and context specific tasks – drug reminders, local health service finder, etc.
- Administrative tasks – appointments, prescriptions, etc.

Benefits for patients

Information and support tailored to changing personal needs

Simplified diabetes self-monitoring

Integration into day-to-day routine

Access to social support

Possibility of improved clinical outcomes



What is the potential?

HbA1c ↓ 1.9% Mean Absolute Reduction

Mobile Diabetes Intervention Study
1 year cluster RCT

Quinn et al. 2011

“Each 1% absolute reduction in mean A1C levels [is] associated with a 37% decrease in the risk of microvascular complications and a 21% reduction in the risk of any diabetes-related complication or death.”

UKPDS
2000

Benefits for clinicians

Flexibility to meet specific clinical needs

Easily 'prescribed'

Balance between delivering consistent messages and per-patient tailoring – mass customisation

Source of monitoring data

Potential for improved clinical outcomes



Introduction

- Definition of HTA, where it fits in & how to use it
- HTA around the world – your partners
- Challenges and issues
- Opportunities and enablers
- Strategic actions for advancing HTA into developing and emerging countries
- Working group session



Definition

- *HTA is “the systematic evaluation of properties, effects, and/or impacts of health-care technology. It may address the direct, intended consequences of technologies as well as their indirect, unintended consequences. Its main purpose is to inform technology-related policy-making in health care. HTA is conducted by interdisciplinary groups using explicit analytical frameworks drawing from a variety of methods”*

HTA Glossary

<http://www.htai.org/>

<http://www.inahta.org/>



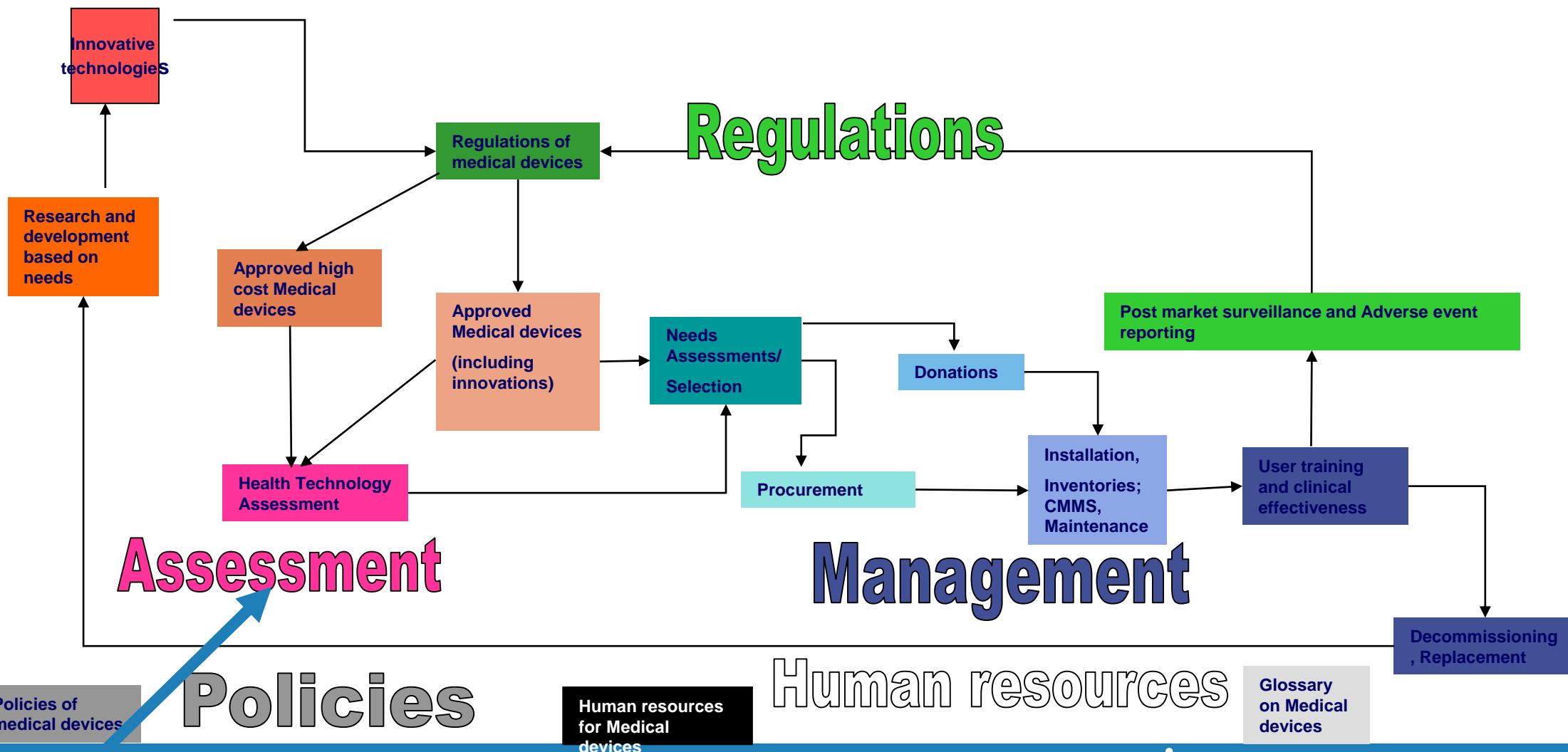
Importance of HTA

- Optimization of decision making processes – balance access, quality and sustainability
- Inform practice and governance
 - contextualization of global knowledge
 - transparent decision-making
 - overall vision of equity and accountability
- Legitimate decisions, policy and practice
- Diffusion of innovation

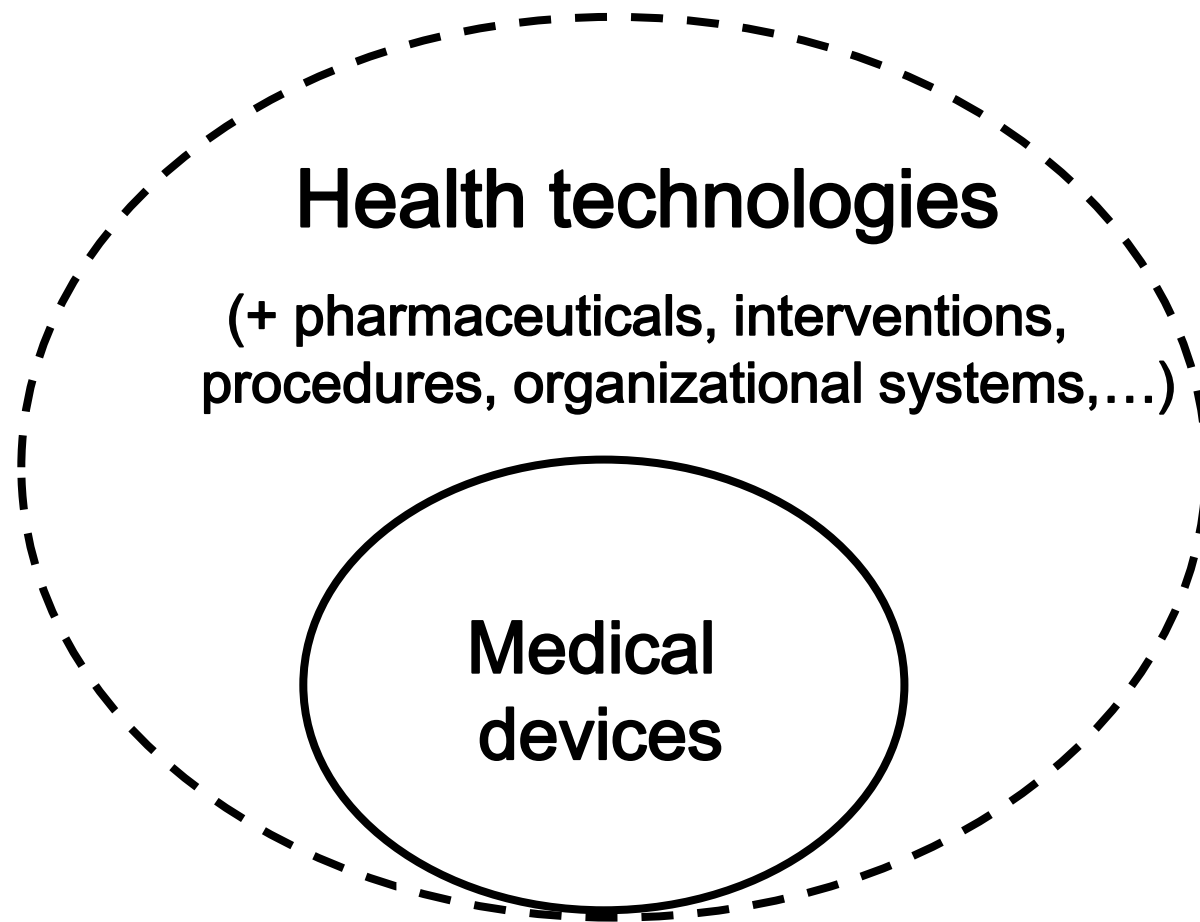


To ensure improved access of safe, quality medical devices

Research and development



Resolution WHA 60.29



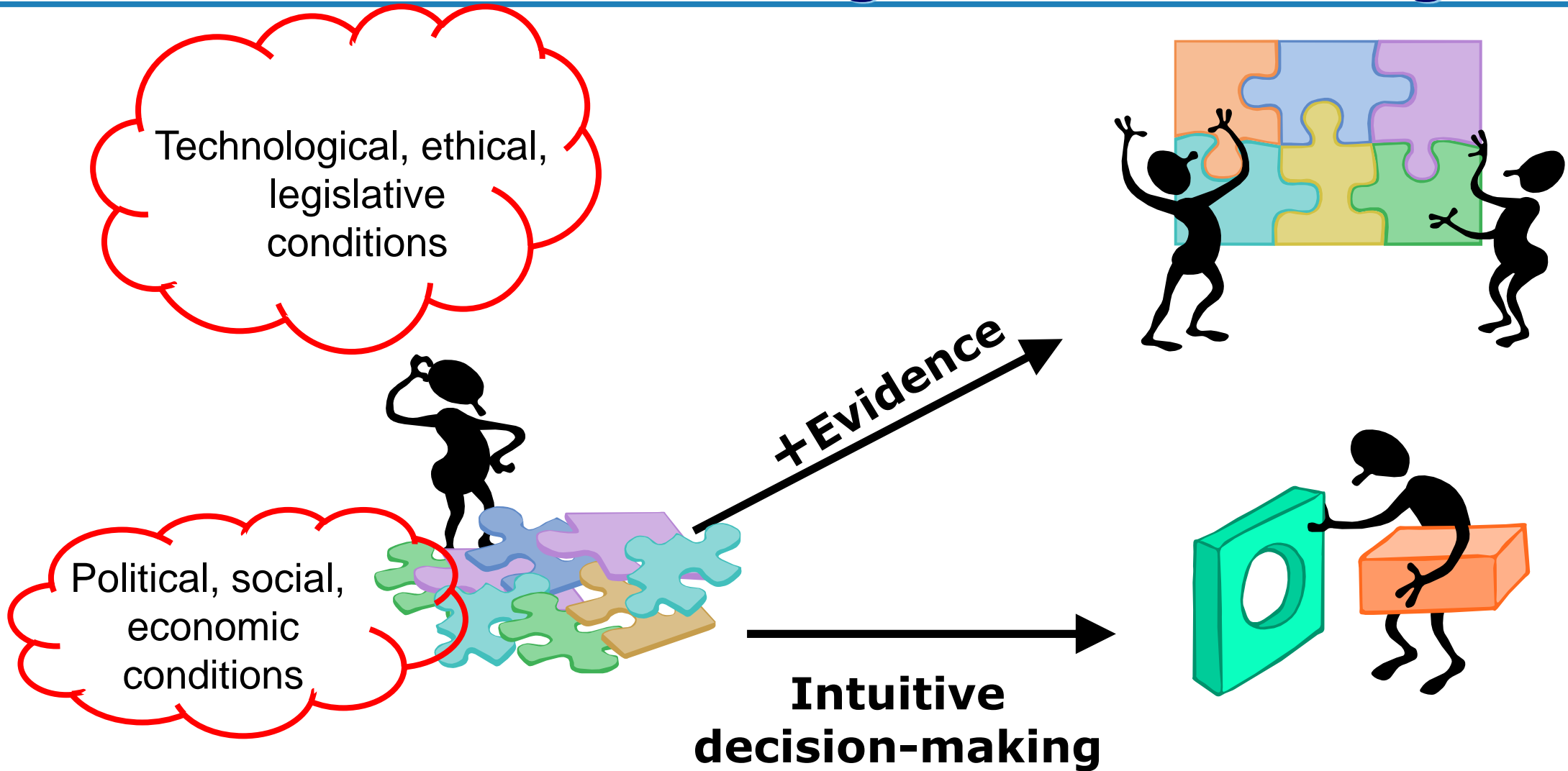
« medical devices as a major subset of health technologies »

Purpose of the lecture

- To provide a background to the concept, best practice and programme of HTA around the world
- To highlight the contribution that HTA can make to informed policy- and decision-making
- To describe strategic actions for advancing HTA into developing and emerging countries
- To support informed decision-making on the introduction of HTA into the health systems of developing and emerging countries.



Evidence for informing decision-making



Evidence...

My facts	Your facts
Adequate facts	Bare facts
Neutral facts	Made up facts
Disputable facts	Indisputable facts

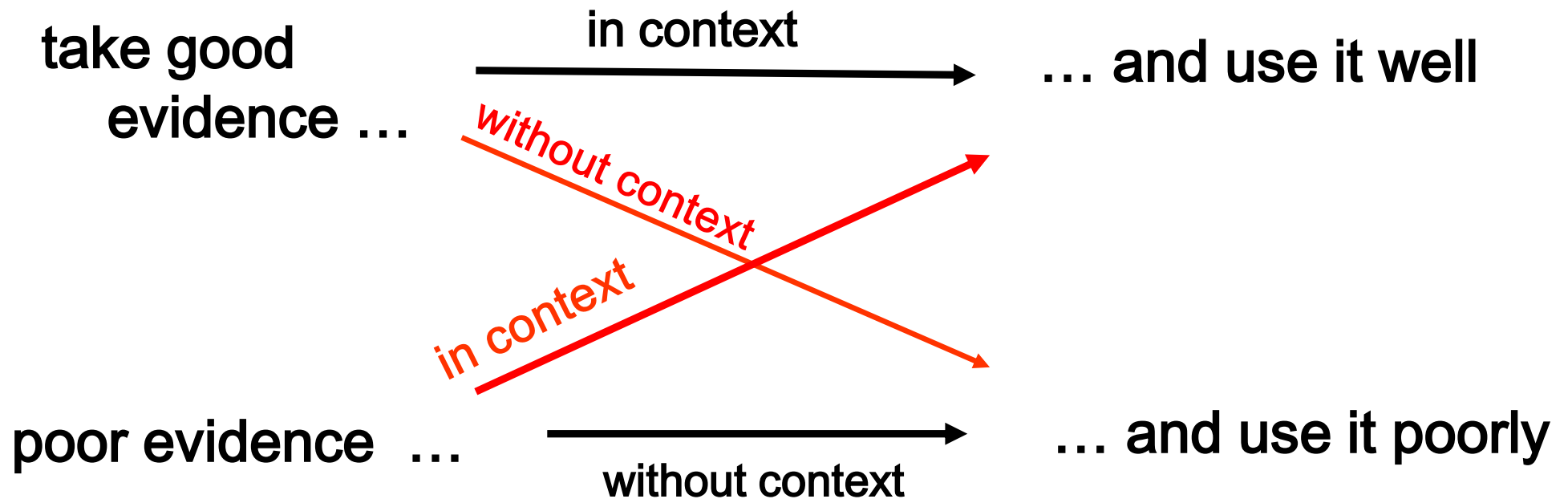


The process of evidence generation and use may be more important than the evidence itself.



Context is essential for evidence-informed decision making

There are decisions that...

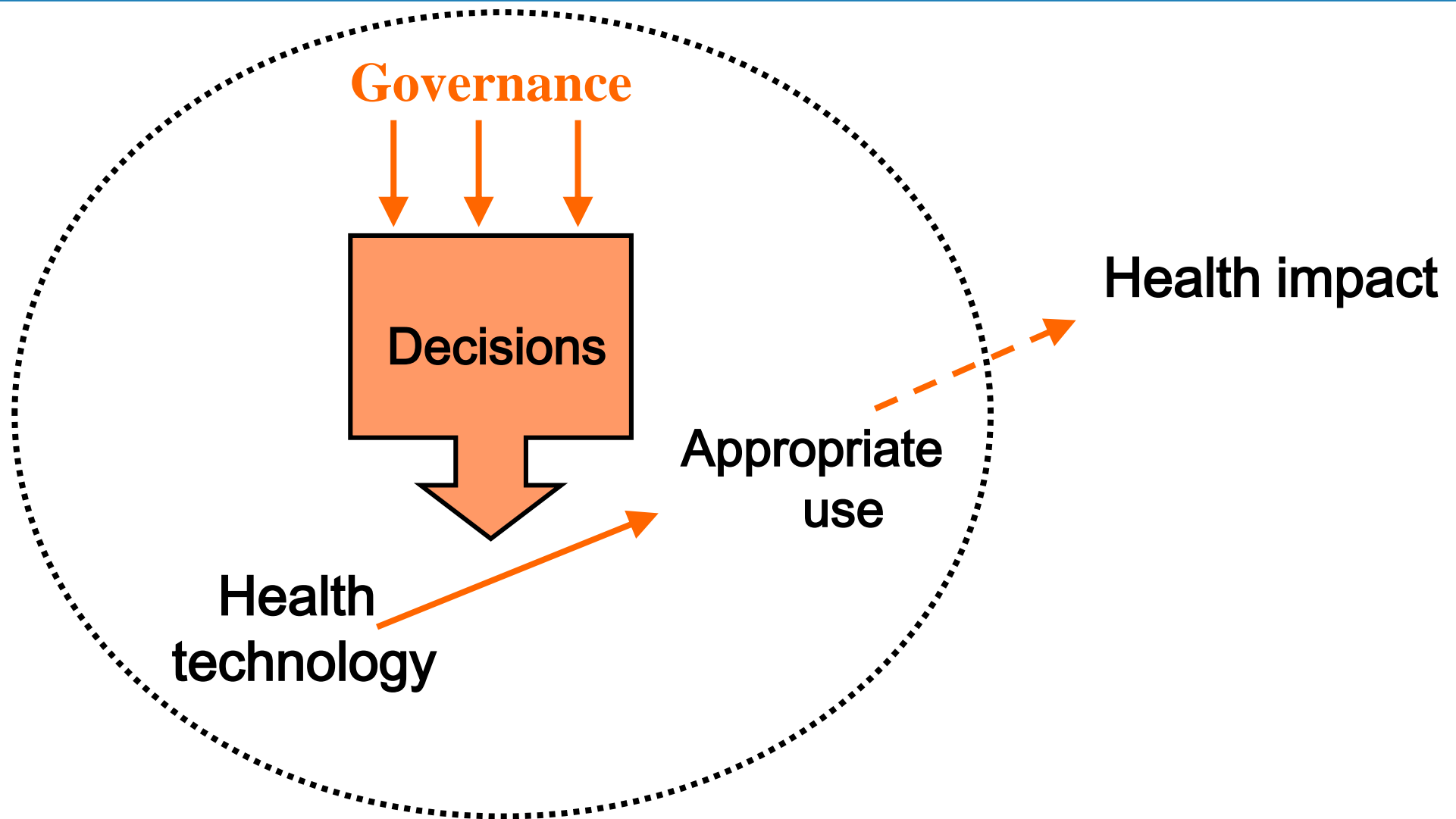


Adapted from Shaxson, L 2004: Evidence-based policy making: if it exists what makes it robust? Available at <http://bit.ly/hlsNC>

Canadian Society for International Health Approach to Health System Strengthening

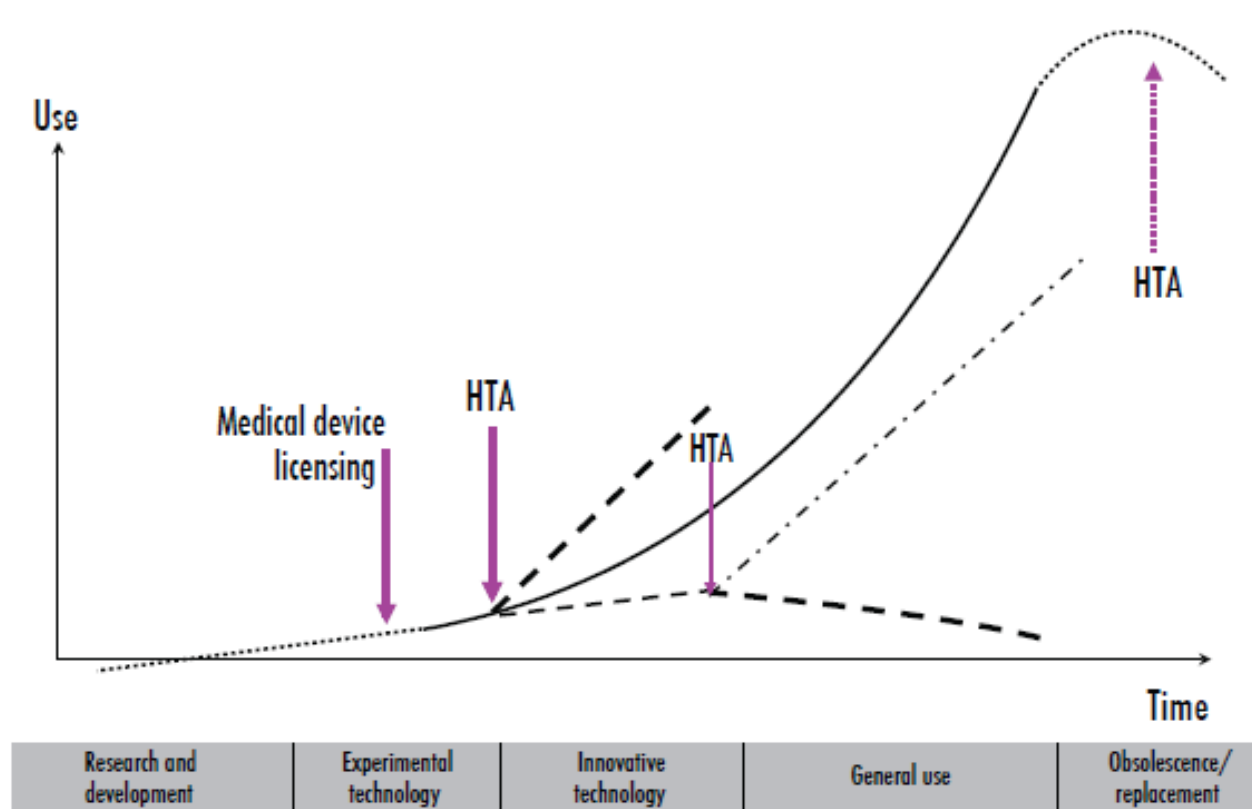


Improving health by improving decision-making



Where can HTA have an impact?

HTA and diffusion of health technologies



HTA products

- HTA report
- Rapid review
- Information service
- Horizon scanning
- Always
 - Policy oriented
 - Research question
 - Context embedded
 - Methodologically sound



HTR and HTA

Characteristics	Health technology regulation	Health technology assessment
Perspective	Safety and efficacy	Efficacy, effectiveness and appropriateness
Requirement	Mandatory	Recommendation on complex technologies
Role	Prevent harm	Maximize clinical and cost effectiveness

HTM and HTA

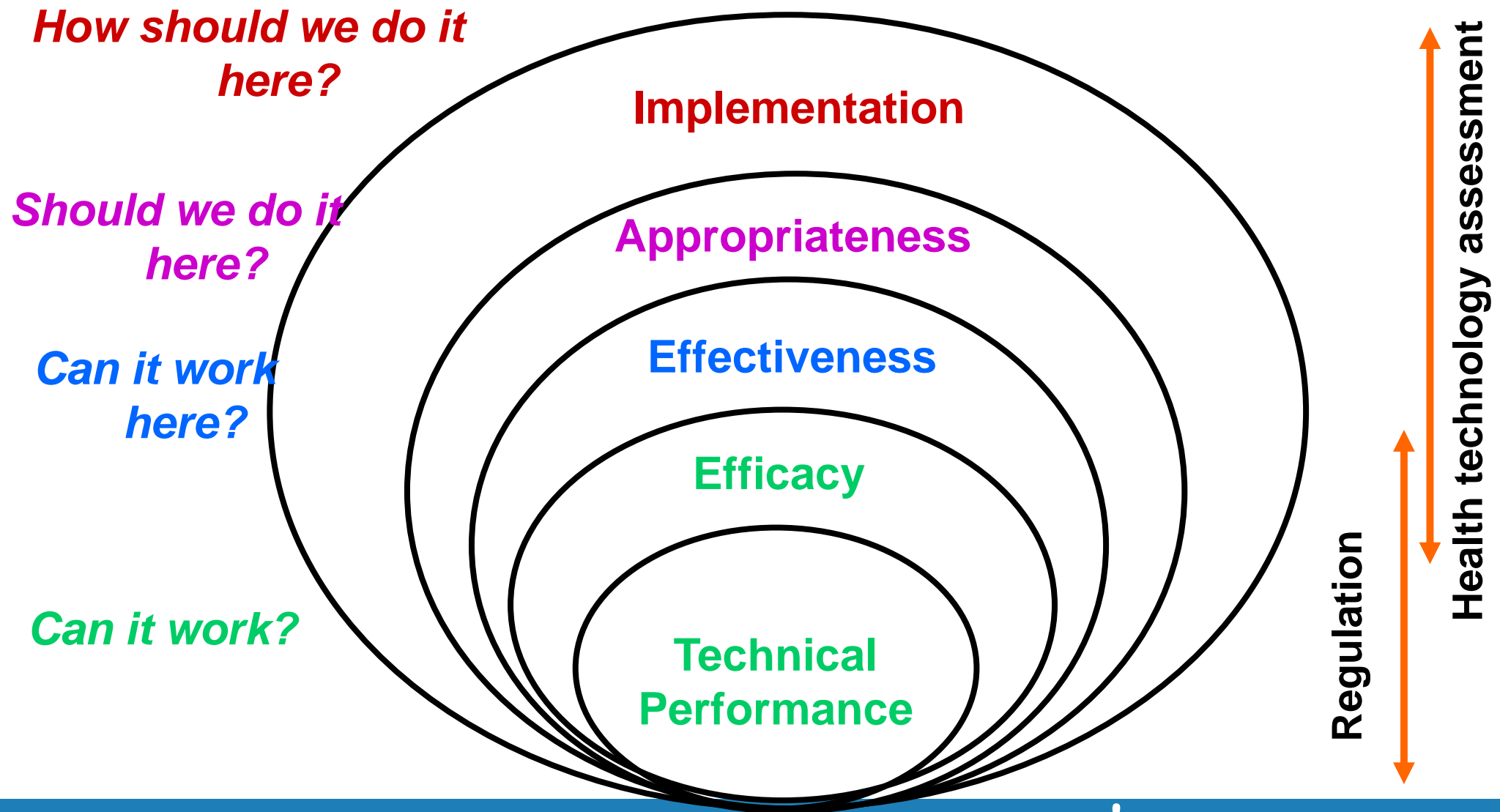
Characteristics	Health technology management	Health technology assessment
Perspective	Health facility	Societal
Orientation	Community served	Population health
Method	Project management, technology life-cycle	Systematic critical review, meta-analysis
Criteria	Needs analysis, alternatives, specifications	Clinical effectiveness, cost effectiveness, appropriateness
Outcome	Decision	Policy/decision/practice



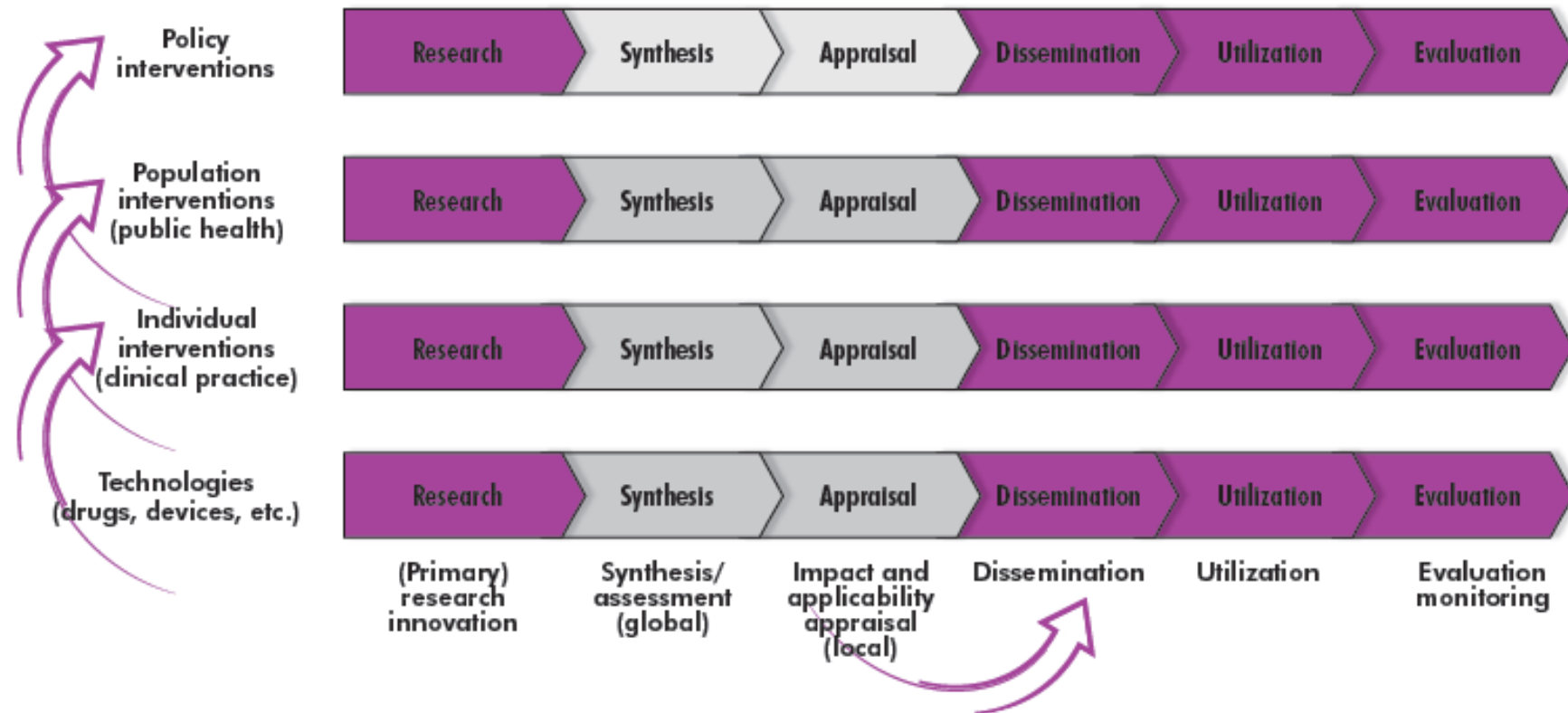
Collaborating for improved health



Layers of questions & layers of evidence



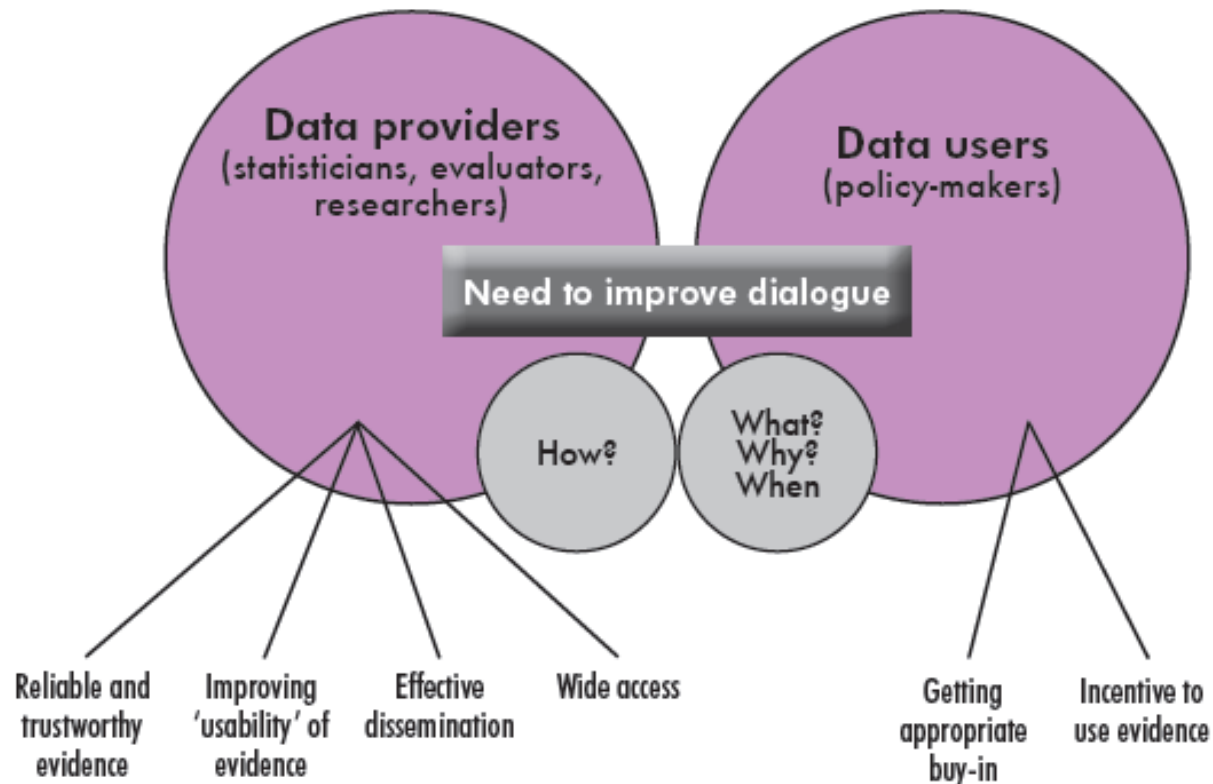
Knowledge chains and learning loops



WHO Research Strategy and goals of HTA

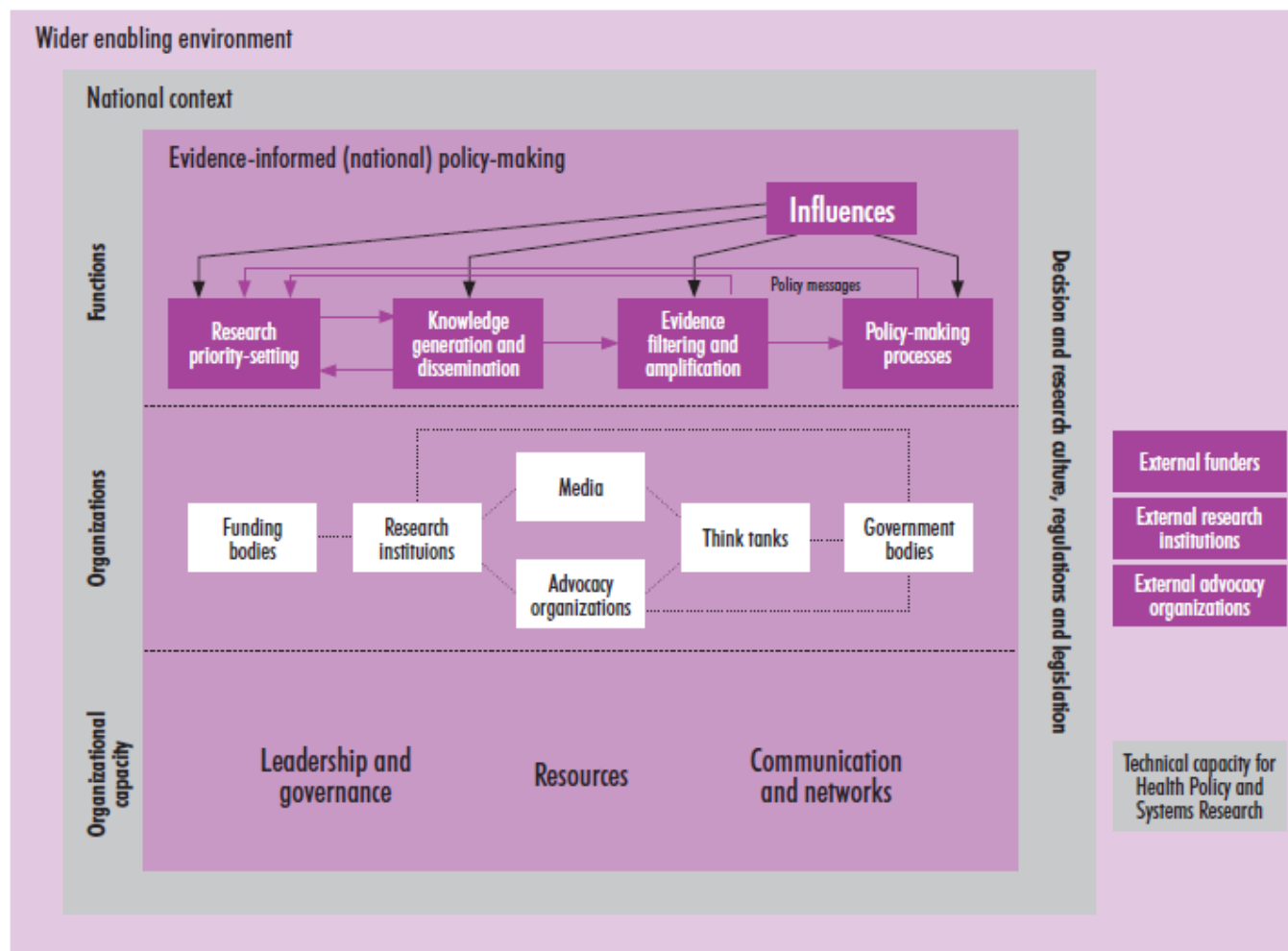


Good quality evidence – matching rigour and relevance



The need to improve the dialogue between policy-makers and evidence providers

Framework for evidence informed policy making



Source: [2]

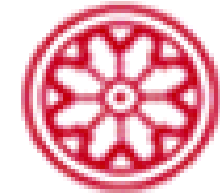
HTA & innovation

- Kind of innovation
 - What is new?
 - Product, process, input, organizational, social
- Subjectivity of innovation
 - New for whom?
 - Individual, group, organization, industry, society
- Degree of innovation
 - How new?
 - Market, technology, organization, environment



International collaborations in HTA

- International Network of Agencies in Health Technology Assessment (INAHTA)
- Health Technology Assessment international (HTAi)
- European network for Health Technology Assessment (EUnetHTA)
- WHO collaborating centres



INAHTA



eunethta





- HTAi scholarship program specifically for capacity-building in Africa (can support academic programs, internships, even appropriate short courses in HTA or related fields). Travel grants to attend our annual meetings
- HTAi Developing Countries Interest Sub-Group, Joseph Mathew
- SIGNET http://www.htai.org/fileadmin/HTAi_Files/Newsletters/HTAi-Newsletter-June2010.pdf.
- HTAi participated in the WHO's First Global Forum on Medical Devices 2010
- HTAi resources on the web www.htai.org



Challenges

- Balancing access, quality of care and sustainability of the health care system
 - Managing expectations
- Population health benefit
- What results in the greatest clinical benefits to the community?
- Are the interventions cost effective?
- Can we afford this? (appraisal)



Challenges

- Different epidemiological environments
- Physical environments
- Financial resources
- Health care financing and distribution mechanisms
- Cultural acceptance of health care interventions
- Values for personal choice, equity, efficiency
- Technology maintenance capacity
- Civil and health care infrastructure
- Skilled human resources
- Training and education
- Regulatory environment
- Health professional standards
- Profitability of health care mkts

Challenges

- Available data is not context-specific (often from high-income countries with different contexts)
- Desirable or acceptable levels of safety, effectiveness, cost-effectiveness, and other attributes of a technology, as well as acceptable trade-offs among these, may vary in different communities, countries, or other circumstances
- Planning and regulatory systems are often in their infancy



7 enablers for supporting use of evidence to inform policy

- Collaborate with others
- Establish strong links with policy makers and involve stakeholders in the work
- Be independent and manage conflicts of interest
- Build capacity among those working in organizations
- Use good methods and be transparent
- Start small, with clear audience, scope and address important questions
- Be attentive to implementation considerations



HTA country pilot projects

- Contextualize the pilot to the setting
- Identify a local organization and champion responsible for the pilot and become the country **focal point** for HTA
- Link the pilot to the government and credible government official with a commitment to sustaining the project
- Develop and nurture appropriate national and international linkages & exchange to the international HTA community and WHO Collaborating Centers



HTA country pilot projects

- Identify and prioritize relevant and timely HTA projects
- Develop a pilot implementation plan with realistic and attainable results in HTA, dissemination and policy engagement
- Evaluate the pilot with lessons learned and opportunities for improvement.



Role of the HTA Focal Point

- Become recognized
- Develop and sustain a network of HTA stakeholders within policy community
- Facilitate flow of information international to local and *vice versa*
- Primary contact for HTA resources and information
- Organize & facilitate meetings and workshops to those wanting to use, interpret and use HTA
- Identify and articulate the HTA needs and priorities of key audiences
- Facilitate interaction between HTA producers and users with sustained relationship and build capacity and capability within a global context



Building HTA Awareness

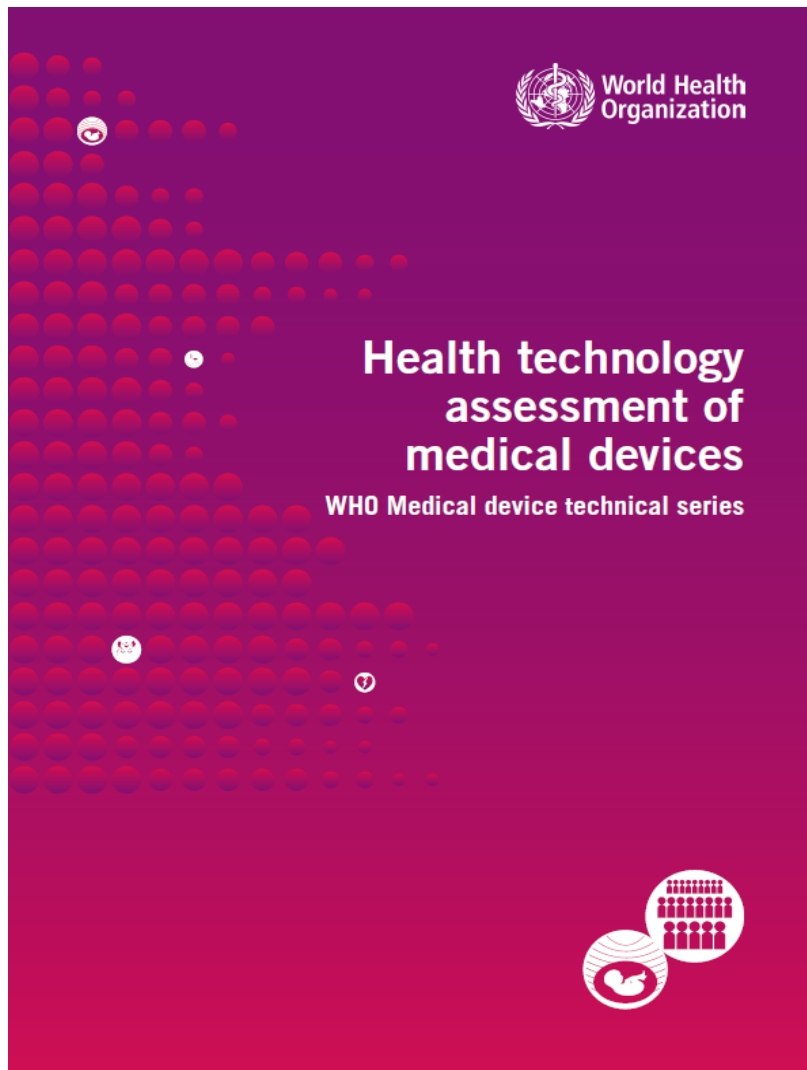


Working group session

- What are the opportunities for advancing HTA?
- What are the challenges?
- What actions can we take to advance an integrated approach to mobilize HTA
- Next steps?



WHO Medical Device technical Series



Training module of :

- **Health technology assessment of medical devices**
- Developed by Dr Reiner Banken and Dr Don Juzwishin
- April 2011
- **Global Initiative on Health Technologies, WHO**
- Supported by the Bill & Melinda Gates Foundation

Implementation of HTA

- Chase D et al. Development of a toolkit and glossary to aid in the adaptation of health technology assessment (HTA) reports for use in different contexts. *Health Technology Assessment*, 2009, 13:59
- McGregor M, Brophy J. End-user involvement in health technology assessment (HTA) development: a way to increase impact. *International Journal of Technology Assessment in Health Care*, 2005, 21(02):263–267.
- Juzwishin D. *Framework for regional health authorities to make optimal use of health technology assessment*. Edmonton, Alberta Heritage Foundation for Medical Research, 2000.
- Juzwishin D, Schneider W. *Screening procedure for use when considering the implementation of health technology*. Edmonton, Alberta Heritage Foundation for Medical Research, 2002.
- Rubinstein A, Pichon-Riviere A, Augustovski F. Development and implementation of health technology assessment in Argentina: two steps forward and one step back. *International Journal of Technology Assessment in Health Care*, 2009, 25(S1):260–269.



Resources available

- The *Health technology assessment* handbook by the Danish Centre for Health Technology Assessment
- *HTA adaptation toolkit* developed as part of the European Network for HTA (EUnetHTA) collaboration
- Hailey D. *Elements of effectiveness for health technology assessment programs*. Edmonton, Alberta Heritage Foundation for Medical Research, 2003
 - <http://www.ihe.ca/documents/HTA-FR9.pdf>



Selected resources

- **HTA database** <http://tinyurl.com/bfu4k5>
- **HTA Resources on INAHTA website**
<http://www.inahta.org/HTA/>
- **HTA Vortal:** <http://www.htai.org/index.php?id=577>
- **HTA Handbook:**
http://www.sst.dk/publ/Publ2008/MTV/Metode/HTA_Handbook_net_final.pdf



Resources

- *Resources for health technology assessment.* Health Technology Assessment international and the International Network of Agencies for Health Technology Assessment, 2005
- http://www.inahta.org/upload/HTA_resources/AboutHTA_Resources_for_HTA.pdf
- Makundi E, Kapiriri L, Norheim O. Combining evidence and values in priority setting: testing the balance sheet method in a low-income country. *BMC Health Services Research*, 2007, 7(1):152.