Global Patient Safety 2017: A Call to Action

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President, National Academy of Medicine

Second Global Ministerial Summit on Patient Safety
March 30, 2017

NATIONAL ACADEMY OF MEDICINE

Leadership • Innovation • Impact | *for a healthier future*

outline

- Who we are
- Early IOM work on quality
- Major milestones in global patient safety movement
- Where we are now
- Core pillars of a patient safety strategy
- current issues in patient safety
- The next horizon
- Megatrends/threats to patient safety
- Importance of global collaboration to move forward

U.S. National Academy of Sciences (1863)

"The academy shall, whenever called upon by any department of the government, investigate, examine… and report upon any subject of science or art,…"

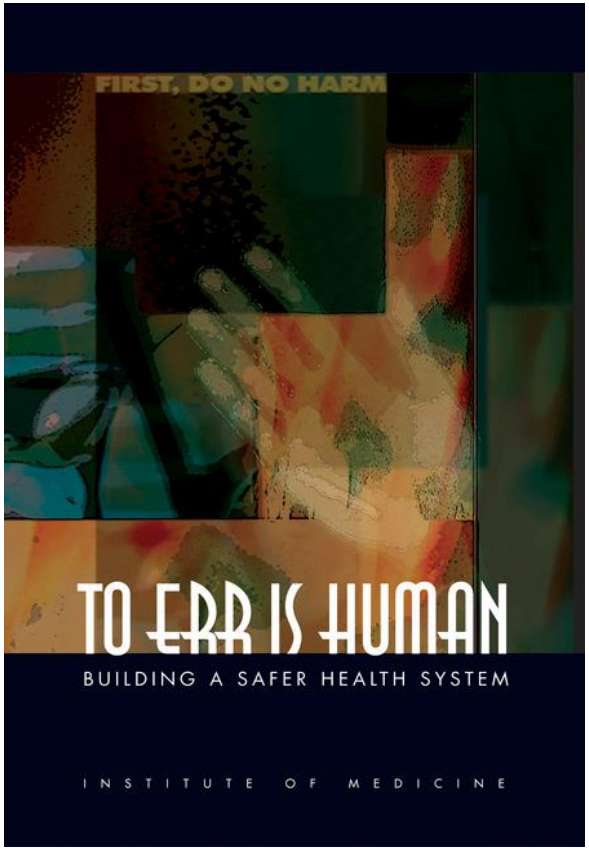
1970 Institute of Medicine founded to advise & improve health of people everywhere.

The New York Times describes the IOM as "the most esteemed and authoritative adviser on issues of health and medicine, and its reports can transform medical thinking around the world."

July 1, 2015 IOM is reconstituted as **the National Academy of Medicine**

The IOM Quality Series

Foundational Reports



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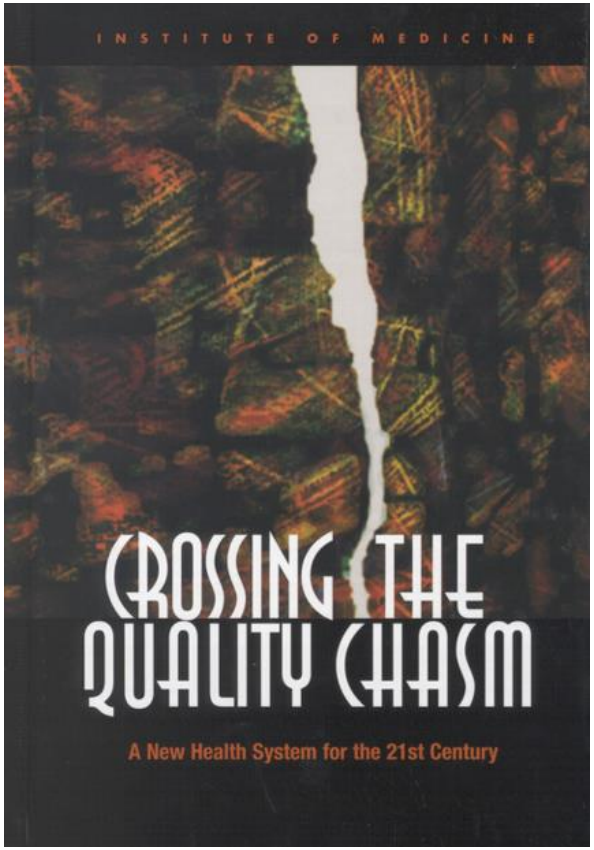


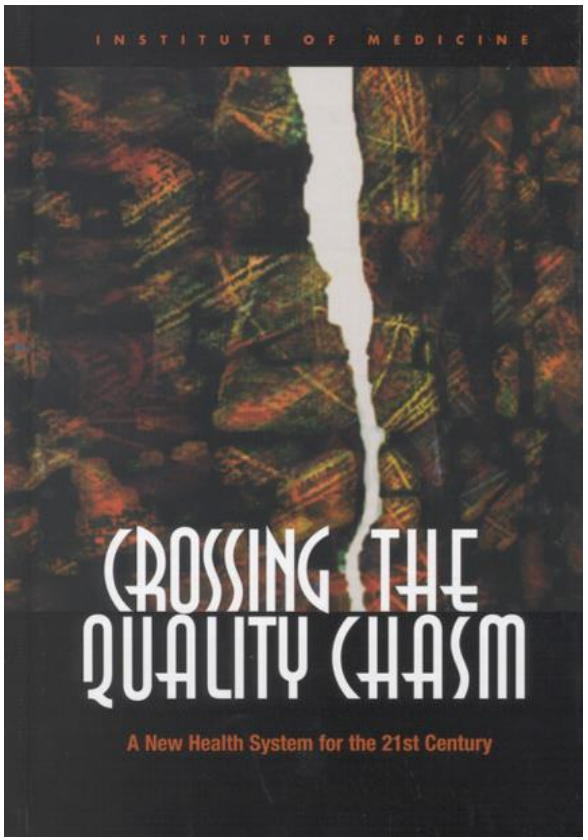
2001

To Err is Human: Building a Safer Health System

- Medical errors can be defined as the failure of a planned action to be completed as intended or the use of a wrong plan to achieve an aim
- The majority of errors are caused by faulty systems, processes, and conditions that lead people to make mistakes or fail to prevent them
- 44,000 - 98,000 people die in US hospitals each year as a result of preventable medical errors
- Errors cost $17 billion – $29 billion per year in hospitals in the US

However, more recent data indicate that these numbers may be substantially higher (James, 2013, JPS)

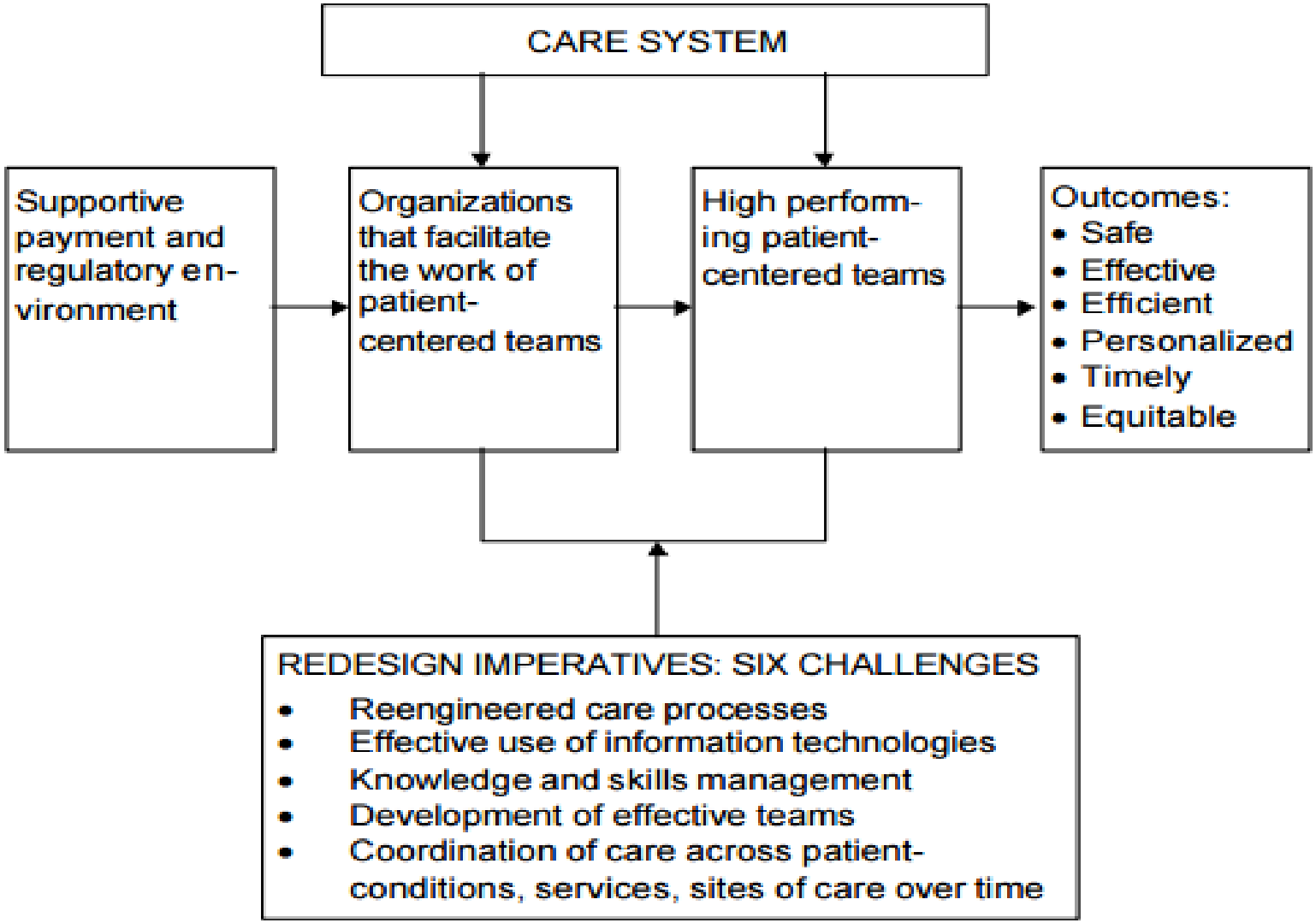
Crossing the Quality Chasm: A New Health System for the 21st Century (2001)



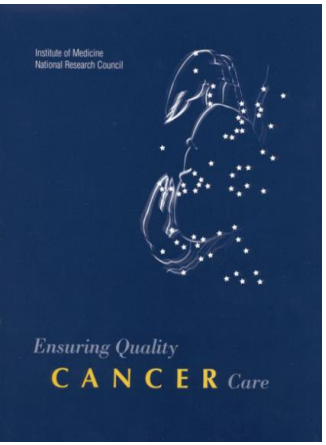
2001

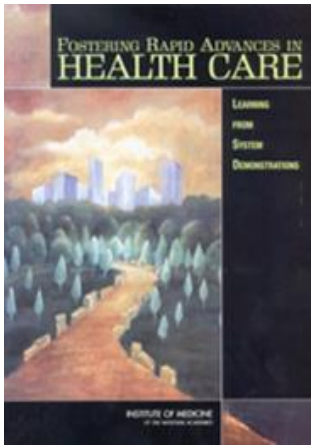
- Described broader **quality issues** and defines six aims—care should be
  - safe,
  - effective,
  - patient-centered,
  - timely,
  - efficient and
  - equitable

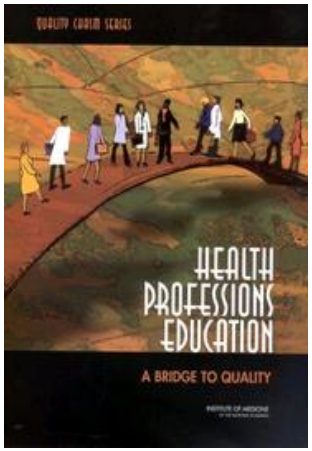
Crossing the Quality Chasm: Redesign a New Health System for the 21st Century

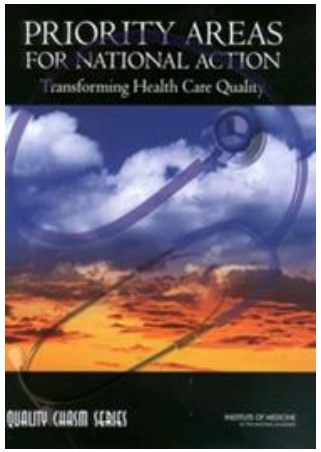


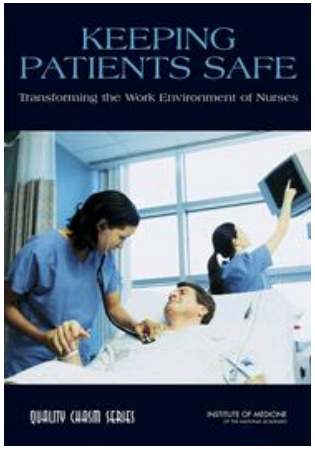
IOM Work on Quality

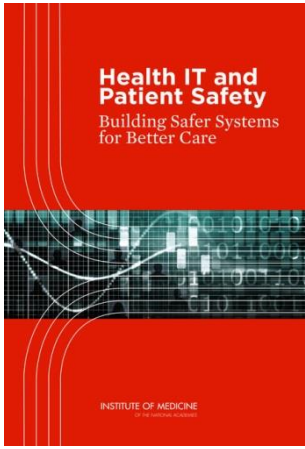


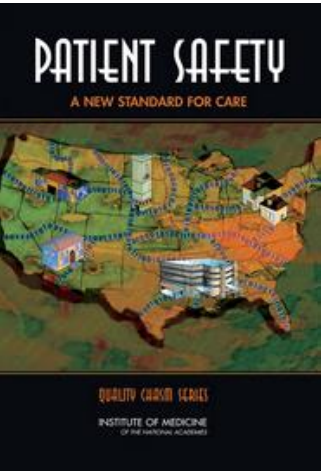


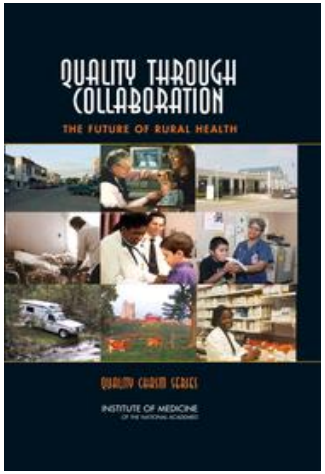


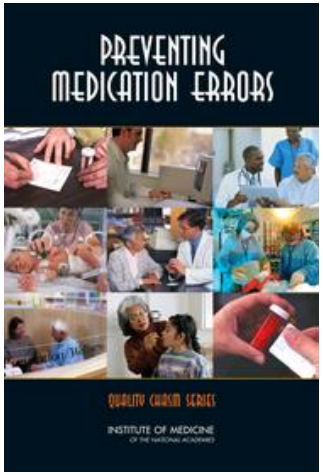


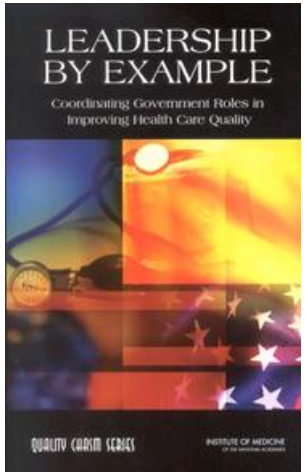


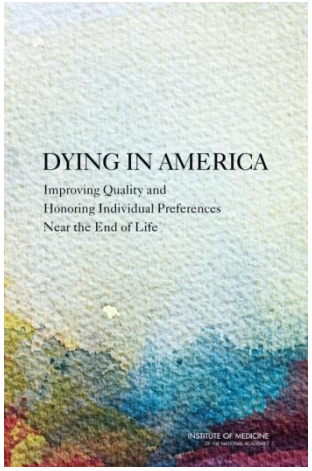


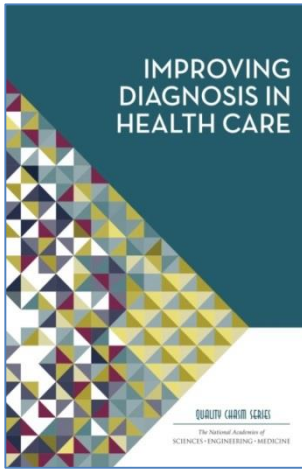








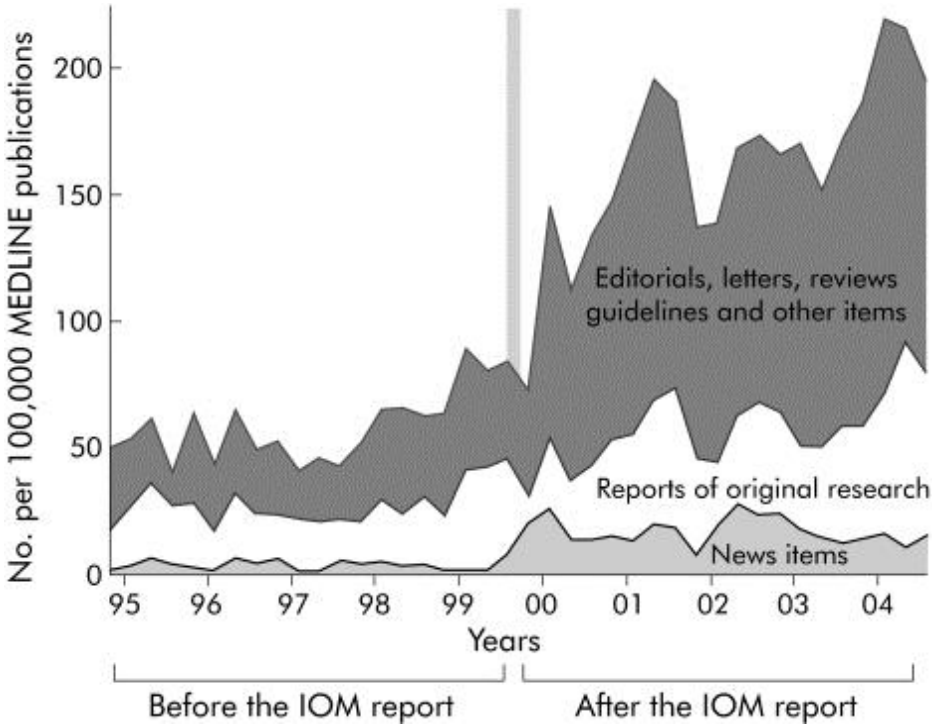




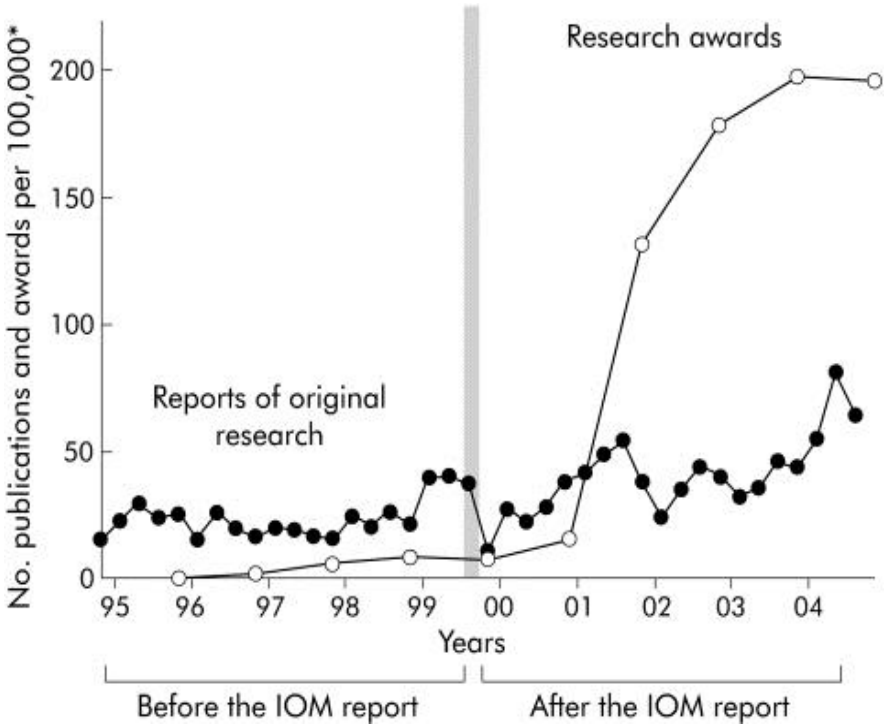
Patient Safety Movement

The “To Err is Human” report and the patient safety literature (Stelfox et al, 2006)

Editorials, letters, reviews, guidelines, and other items



Research awards



Stelfox, 2006, Qual Saf Health Care

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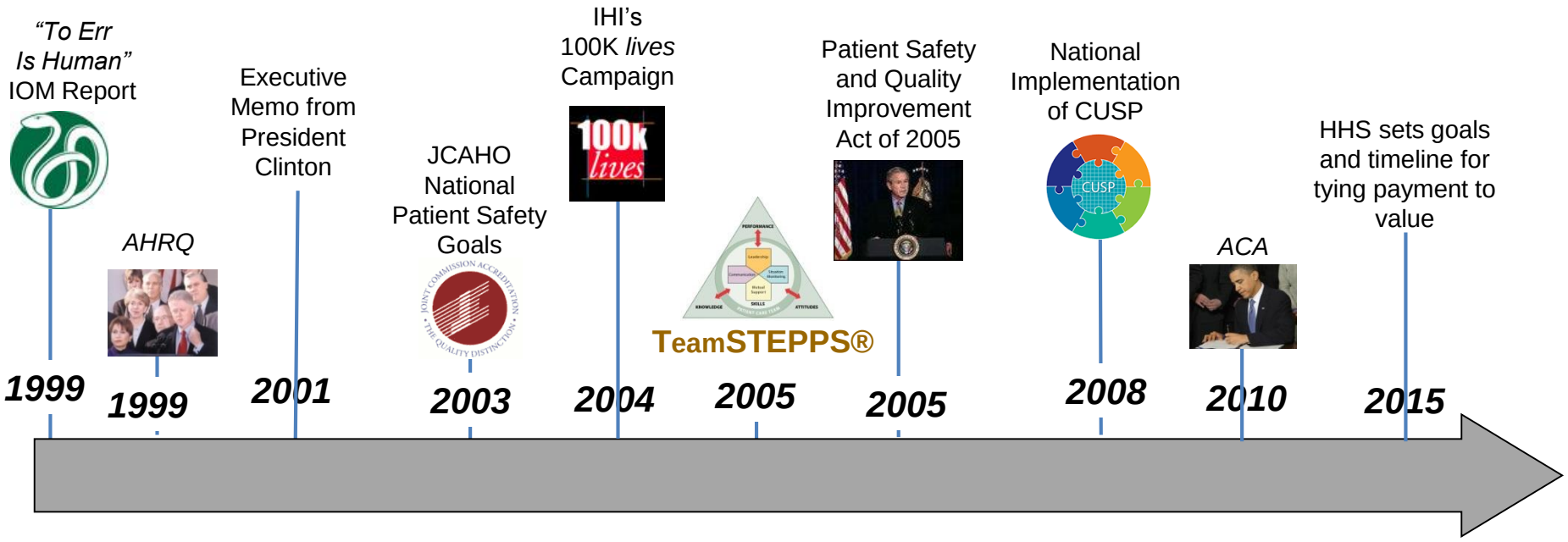
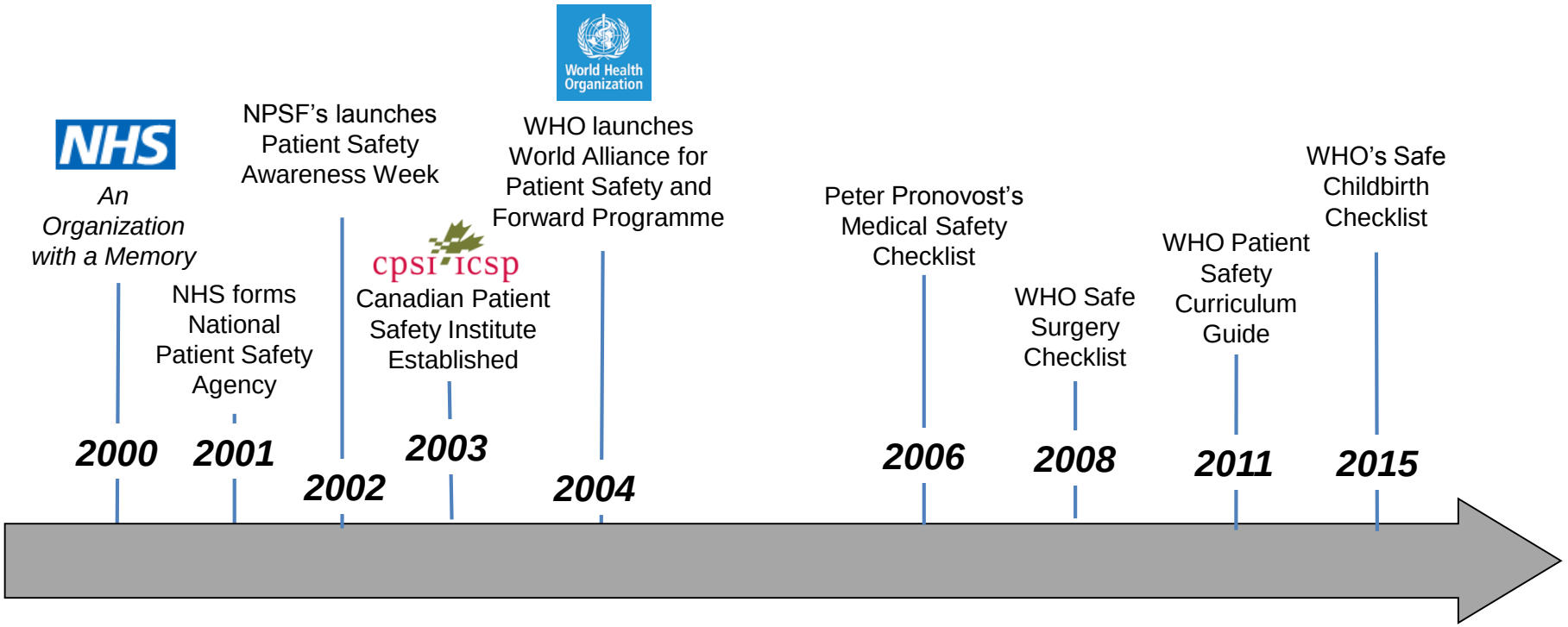
Patient Quality & Safety Movement: United States



Patient Quality & Safety Movement: Worldwide



Where are we now?

- Even countries that are pioneers in patient safety, such as the US and UK, still struggle, e.g.,
  - Number of preventable hospital associated deaths estimated to be over 200,000 each year in the US
  - European data consistently show that medical errors and health-care related adverse events occur in 8% - 12% of hospitalizations
- National Patient Safety Foundation Survey (2015): “Although the current evidence regarding overall improvement in patient safety is mixed…the majority of the panel felt that overall health care is safer than in the past.”

Beyond Mortality - The Burden of Medical Error: United States

- 1 in 10 patients develops an adverse event during hospitalization (AHRQ Efforts, 2014)
- More than 700,000 outpatients are treated in the emergency department every year for an adverse event caused by a medication
  - 120,000 of these patients require hospitalization (Budnitz et al. 2006)
- One-third of Medicare beneficiaries in skilled nursing facilities experienced an adverse event; half of these events were deemed preventable (OIG 2014)

Principles of Safe Patient Care

- The Importance of Culture in achieving Safe Patient Care
- Achieving Effective Communication and Teamwork
- Patient Centered Culture – engagement & empowerment
- Moving from Blame to Accountability
- Managing Behavior (www.justculture.org)
- Disclosing Unanticipated Outcomes
- Performance Measurement & Measuring our Progress
- Measuring Safety Culture: Safety Attitude Questionaire

Measuring Safety Culture: SAQ

Two overall domains of interest:

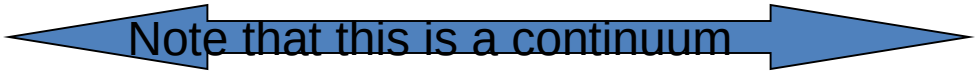
- **Teamwork Climate** (interaction norms: <60% needs action)
- **Safety Climate** (pt safety norms: <60% needs action)

Three supporting domains:

- **Stress Recognition** (threat awareness/believability barometer: <40% needs action)
- **Resilience** (pace/intensity barometer: <60% needs action)
- **Work Life Balance** (self care norms: descriptive only/no threshold)

Managing Behavior (www.justculture.org)

Human Error	At-Risk Behavior	Reckless Behavior
Product of our current system design Manage through changes in: • Processes • Procedures • Training • Design • Environment	*Unintentional Risk-Taking* Manage through: • Removing incentives for At-Risk Behaviors • Creating incentives for healthy behaviors • Increasing situational awareness	*Intentional Risk-Taking* Manage through: • Remedial action • Disciplinary action
Console	**Coach**	**Punish**

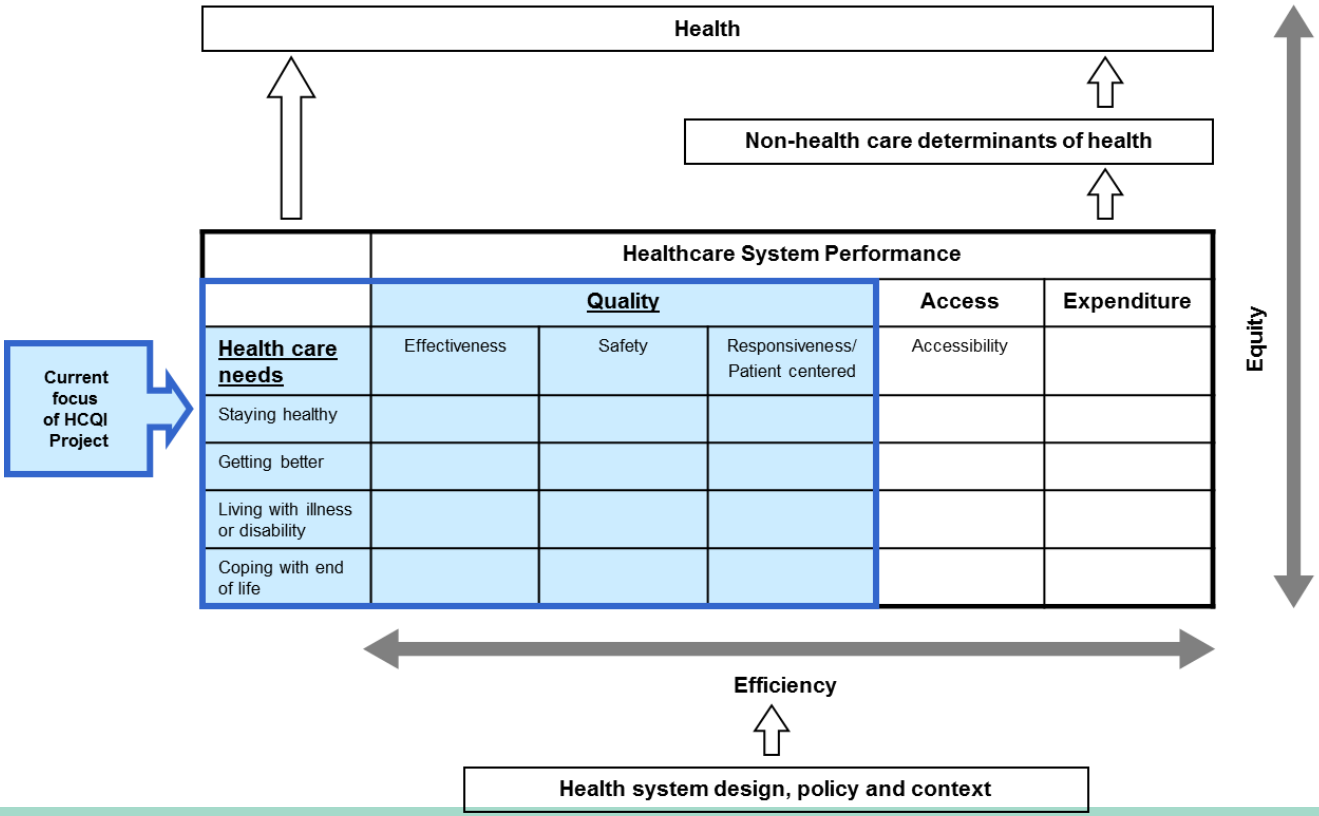


Investing in patient safety wisely requires good knowledge about the strength and flaws of our national systems, our hospitals, our practices

– Ingo Härtel (2017)

OECD Health System Performance Assessment Framework

Health system performance assessment framework



Patient Safety Global Action Summit 9-10 March 2016, London, UK

- Political commitment and leadership,
- Policies that encourage and enable patient safety improvement,
- Paradigm shift: providing a safe space for people to report,
- Performance measurement: benchmarking, developing indicators and data systems,
- Patient safety movement: a call for urgent action by governments.

Current & Emerging Issues in Patient Safety
(Expert Workshops)

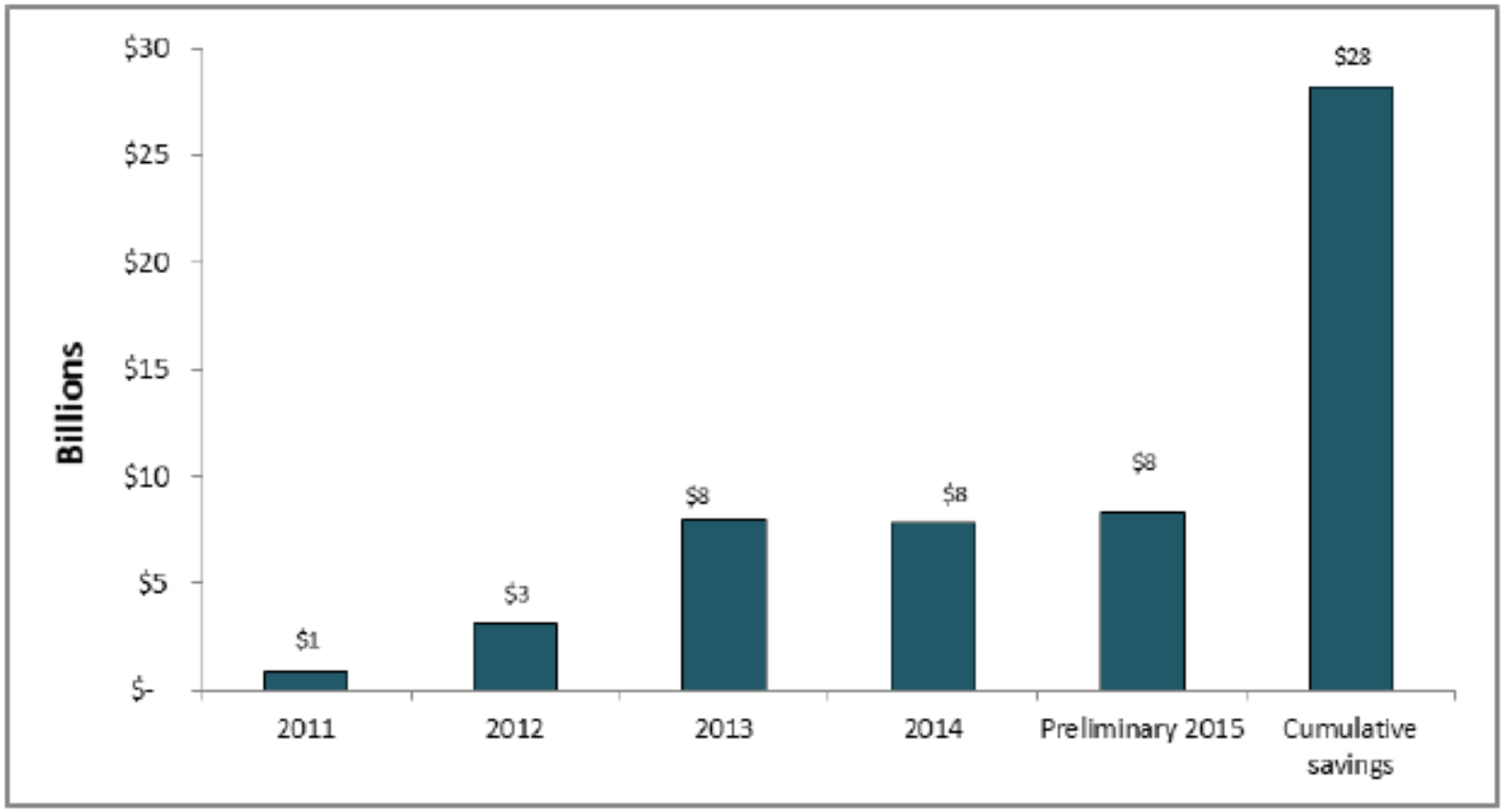
- Economy and Efficiency of Patient Safety
- Prevention and Control of Infectious Diseases
- Global Patient Safety – Perspectives from LMICs
- Patient Safety and mHealth, Big Data, and Handheld Devices
- Increased Safety of Diagnostics and Treatment – Checklists and Other Tools
- Safety of Medication Therapy

Economy and Efficiency of Patient Safety

Key Findings on the Costs of Failure (OECD, 2017)

- Patient harm is the **14th leading cause of the global disease burden**.
- Most research on the cost of patient harm has focused on the acute care setting in the developed world**.**
- The financial impact of safety failure is considerable. Approximately **15% of total hospital activity and expenditure** is a direct result of adverse events. The most burdensome adverse event types include venous thromboembolism, pressure ulcers, and infections
- Less is known about harm in primary and ambulatory care. Research indicates that **wrong or delayed diagnosis** is a considerable problem.
- The flow-on and indirect costs of harm include loss of productivity and diminished trust in the healthcare system. In 2008, the economic cost of medical error in the US was estimated to be almost **USD 1 trillion.**
- The **costs of prevention are dwarfed by the cost of failure**.
  - For example improving patient safety in US Medicare hospitals is estimated to have **saved USD 28 Billion** between 2010 and 2015.

National efforts to reduce harm and improve safety can deliver considerable savings

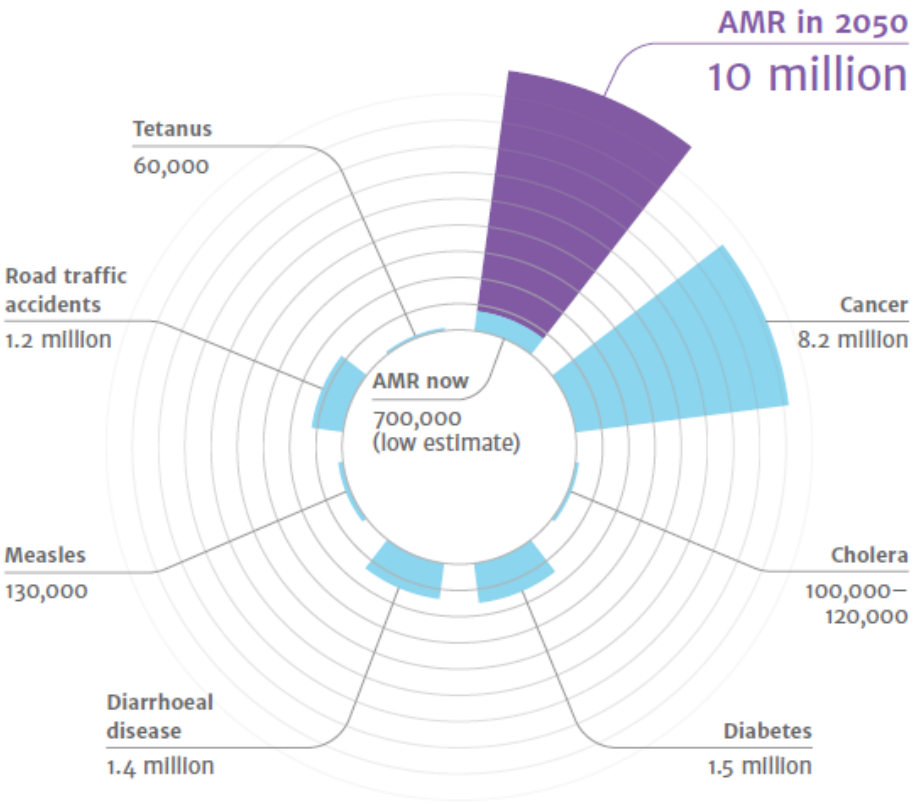


Source; AHRQ 2016

Prevention and Control of Infectious Diseases

- Burden of health care-associated infections in Europe and worldwide
- WHO core components for infection prevention and control
  - Implementation in LMICs
- How to measure the degree of implementation? Establishment of surveillance systems, external assessments vs self-assessment
- The special problem of sepsis: how to prevent and recognize it
- Best Practices
  - 10-year sustained IPC national programme in Chile
  - The development of a European surveillance system for HAI
  - National monitoring IPC indicators in Liberia
  - Duplication of hand rub consumption in Germany within 10 years
  - The sepsis campaign in England

Antimicrobial Resistance (AMR)



A continued rise in resistance by 2050 would lead to 10 million people dying every year and a reduction of 2% to 3.5% in Gross Domestic Product (GDP). It would cost the world up to 100 trillion USD.

O'Neill, 2016

Combating AMR

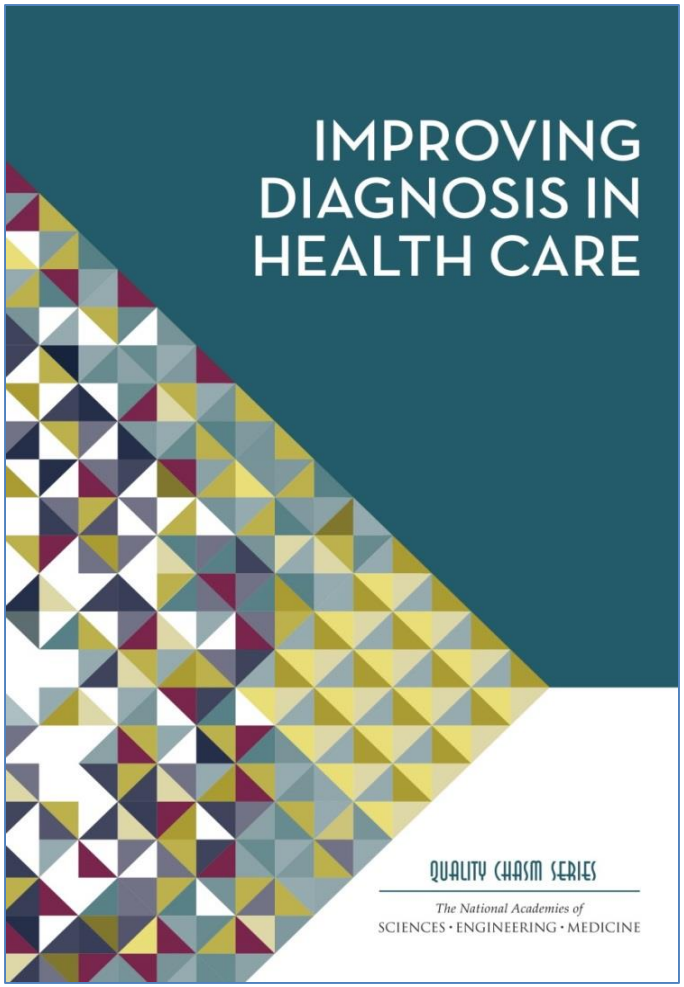
- Reduce demand through
  - Global public awareness campaign
  - Improve hygiene and prevent the spread of infections
  - Reduce unnecessary use of antimicrobials in agriculture and their dissemination into the environment
  - Improve global surveillance of drug resistance and antimicrobial consumption in humans and animals
  - Promote new, rapid, diagnostics to cut unnecessary use of antibiotics
  - Promote development and use of vaccines and alternatives
- Increase the number of effective antimicrobial drugs

Diagnostic Error

- A conservative estimate found that 5 % U.S. adults seeking outpatient care each year experience a diagnostic error.
- Postmortem examination research has shown that diagnostic errors contribute to approximately 10 percent of patient deaths.
- Medical record reviews suggest that diagnostic errors account for 6-17 % of hospital adverse events.
- In a review of 25 years of malpractice claims, diagnostic errors were
  - Leading type (28.6%)
  - More outpatient than inpatient (68.8% vs 31.2%)
  - Responsible for payments of US$38.8 billion (inflation-adjusted)

The IOM Quality Series: Improving Diagnosis

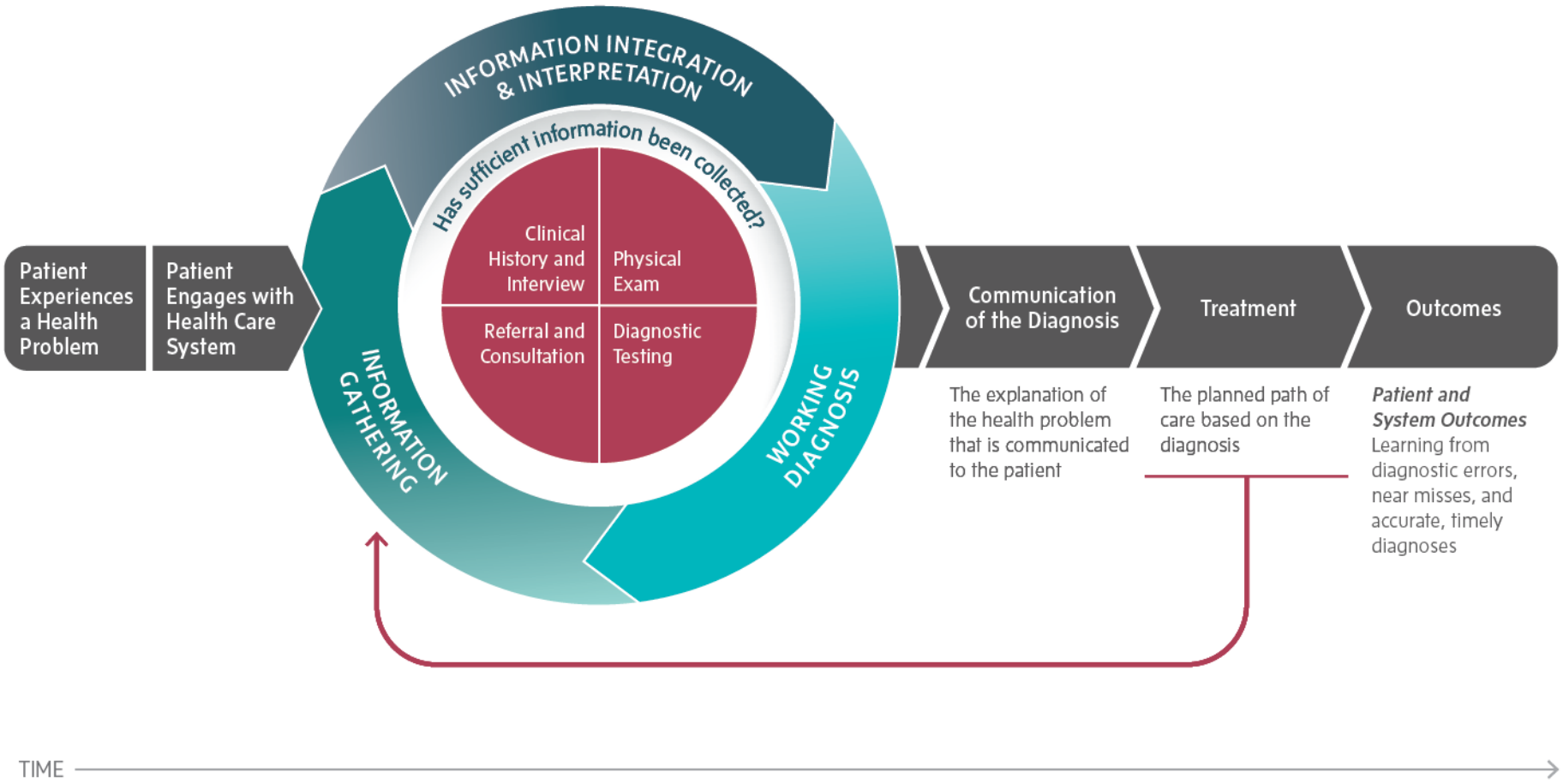
The failure to:
(a)establish an **accurate** and **timely** explanation of the patient's health problem(s); or
(b) **communicate** that explanation to the patient



" It is likely that most of us will experience at least one diagnostic error in our lifetime, sometimes with devastating consequences."

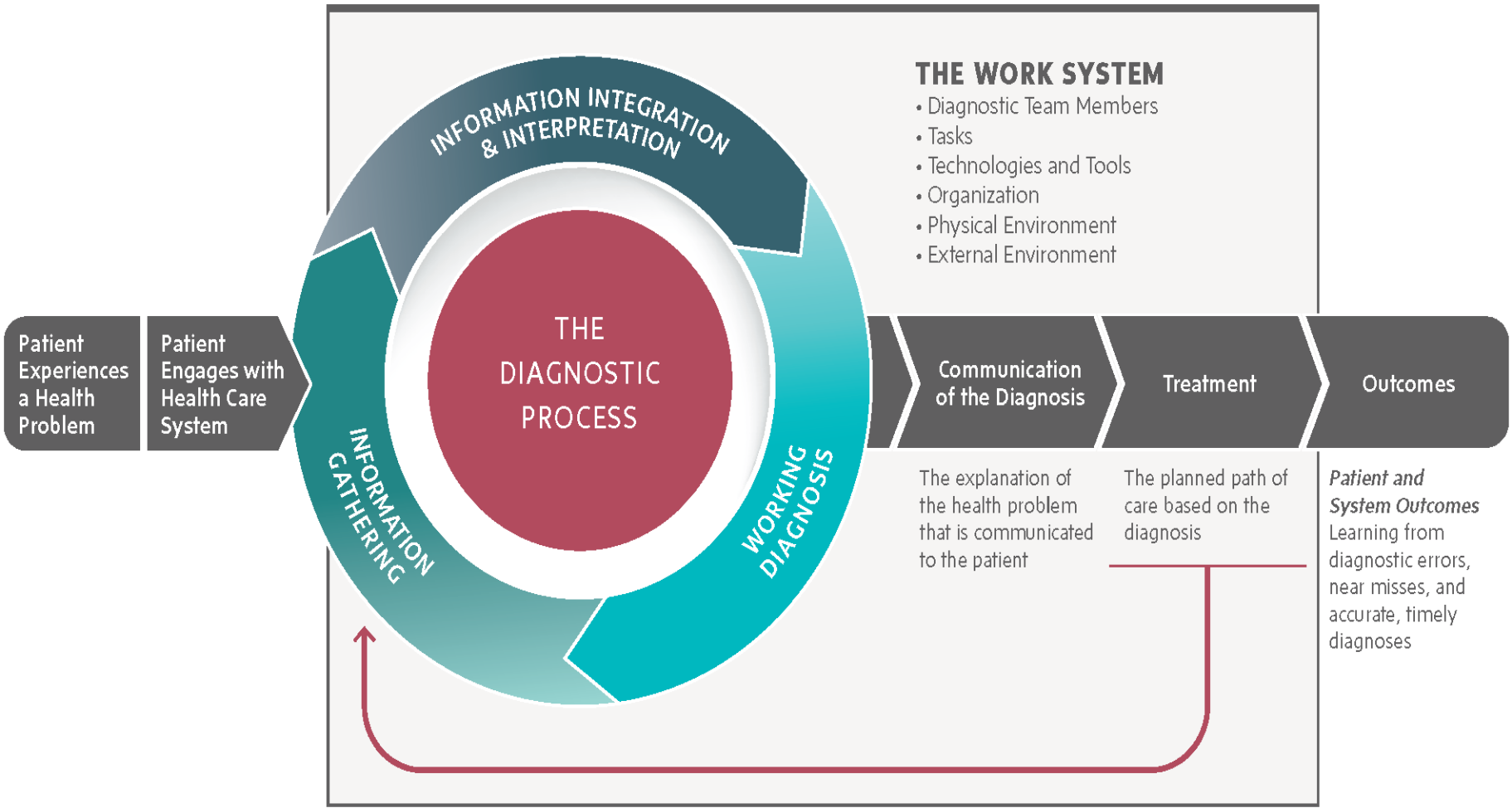
2015

The Diagnostic Process

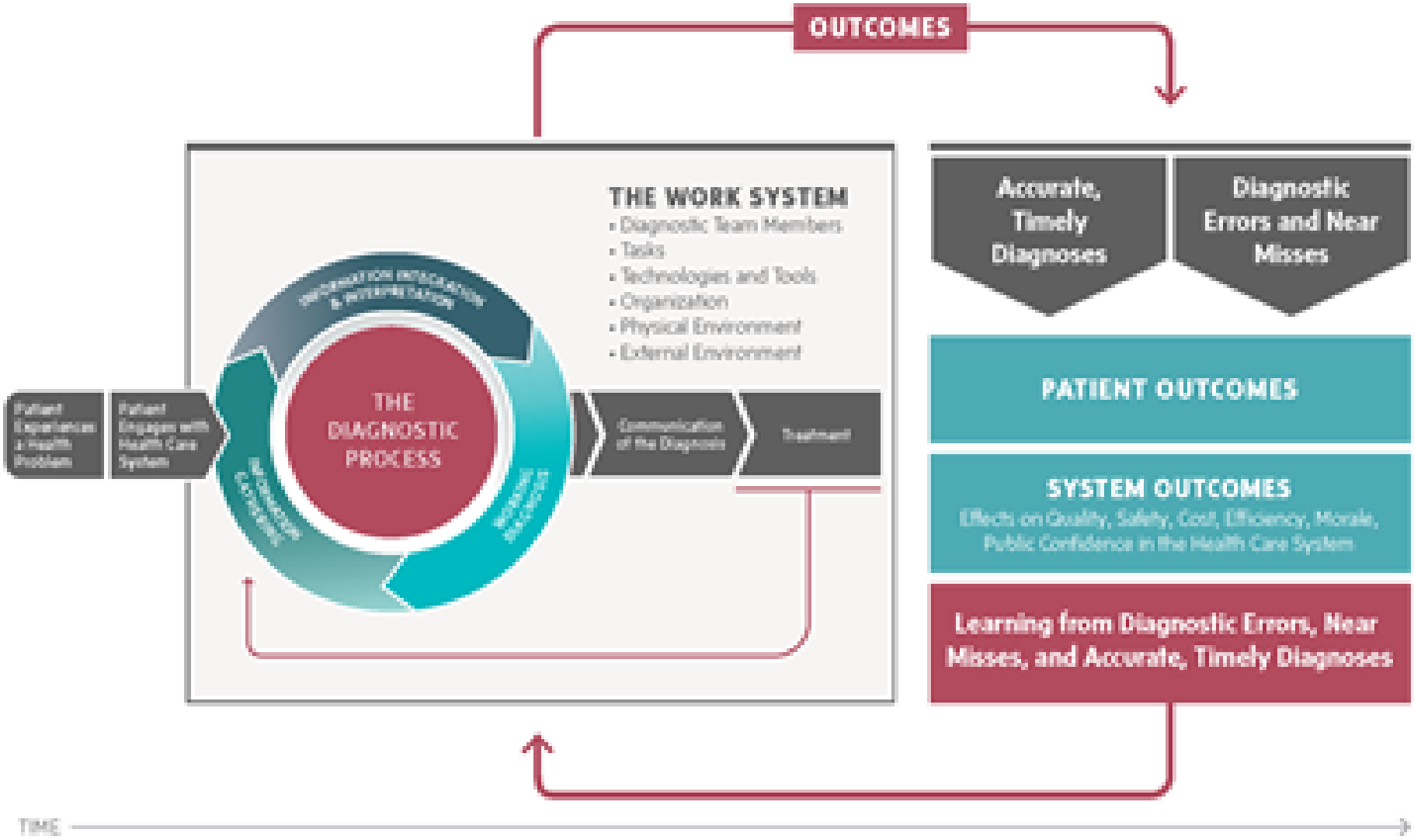


Where Failures in the Diagnostic Process Occur

- Failure of Engagement
- Failure in Information Gathering
- Failure in Information Integration
- Failure in Information Interpretation
- Failure to Establish an Explanation for the Health Problem
- Failure to Communicate the Explanation



Diagnostic Process: Learning Healthcare System



8 Goals to Improve Diagnosis and Reduce Diagnostic Error

GOAL 1 **more effective teamwork** in the diagnostic process

GOAL 2 **education** and **training** in the diagnostic process

GOAL 3 **health information technologies** support patients and care professionals

GOAL 4 **identify**, **learn from**, and **reduce** diagnostic errors

GOAL 5 **work system** and **culture**

GOAL 6 **reporting environment** and **medical liability system** that facilitates **learning from diagnostic errors and near misses**

GOAL 7 **payment** and **care delivery environment** that supports the diagnostic process

GOAL 8 **dedicated funding for research**

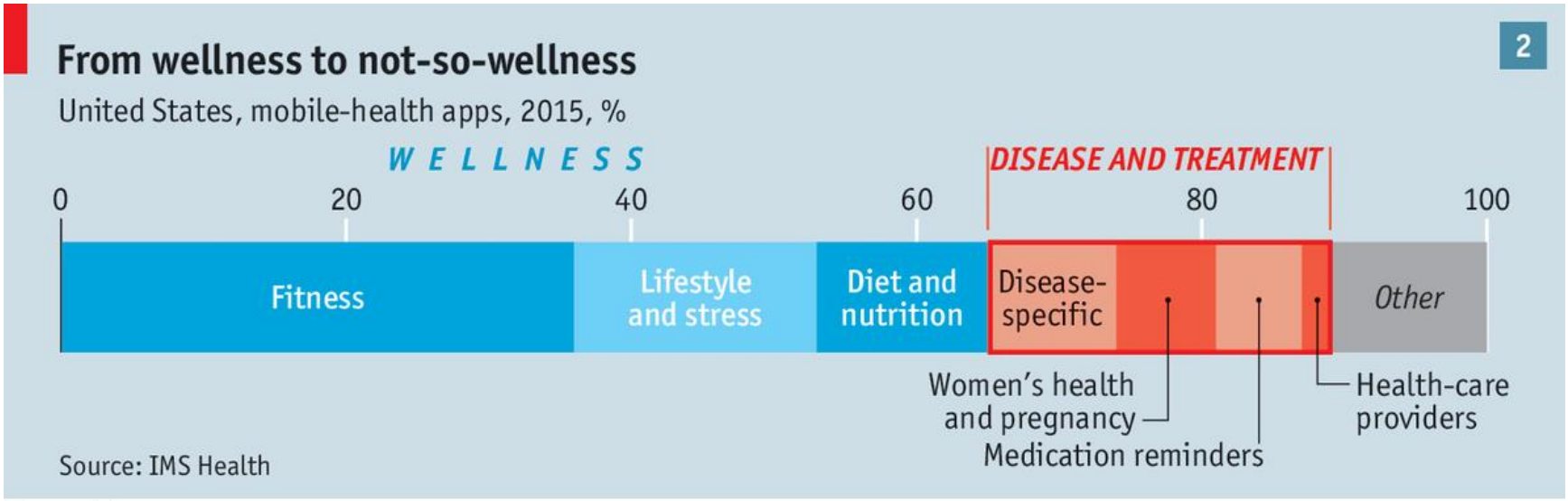
Patient Safety and mHealth

mHealth

- "Mobile Health (mHealth) is an area of electronic health (eHealth) and it is the provision of health services and information via mobile technologies such as mobile phones and Personal Digital Assistants (PDAs).“ (WHO)
- BCC Research, which studies technology-based markets, forecasts that global revenues for m-health will reach $21.5 billion in 2018, with Europe the largest m-health market

- mHealth products hold the promise of improving health outcomes, reducing medical errors, avoiding costly interventions, and broadening access to care
- However, mHealth risks are not well understood

Range of mHealth Apps



mHealth Risks

- Privacy concerns
- Poor quality patient data
- Quality of clinical decision, e.g.,
  - Incorrect diagnosis
  - Incorrect care advice
- Inaccurate or out of date content

mHealth Risks

JAMA

STUDY

Diagnostic Inaccuracy of Smartphone Applications for Melanoma Detection

Joel A. Wolf, BA; Jacqueline F. Moreau, BA; Oleg Akilov, MD; Timothy Patton, DO; Joseph C. English III, MD; Jonhan Ho, MD; Laura K. Ferris, MD, PhD

Daily Mail .com

Smartphone apps that diagnose skin cancer give 'misleading' results and could delay life-saving treatment

- Three quarters of apps that check photos of skin lesions gave misleading results - or diagnosed deadly melanomas as 'unconcerning'
- Experts warn such inaccurate feedback could result in life-threatening delays in visiting the doctor and getting treatment
- Number of smartphone apps giving health advice is growing

By JENNY HOPE FOR THE DAILY MAIL
PUBLISHED: 16:44 EST, 16 January 2013 | **UPDATED:** 16:44 EST, 16 January 2013

Los Angeles Times

LOCAL U.S. WORLD BUSINESS SPORTS ENTERTAINMENT HEALTH

MONEY & CO. TECHNOLOGY HIGHWAY 1 COMPANY TOWN PERSONAL I

FTC obtains court orders against two acne-fighting apps

Three people are barred from marketing applications that claim to cure acne. Also, the BBB warns about bogus StubHub ticket order emails, and a West Covina woman gets nine years in prison in a real estate fraud case.

October 31, 2011 | By Stuart Pfeifer, Los Angeles Times

Pfizer recalls Rheumatology Calculator smartphone App

By Mitch on Thursday 5 January 2012, 19:45 - Misc - Permalink

mHealth mobile medical app Recall

mHealth Regulation: US

Table 1. Jurisdiction of the FDA over Products Used in Health-Information Technology.*

Function of Products	Examples of Products	FDA Jurisdiction
Administrative	Billing software, claims software, scheduling software	No, since functions do not meet the definition of a "device"
Health management	Provider order-entry software, medication-management products, data-capture and clinical-encounter-management software, most clinical-decision-support tools	Possibly, since functions might meet the definition of a "device," but they are seen as low-risk and subject to discretion for FDA enforcement
Medical device	Mobile medical apps, medical-device accessories, high-risk clinical-decision-support tools	Yes, since functions meet the definition of a "device"

* Product categories are based on the taxonomy of health-information-technology products proposed in the Health IT Report.[12]

Cortez et al, 2014

mHealth Regulation: US FDA

- Risk Based Approach
- Most consumer devices free from regulatory requirements
  - unless the application is working with an accessory which is a medical device, makes specific medical claims that the app could treat or cure a disease, or stores or analyzed patient-specific medical data
- FDA can review mHealth devices through the FDCA's device-review process
  - Class I: Generally low risk and subject to minimal regulatory oversight.
  - Class II: Moderate-risk devices subject to both general controls and "special controls" established for the type of device. Many are subject to premarket notification (the "510(k)" pathway) which requires FDA to review a device.
  - Class III: The riskiest devices, almost always must be approved by FDA before they are allowed on the market, and typically rely on evidence obtained through clinical testing.

mHealth Regulation: Europe

- European Union: guidelines with little clarity
  - While standalone software can be deemed a medical device under the Medical Device Directive, the definitions are not explicit and therefore are open to interpretation.
- Most countries do not have mHealth specific legislation implemented
  - Countries/regions that do have legislative and governance framework covering mHealth are UK, Catalonia and Finland. UK has set up an Information Governance toolkit, a code of practice for application developers. Catalonia also has an accreditation application model in place, and similarly, Finland has set certification criteria for mHealth applications.

Dell, 2014; Report on national mHealth strategies, 2016

mHealth Regulation: Germany

- German Federal Institute for Drugs and Medical Devices has published guidance for differentiation between lifestyle applications and medical devices, and the subsequent risk classification
- a number of questions regarding the regulatory requirements for health apps remain
  - In practice, there is legal uncertainty regarding what app classifies as a medical device

mHealth Regulation: Germany

Plan to develop a national action plan for mHealth:

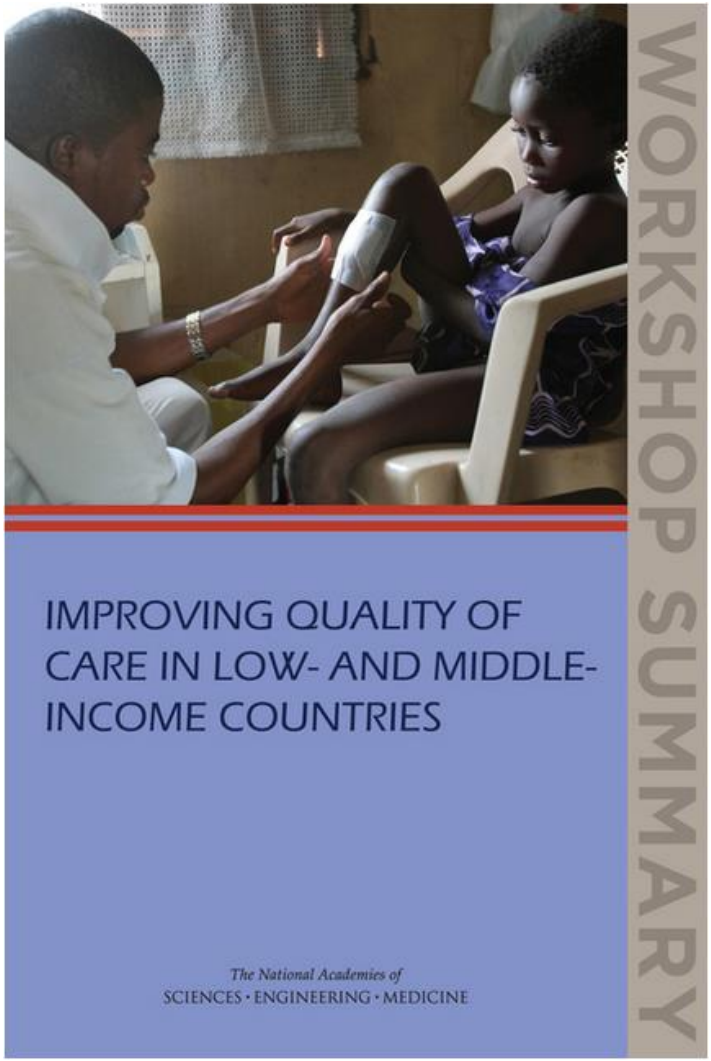
- an independent and in-depth study of the status quo, opportunities and risks of mHealth
- a structured dialogue with all stakeholders and
- an activity plan to be set up (covering development of guidelines; improving market access and regulatory environment; and analyses of the use of mHealth applications).

#	Risk Assessment	Example App Functionality	Medical App Regulation/Risk Assessment Model
A	Apps are predominantly **low risk** and pose minimal risk to patients if misused.	BMI Calculators, patient education, accessing EHRs, access guidelines , other learning materials	Clinician Self-Assessment
B	Apps may cause harm if used inappropriately or without adequate training.	Interprofessional consultation and referral, entering treatment requests	Self-certification model, peer review
C	Apps pose significant risk to patients due to either inherent complexity, functionality or potential for harm if misused	Diagnostic support apps, specialist apps, patient decision apps	Best practice guidelines, formal assessments by local health organization
D	Apps pose significant risk to patients due to combination of inherent complexity, functionality and potential for major harm if misused.	Clinical decision support tools, control devices, closed loop apps	Formal assessment and regulation by professional and/or government body, e.g., FDA

Lewis and Wyatt, 2014

Global Patient Safety – Perspectives from LMICs

Universal Health Care: Need to Assure Quality



- Unsafe care causes 43 million injuries a year and the loss of 23 million disability-adjusted life years (DALYs), about two-thirds of them in low- and middle-income countries (Jha et al., 2013)
- The probability of a patient receiving the correct diagnosis is, depending on other factors, in the range of 30 to 50 percent
- The probability of a patient receiving non-harmful treatment found a likelihood of about 45 percent

NASEM Consensus Study: Improving Quality of Care in Low- and Middle-Income Countries

- Determine the scope of the problem in LMICs
- Evaluate the evidence base related to safety, effectiveness, patient – centeredness, timeliness, efficiency, and equity
- Assess current measurements of health-care quality and develop new measurements as needed
- Create decision support frameworks for systemic interventions and changes in delivery and patient care processes to improve quality
- Identify where costs can be reduced by improving quality
- Assess the impact of quality on UHC- outcomes and economics

Summary

- Patient safety has generated a lot of momentum over the last 20 years
- Need for a systems approach and local solutions to improve patient safety
- Economic constraints necessitate a value based approach
  - Patient safety efforts can generate significant cost savings
- Current and emerging issues of importance: health care associated infections, diagnostic error, mHealth
- Extending the quality agenda to LMICs

Advancing Patient Safety in 2017: Call to Action

- Continued emphasis on a systems approach to improving patient safety
- Assess performance - understand the scale of the patient safety challenges, both nationally and internationally
- Mutual learning – share best practices

- Sustained commitment from policy makers
- WHO Annual Patient Safety Day

The Journey Continues

Thank you

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