Patient Safety

quantifying patient harm in a field dedicated to "doing no harm" implications for health system performance measurement

Liana Woskie, Session 7

Webinar Series on Health Systems Assessment

September 17th, 2021

HARVARD T.H. CHAN
SCHOOL OF PUBLIC HEALTH

Happy World Patient Safety Day!

- The first ever WPSD was observed on September 17, 2019

- This year's theme is "Unite for Safe Care"
  - Designed to bring global awareness to the public and human rights issues we are all now facing: the lack of safety in health care that the pandemic brought to light
  - Join the conversation on Twitter: #uniteforsafecare

Objectives of this session

- **Definition & burden**
  - Define patient safety
  - Understand the known burden of unsafe medical care
  - Place patient safety in the Control Knob Framework, other quality frameworks & understand why it is important for health system assessment
- **Assessment**
  - Understand the global burden of unsafe care and how it is used to estimate human harm
  - Examine issues related to counterfeit care and expanding definitions of safety
  - Understand key tools for assessing patient safety, their strengths and weaknesses
  - Engage in critical discussion with peers on the implications of how to assess patient safety

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DEFINITION & IMPORTANCE

"I will follow that system of regimen which, according to my ability and judgment, I consider for the benefit of my patients, and abstain from whatever is deleterious and mischievous."

The Hippocratic Oath (Ορκος), AD 275

One of the oldest binding documents in history, the Oath written by Hippocrates

History & Importance: Institute of Medicine

- Despite the longstanding principle to “do no harm”, unsafe medical care appears to cause significant morbidity and mortality throughout the world.
- The Institute of Medicine (IOM) released a report in 1999 entitled “*To Err is Human: Building a Safer Health System*”.[1]
- The report stated that errors cause between 44,000 and 98,000 deaths every year in American hospitals, and over one million injuries.[1]
- Based on this report and corresponding research, healthcare appeared to be far behind other high-risk industries in ensuring basic safety.
- As a result - the IOM report called for a 50% reduction in medical errors over 5 years.[1] Its goal was to break the cycle of inaction regarding medical errors by advocating a comprehensive approach to improving patient safety.

India & Patient Safety

- In the last 1.5 decades several initiatives have been taken by the Government of India to improve quality of healthcare services and strengthen patient safety (Lahariya, 2019)
- The release of National Patient Safety Implementation Framework (NPSIF, 2018-2025) is a major development, which intends to integrate key patient safety initiatives in India.
- The six strategic objectives are:
    - establishing institutional framework/mechanisms;
    - assessment and reporting of adverse events;
    - competent health workforce;
    - infection prevention and control;
    - safety in programmatic and clinical domains and patient safety research

Definition

- The Institute of Medicine (IOM) defined *patient safety* as the "prevention of harm to patients." (IOM, 2001)

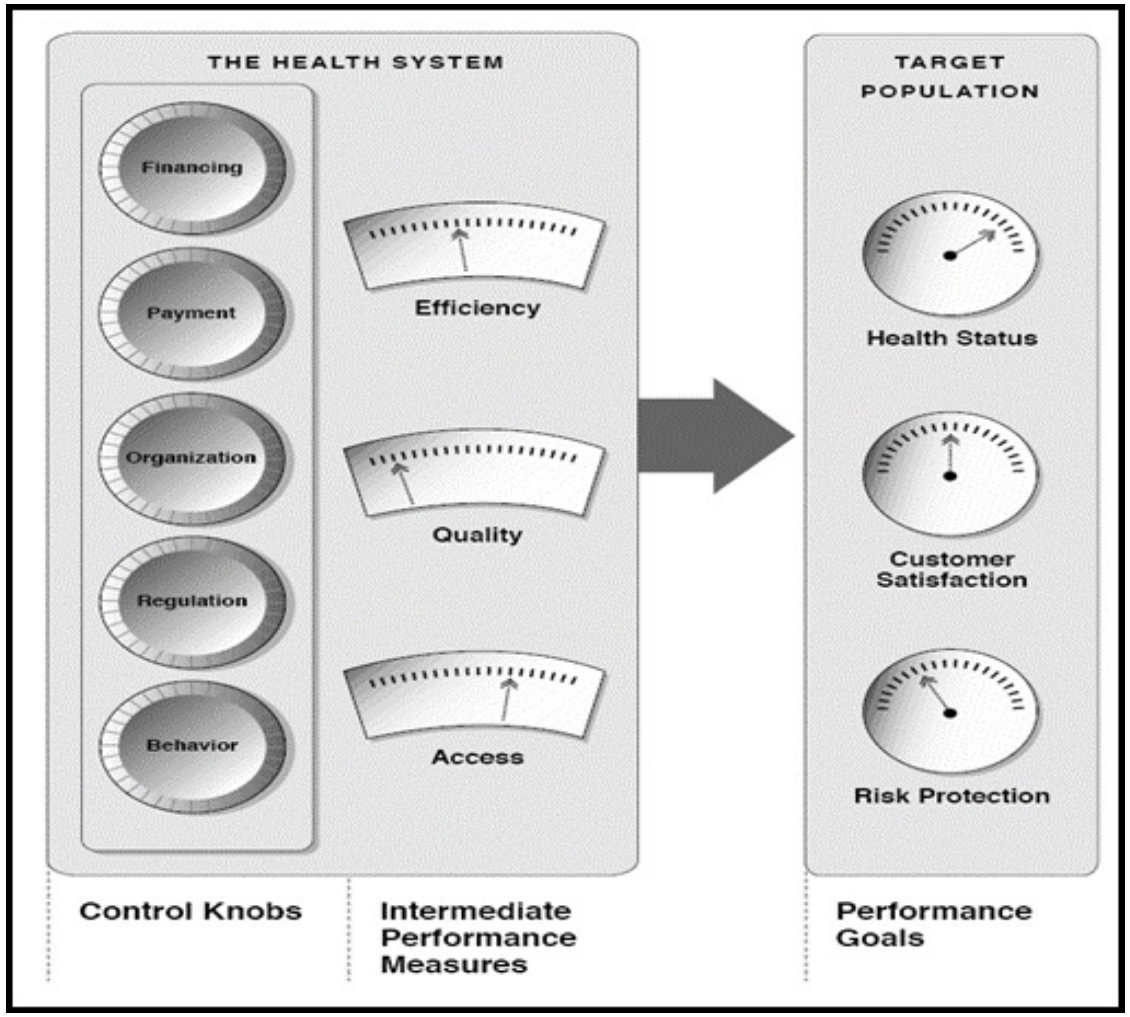
- Emphasis is placed on the system of care delivery that:
  - prevents errors;
  - learns from the errors that do occur; and
  - is built on a culture of safety that involves health care professionals, organizations, and patients

- Patient safety is often measured by assessing adverse events, that may include:
  - **preventable disease,**
  - **Injury,**
  - **and medical error** to the patient.

A Call to Action

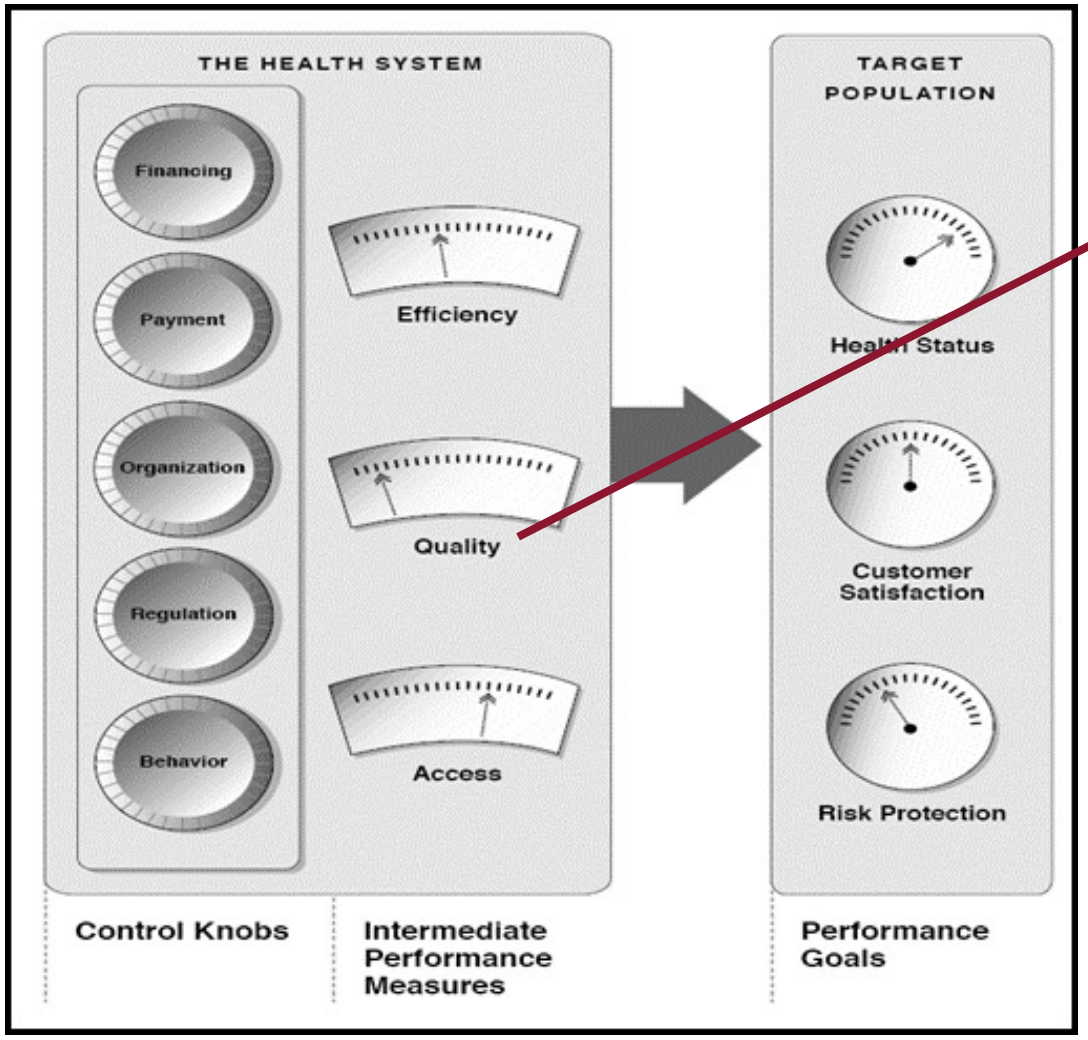
- This IOM report received tremendous attention from both the public and the healthcare industry.[2]
- There was extensive media coverage that was closely followed by the American public.[2,3]
- The healthcare industry responded almost immediately with a wide range of patient safety efforts.[4,5]
- The federal government appropriated $50 million annually for patient safety research.[6]
- Non-governmental organizations issued briefs indicating that patient safety was now a priority.[5]
- Healthcare purchasers such as The Leapfrog Group encouraged hospitals to adopt safer practices and emphasized that safety was also now a priority for them.[7]

Poll 1: Where do you think safety fits in into the control knob framework?



a) Efficiency
b) Quality
c) Access
d) Health status
e) Customer satisfaction
f) Risk protection

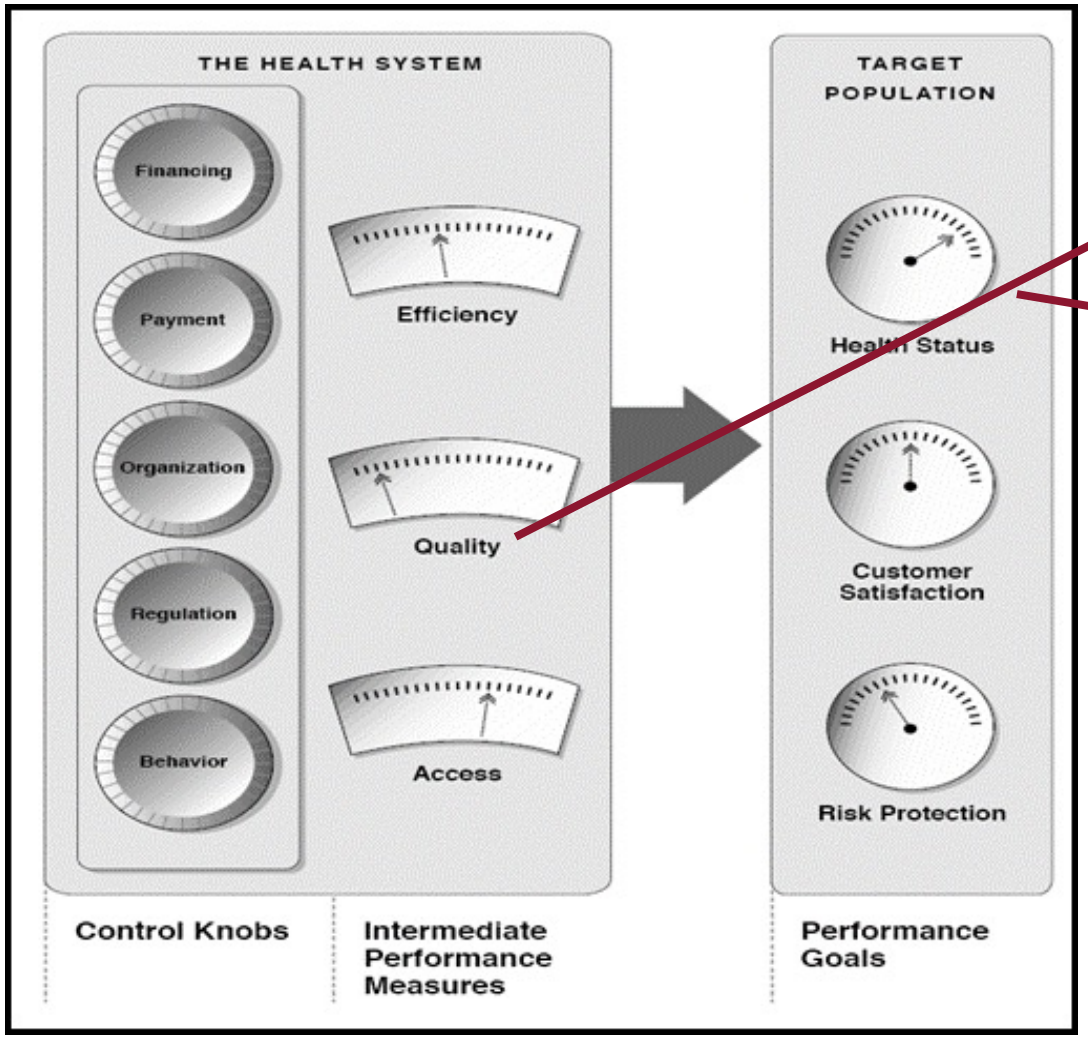
The Control Knob Framework



Patient Safety is a key domain of care quality

- Adverse events, primary measures of safety = intermediate performance measures

The Control Knob Framework



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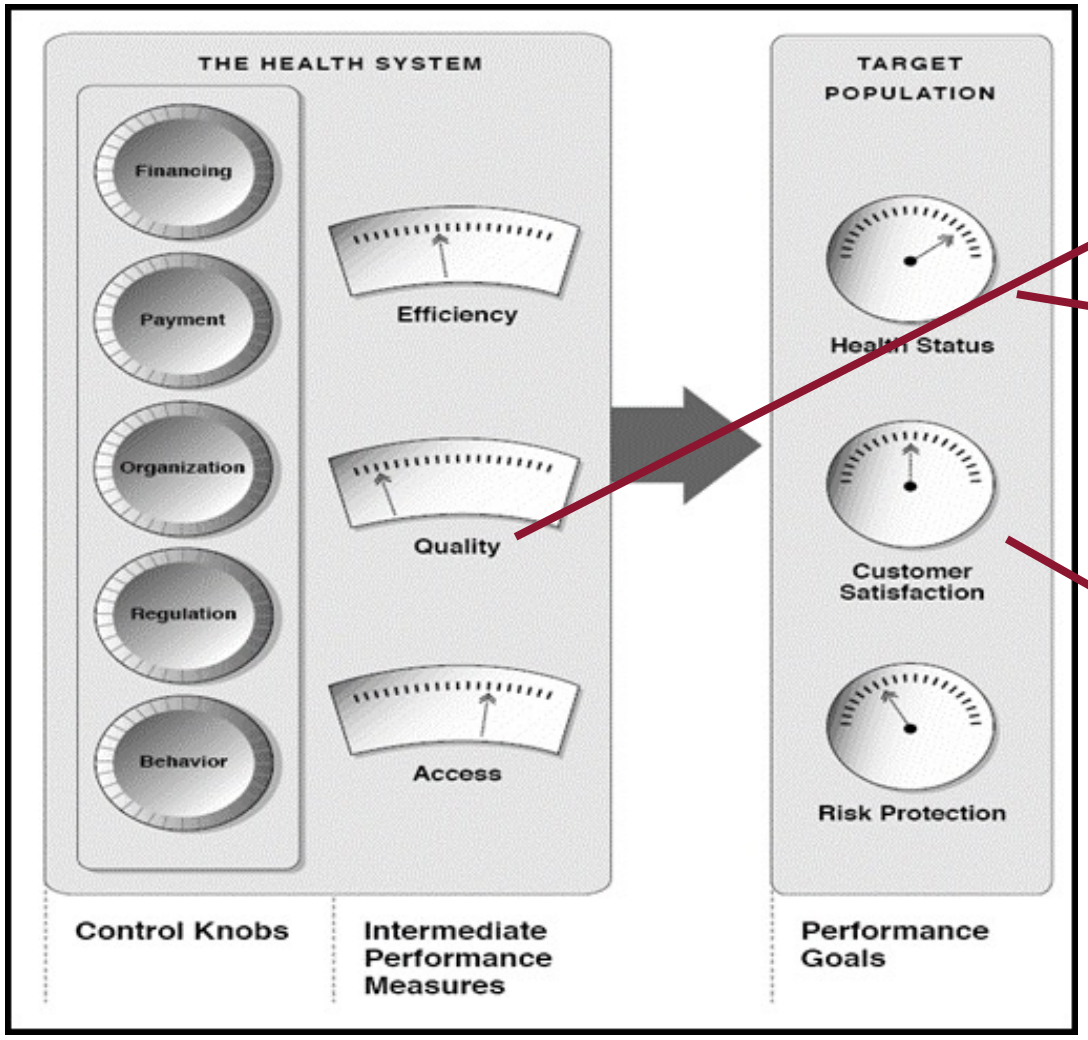
Unsafe care results in lower **health status**
- Longer recovery
- Lower functional status
- Death / disability

The Control Knob Framework



Patient Safety is a key domain of care quality
- Adverse events, primary measures of safety = intermediate performance measures

Unsafe care results in lower **health status**
- Longer recovery
- Lower functional status
- Death / disability

Unsafe care can also result in lower **customer satisfaction**

Like clinical effectiveness & patient-centeredness **safety** is one domain of care quality

Quality Domains	
Clinical Effectiveness	Do patients receive appropriate/ evidence-based treatment when they seek care?
Patient Safety	**Do patients receive care that is free from harm or excess?**
Patient Centeredness	Are patients treated with respect & involved in decisions regarding their care?

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Poll 2: Which of the following is not an adverse medical event?

a. Catheter-associated urinary tract infection

b. Patient fall (e.g. out of hospital bed)

c. Community-acquired pneumonia

d. Decubitus/pressure ulcer (e.g. bed sore)

e. Ventilator associated pneumonia

Defining "Harm" What are Adverse Events?

Injuries can occur in association with many medical interventions, from healthcare-associated infections (due to unhygienic practices) to counterfeit or substandard drugs (due to regulatory and over-sight failures)

Typical characteristics (WHO, 2010):

- Physical **harm** to the patient
- Resulting directly **from the provision / receipt of healthcare**
- Theoretically **preventable** / "never-events"

Expanding definitions:

- Counterfeit / substandard medicines (Woskie, 2019)
- Hitting / physical abuse (e.g. obstetric violence) (Shrivastava, 2019)

These injuries are, by definition, preventable and, therefore, particularly troubling given their prevalence in the delivery of healthcare

Situating Adverse Events

Measurement Type		Example Patient Safety Issues
Structural factors		• Organizational determinants & latent failures • Structural accountability mechanism: e.g. accreditation • Inadequate training, education, manpower • Stress and fatigue
Processes		• Errors in process: misdiagnosis • Errors in process: incorrect treatment • Errors in process: unsafe practice i.e. injection • Errors in process: inadequate follow up
Outcomes	Intermediate	• Adverse events / injuries due to medical devices • Adverse events due to healthcare associated infections • Adverse events due to unsafe blood products • Adverse events due to medications • Etc.
	Health Status	• Functional status • Mortality

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Errors in process are issues of **effectiveness** & can lead to safety events

Global Burden & Effects of Unsafe Care

- Adverse events, or injuries as a result of medical care, lead to direct harm and waste (Jha, 2013)
- This includes disability, but also premature mortality (Jha, 2013)
- Unsafe care also has been found to have spillover effects on patient confidence in the healthcare system (Thomas, 2003)

ORIGINAL RESEARCH

The global burden of unsafe medical care: analytic modelling of observational studies

Ashish K Jha,[1] Itziar Larizgoitia,[2] Carmen Audera-Lopez,[2] Nittita Prasopa-Plaizier,[2] Hugh Waters,[3] David W Bates[4]

- The global burden of disease (GBD) is a standard metric used by policymakers throughout the globe to determine how much suffering is caused by individual diseases.
- DALYS are used by policymakers to better prioritize the interventions likely to improve care and health for the world's citizens.

Table 2 Incidence rates of adverse events among high versus low and middle-income countries

	High-income countries (%)	Low-income and middle- income countries (%)
Catheter-related UTI	1.1 (0.8 to 1.5)	2.0 (0.5 to 3.5)
Adverse drug events	5.0 (2.7 to 7.2)	2.9 (0.6 to 5.2)
Falls in the hospital	1.1 (0.3 to 2.0)	1.6 (1.3 to 2.0)
Catheter-related blood stream infection	0.4 (0.2 to 0.6)	0.4 (0.3 to 0.6)
Nosocomial pneumonia	0.8 (0.7 to 1.1)	0.4 (0.2 to 0.6)
Decubitus ulcers	2.4 (0.8 to 4.7)	2.4 (0.8 to 4.7)
Venous thromboembolisms	3.3 (1.9 to 4.8)	3.0 (1.0 to 4.8)
Overall incidence rate of adverse events	14.2	12.7

*Rates are means (95% CIs) per 100 hospitalisations per year.

Common and Measurable Adverse Events

- Decubitus ulcers
- Falls in the hospital
- Adverse drug events (ADE)
- Venous thromboembolisms (VTE)
- Nosocomial pneumonia / ventilator associated pneumonia (VAP)
- Catheter-related urinary tract infection (CAUTI)
- CR blood stream infections (CLABSI)

What are we missing?

Poll 3: If you had to choose one, at what level do you think adverse events should be reported?

a) The physician

b) The department

c) The hospital

d) The district

e) The state

“To Err is Human”

- The IOM report was entitled “To Err Is Human” because it asserted that unsafe care was not an issue of bad providers, it was fundamentally an issue of good people working in bad systems that need to be made safer (IOM, 2000)
- It also explained how patients themselves can influence the quality of care that they receive once they check into the hospital.

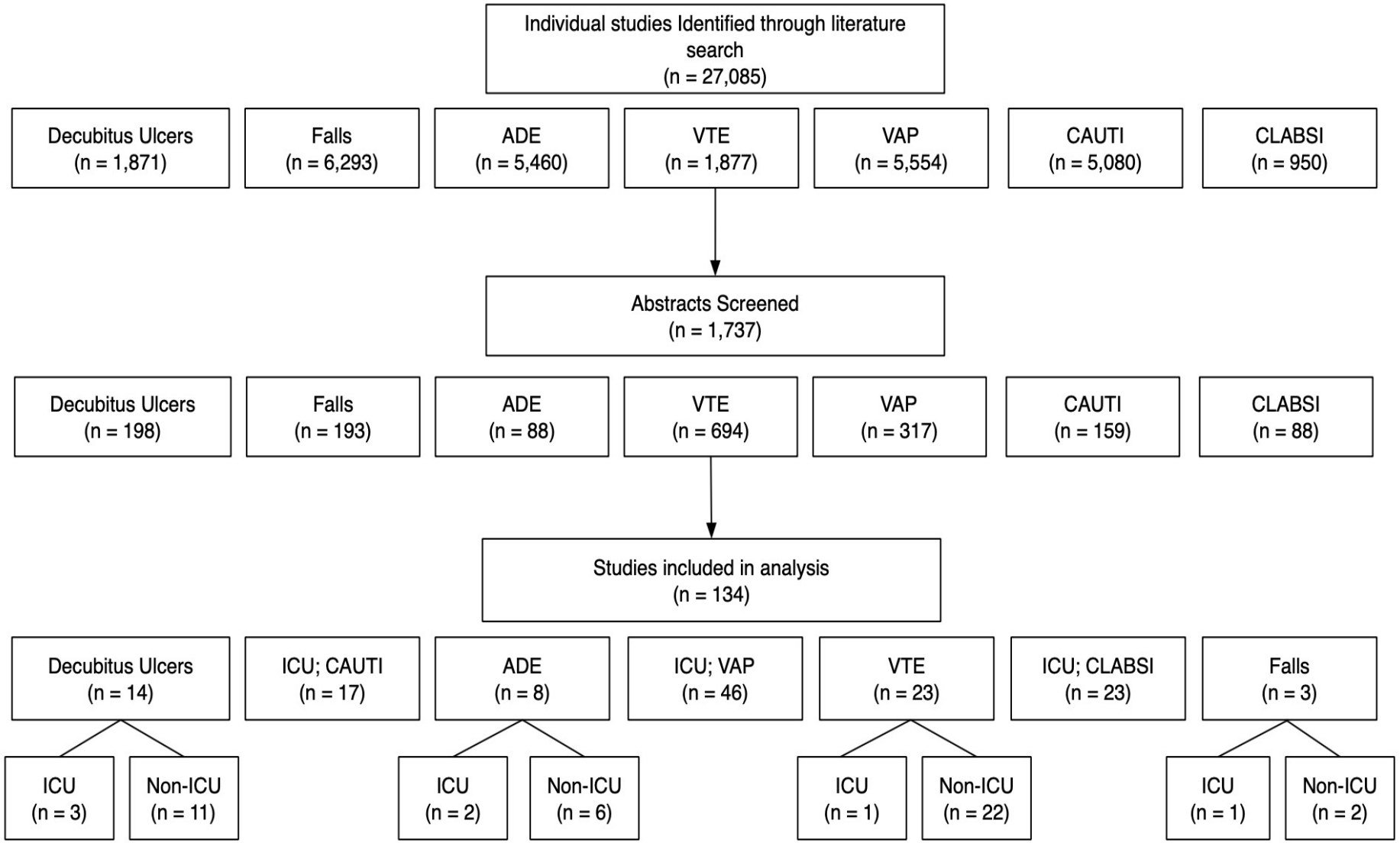
STATE OF THE EVIDENCE

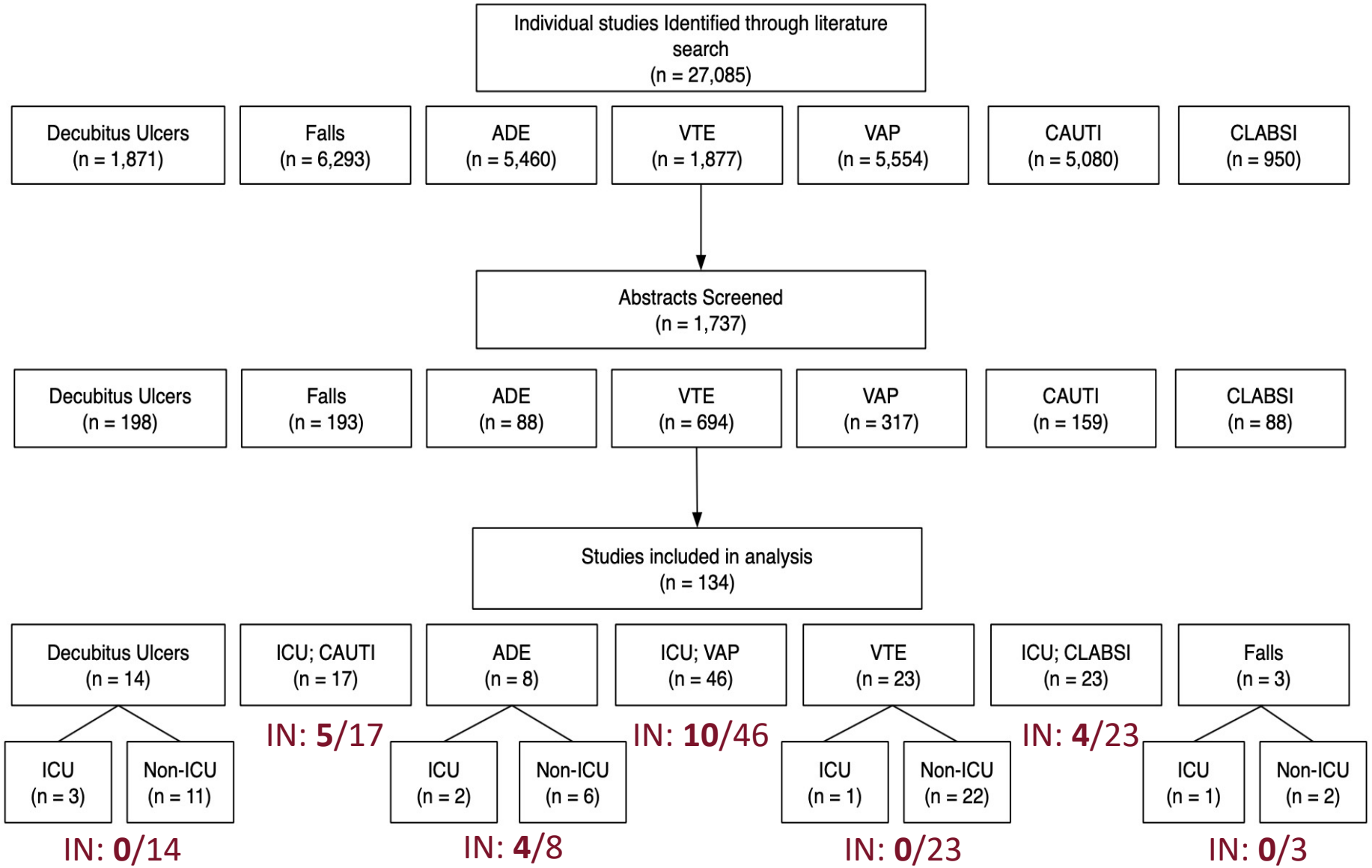
Paucity of Robust, Routinely Collected Data

- Despite the importance of quantifying the burden of unsafe care across countries, lack of data availability on the incidence of adverse events has made this difficult.
- Even where databases do exist, they often rely on death certificates that assign International Classification of Disease (ICD) codes to categorize causes of death.
- As a result, death not associated with an ICD code (such as system and human factors) are not recorded.
- The global burden of unsafe care studies therefore attempt to understand the extent to which the incidence of adverse events has been studied and reported using incidence rates taken from the peer-reviewed literature.

Rates of Adverse Events in HICs

- When you are hospitalized, likelihood of injury
  - 10%-15% across U.S. hospitals
  - Canada 9%
  - Australia – 16%
  - UK - 12%
- Some estimates suggest Adverse Events are the 3rd leading cause of death in US
  - 200K to 400K deaths a year


Individual studies Identified through literature search
(n = 27,085)
Decubitus Ulcers
(n = 1,871)
Falls
(n = 6,293)
ADE
(n = 5,460)
VTE
(n = 1,877)
VAP
(n = 5,554)
CAUTI
(n = 5,080)
CLABSI
(n = 950)
Abstracts Screened
(n = 1,737)
Decubitus Ulcers
(n = 198)
Falls
(n = 193)
ADE
(n = 88)
VTE
(n = 694)
VAP
(n = 317)
CAUTI
(n = 159)
CLABSI
(n = 88)
Studies included in analysis
(n = 134)
Decubitus Ulcers
(n = 14)
ICU; CAUTI
(n = 17)
ADE
(n = 8)
ICU; VAP
(n = 46)
VTE
(n = 23)
ICU; CLABSI
(n = 23)
Falls
(n = 3)
ICU
(n = 3)
Non-ICU
(n = 11)
ICU
(n = 2)
Non-ICU
(n = 6)
ICU
(n = 1)
Non-ICU
(n = 22)
ICU
(n = 1)
Non-ICU
(n = 2)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Falls
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(n = 11)
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IN: 5/17
ICU
(n = 2)
Non-ICU
(n = 6)
IN: 4/8
IN: 10/46
ICU
(n = 1)
Non-ICU
(n = 22)
IN: 0/23
IN: 4/23
ICU
(n = 1)
Non-ICU
(n = 2)
IN: 0/3

One of the most important considerations in assessing safety for performance (e.g. in a national database) is **ensuring that like is compared with like**.

- Many safety events are measured amongst people with high acuity conditions that require intensive, or device-specific care. For example: surgical site infections amongst surgical patients, catheter-related infections amongst people with catheters and bed sores amongst multi-day inpatients.

- To compare rates of unsafe care between facilities, it is critical to understand the at-risk population in each hospital. For example, comparing rates of adverse events between hospitals with intensive care unit (ICU) capacity versus hospitals that predominantly provide outpatient care, is unlikely to capture performance.

- Hospitals with similarly complex patient populations and acuity of services (i.e. similar risk profiles), should – if providing high quality care – have similar rates of adverse events.

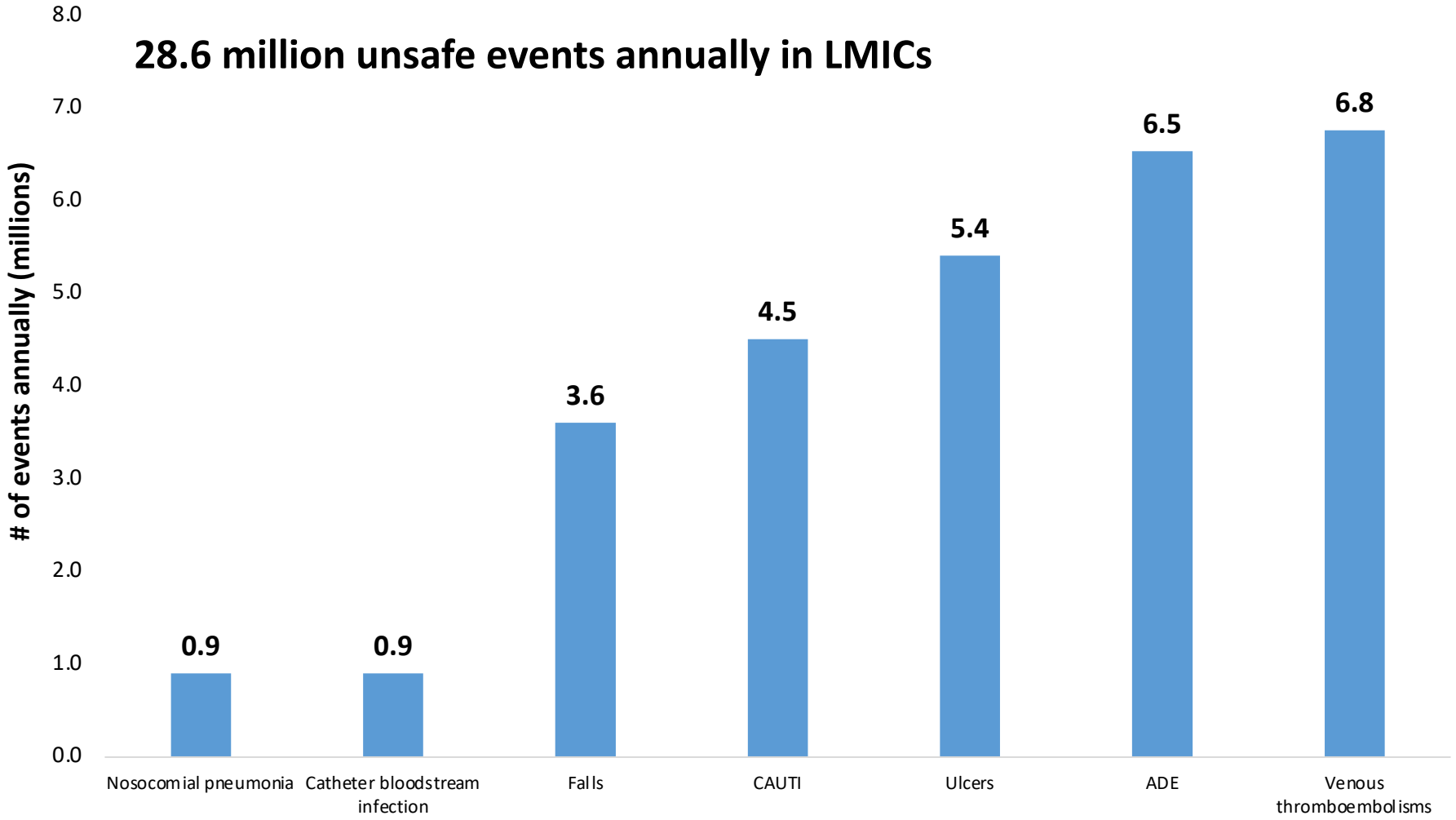
Number of Studies and Corresponding Incidence Estimates by Adverse Event

	Number of Studies	Total Sample Size	Unweighted Incidence	Monte Carlo Incidence
Estimates for the General Hospital Population				
ADE	6	5,006	16.1%	16.1%
Falls	2	2,768	5.1%	5.6%
DU	11	7,751	13.4%	8.2%
VTE	22	133,415	8.5%	2.6%
Total	41	148,940	-	-
Estimates for the ICU Population				
CAUTI	17	5,342	18.1%	10.7%
ADE	2	23,106	7.4%	-
Falls	1	1,815	3.6%	3.6%
VAP	46	30,672	22.6%	8.0%
DU	3	671	26.0%	18.3%
VTE	1	141	6.4%	6.4%
CLABSI	23	9,400	15.2%	7.0%
Total	93	71,147	-	-

Poll 4: What share of hospitalizations lead to adverse events in low and middle income countries every year?

- 4%
- 22%
- 13%
- 1%
- 7%

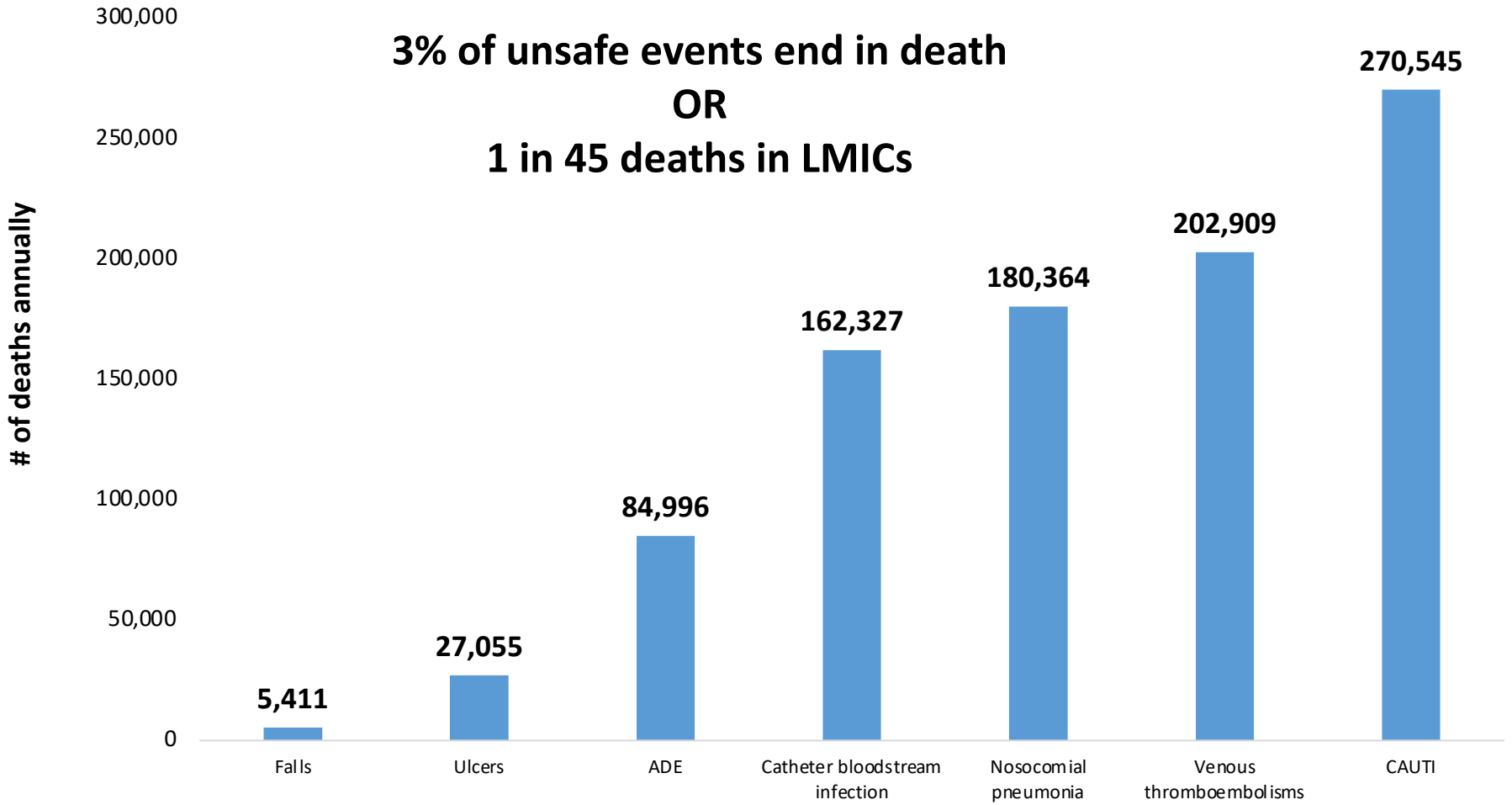
12.7% of hospitalizations result in adverse events



Poll 5: Approximately how many deaths do you think unsafe care leads to each year in low and middle income countries?

- 100 deaths
- 1,000 deaths
- 10,000 deaths
- 100,000 deaths
- 1,000,000 deaths

Nearly 1 million deaths annually due to unsafe care



Reason for Hope

Before the IOM report, adverse events such as hospital-acquired infections were considered a cost of doing business.

Central line–associated bloodstream infections (a type of hospital-acquired infection) represent a notable example.

Peter Pronovost and his team from Johns Hopkins University showed that by following a bundle of safety procedures, they could reduce the incidence of these infections to nearly zero.[8]

The bundle included steps to follow in central venous catheter insertion, the handling and maintenance of lines, and the prompt removal of unnecessary lines. Many felt that these initial results might be too good to be true, but Pronovost and colleagues were later able to replicate the results across the state of Michigan.[9]

This resulted in a change in how people thought about harm, because even in situations in which no obvious error had been made, it was possible to dramatically reduce the risk of harm.

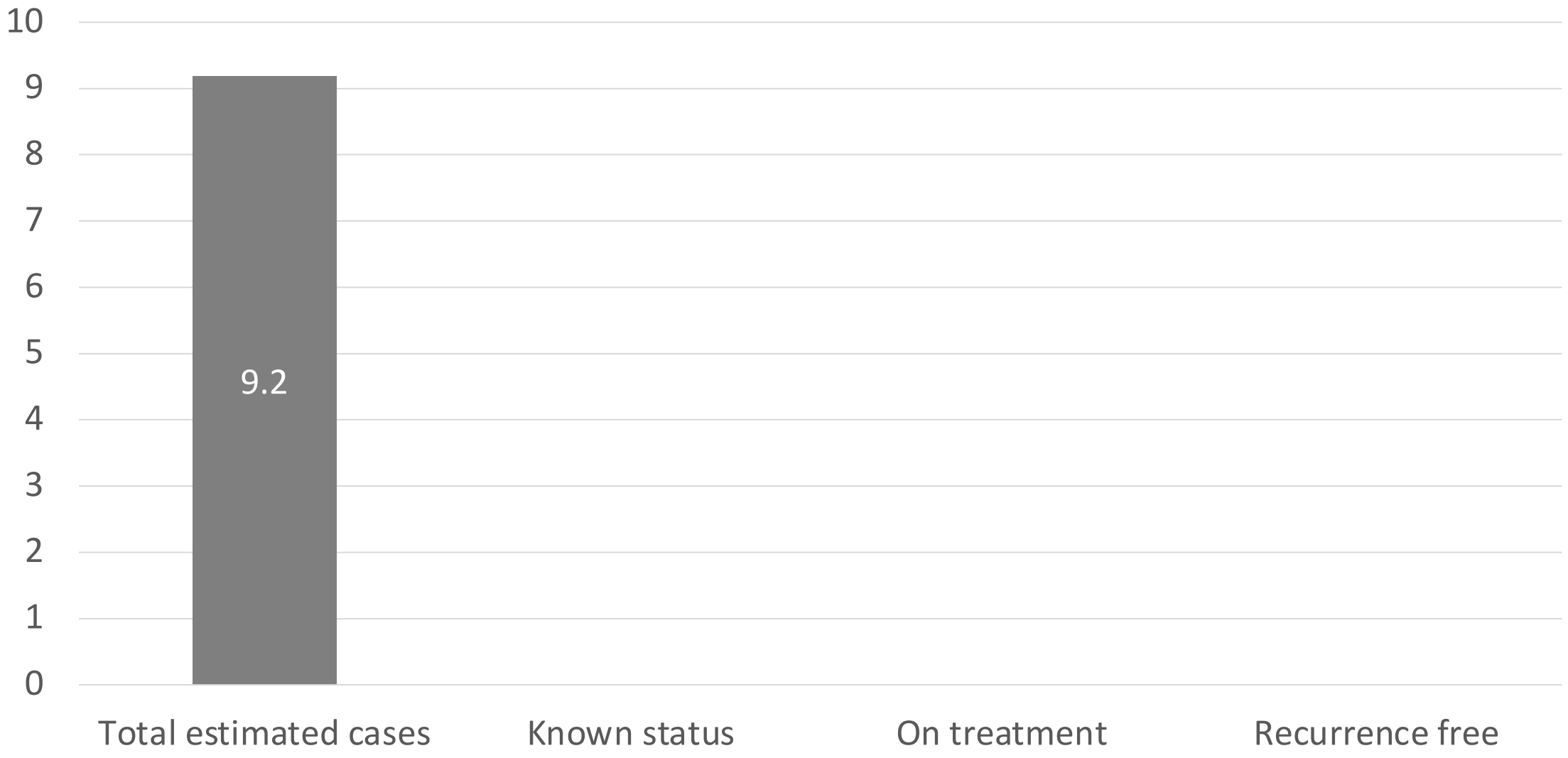
Bates, 2017

In Summary

- Based on our estimates, adverse events constitute the fourth leading cause of death in LMICs, after ischemic heart disease, stroke and COPD.
- In addition to producing estimates of unsafe care that correspond to the total number of hospitalised patients in LMICs, we can parse apart different rates of incidence for adverse events that take place in the ICU setting, such as for VAP or CLABSI.
- We estimate that 1 in every 3 ICU patients in LMICs experience an adverse event annually, resulting in 14 million DALYs annually.
- These death and disability, that we attribute to unsafe care, are likely not a new burden of illness that have been left unrecorded, but **rather an area of harm that has been misattributed to other causes of death and disability**.
- As more people gain access to healthcare through universal coverage, there is a pressing need to better understand, and address, this burden of illness. There are examples of positive change.

COUNTERFEIT CARE EXAMPLE

Estimated TB Cases in all LMICs (millions)



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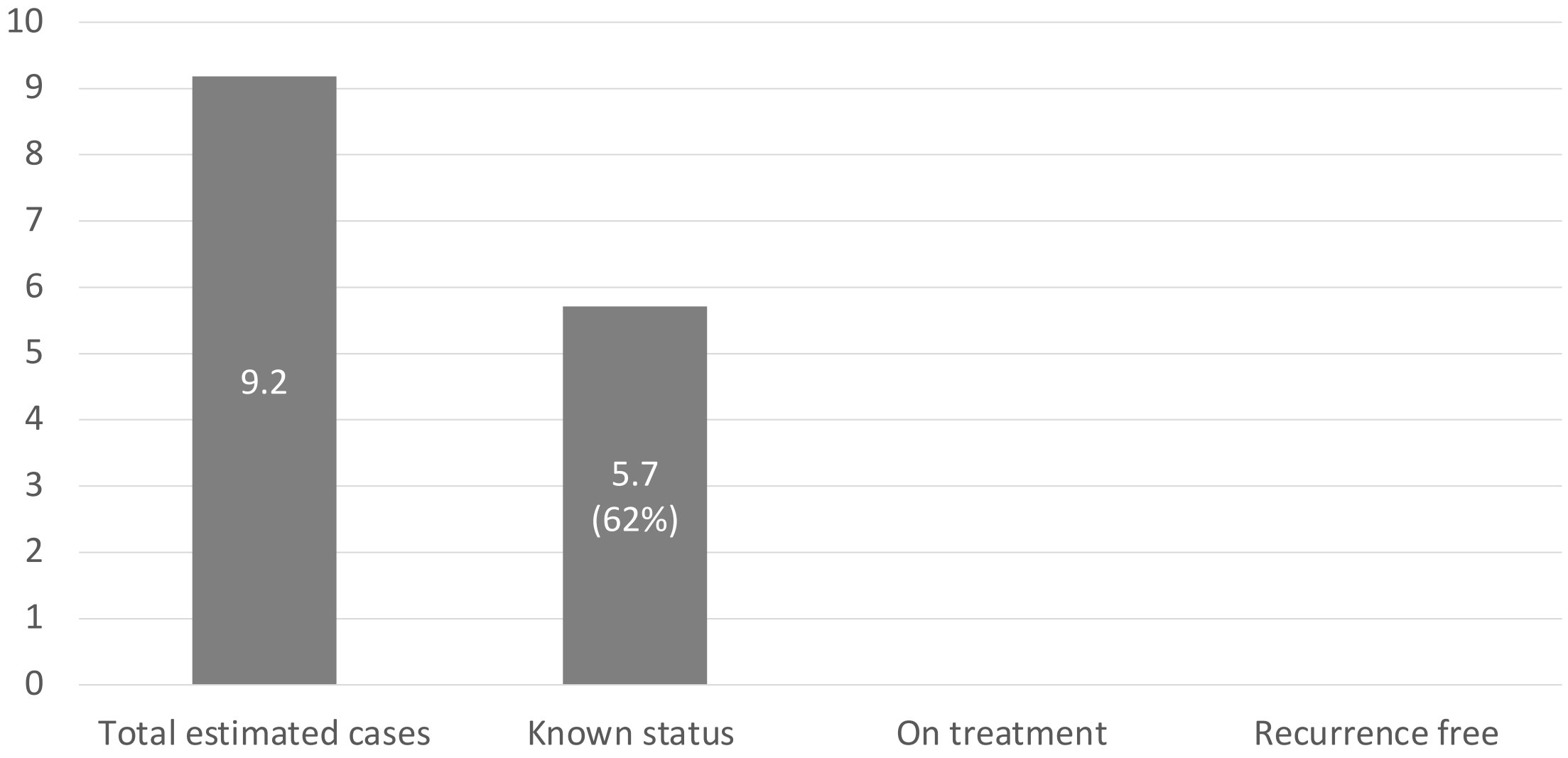

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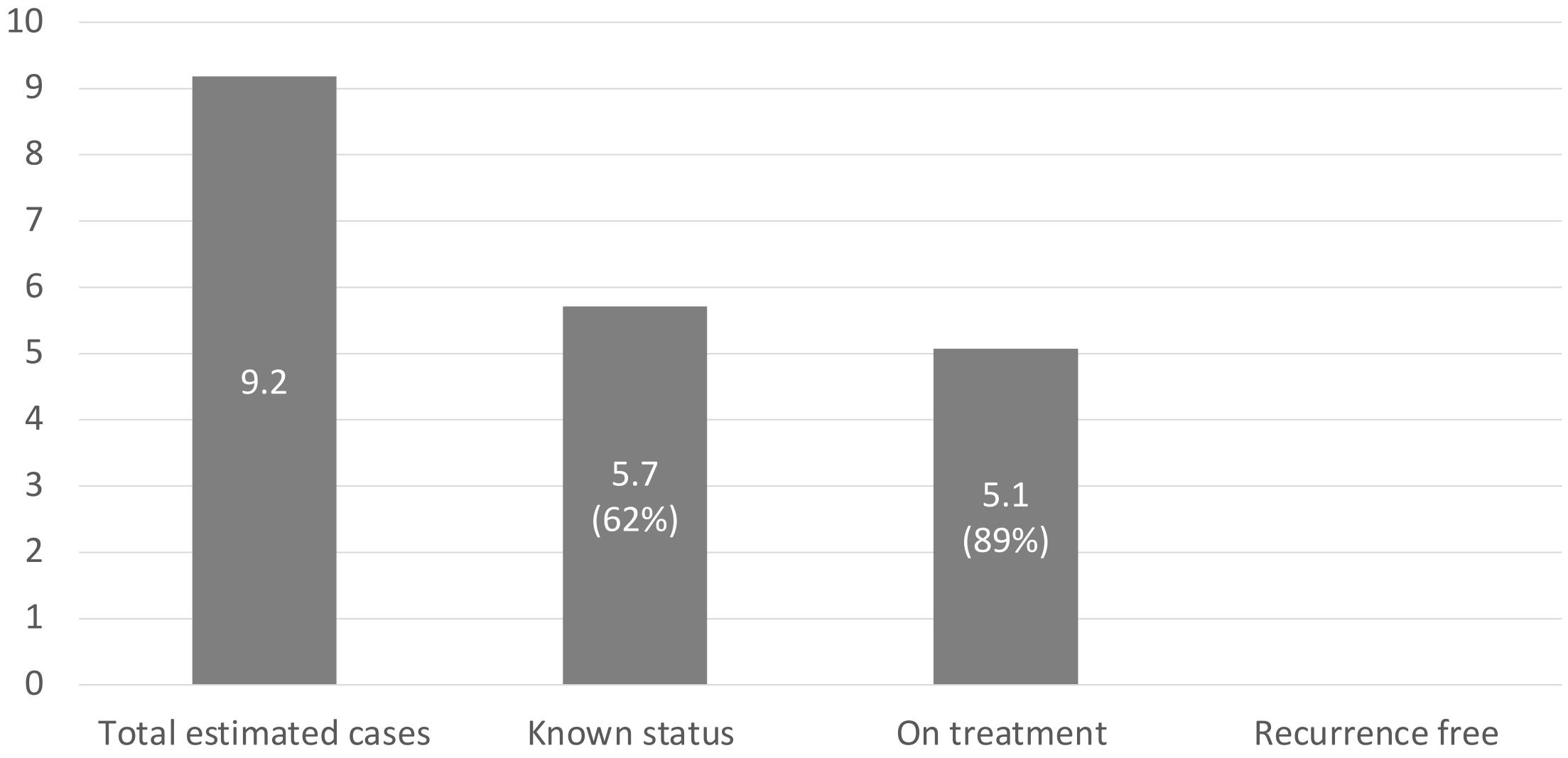

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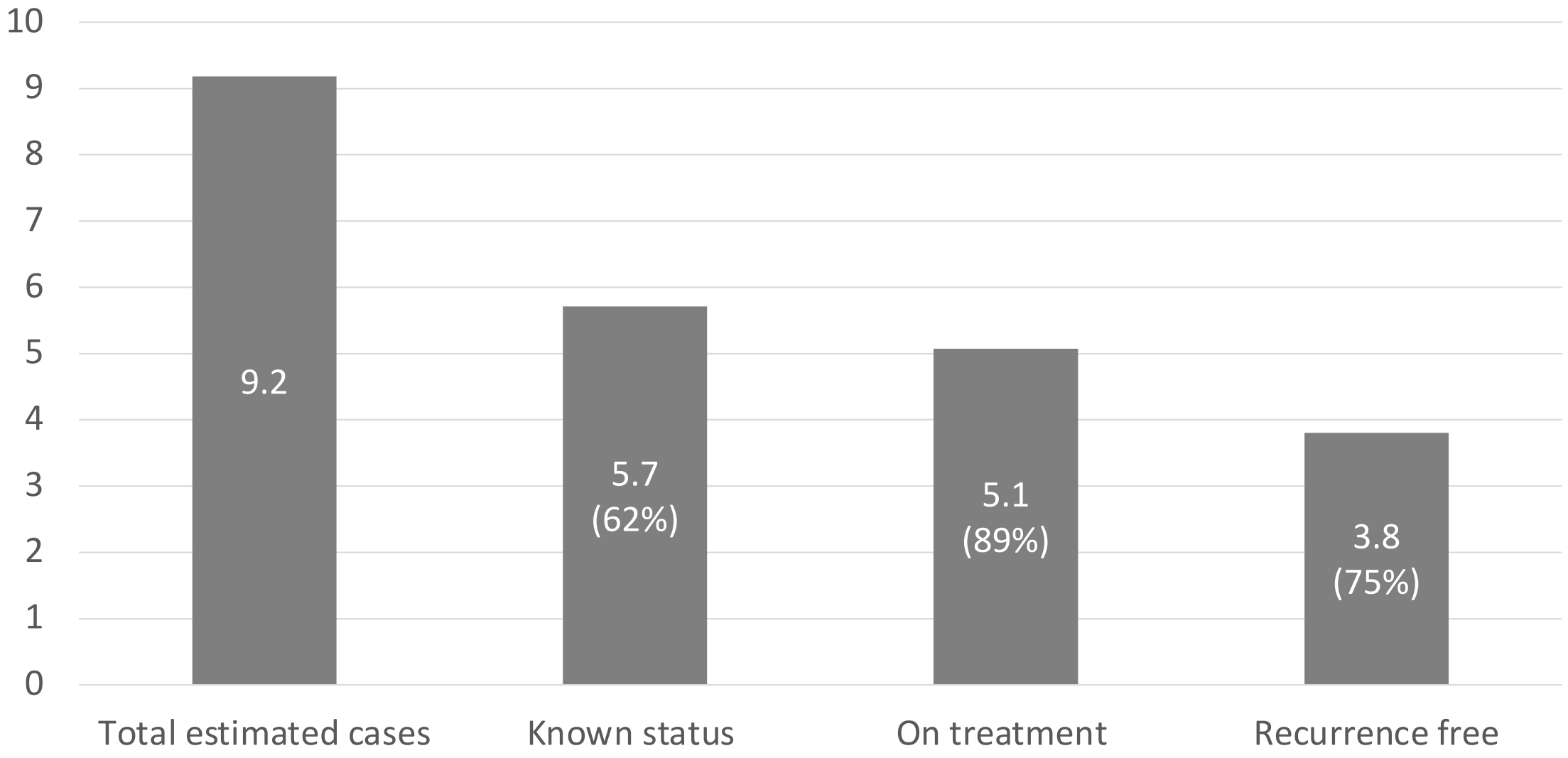


Known Factors that Influence why People on Treatment don't Reach Clinical Goals

Patient-related factors

- Access: resources required to routinely get, and take, drug regimen
- Knowledge & beliefs: perceived importance of following a given regimen

Condition-related factors

- Rate of progression & severity of the disease
- Co-morbidities (such as depression or drug/alcohol dependence) acting as important modifiers

Therapy-related factors

- Complexity of regimen & duration of treatment

"Improving clinical performance amongst people initiated on treatment in LMICs" (WHO, 2015)

1 in 10 medical products in developing countries is substandard or falsified

28 November 2017 | News release | Geneva

WHO urges governments to take action

An estimated 1 in 10 medical products circulating in low- and middle-income countries is either substandard or falsified, according to new research from WHO.

Research Questions

1. **Share**: For TB patients who are *on treatment*, but not achieving their clinical goal, how much of this gap may be due to fake medicines?

2. **Human burden:** What is the health burden resulting from fake medicines for these two conditions?

Defining “Fake Medicines”

- **Active pharmaceutical ingredient (API)** required for intended therapeutic purpose
- We use standard global definitions to determine inadequate API
- Can also use the term *Fake Medicines*

Situating Fake/Counterfeit Medicines as A Safety Issue

Measurement Type		Example Patient Safety Issues
Structural factors		• Organizational determinants & latent failures • Structural accountability mechanism: e.g. accreditation • Inadequate training, education, manpower • Stress and fatigue
Processes		• Errors in process: misdiagnosis • Errors in process: incorrect treatment • Errors in process: unsafe practice i.e. injection • Errors in process: inadequate follow up
Outcomes	Intermediate	• Adverse events / injuries due to medical devices • Adverse events due to healthcare associated infections • Adverse events due to unsafe blood products • Adverse events due to medications • Etc.
	Health Status	• Functional status • Mortality

Medicines with inadequate/inactive API either do not provide their intended clinical benefit or actively cause harm & can be considered a form of **adverse events due to medications**

Data, Fake Medicines

Our data came from the WHO which is made up of 2 main sources:

- 34k Samples: Independent peer-reviewed studies
- 14k Samples: Medicines Quality Database

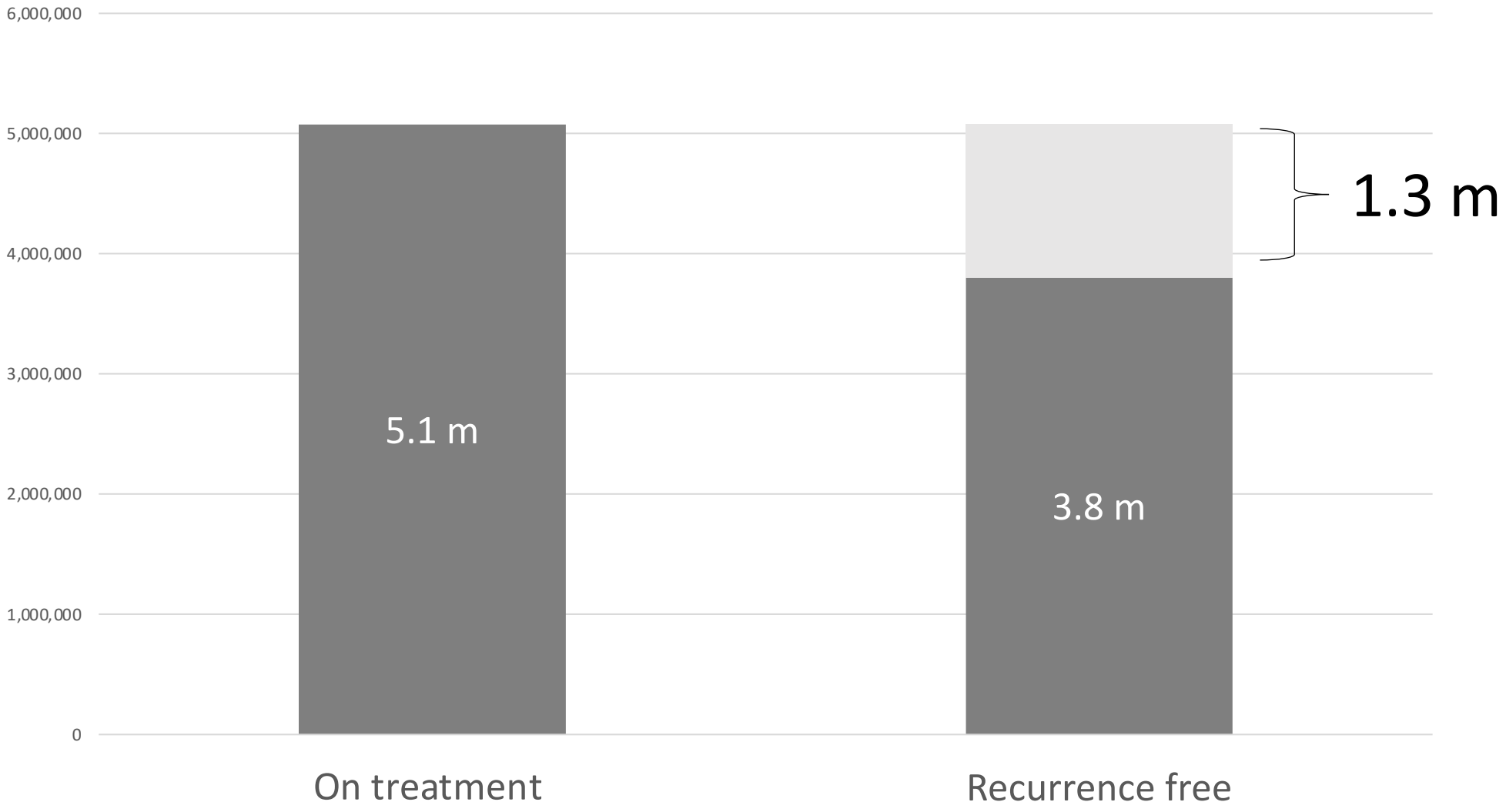
In total this includes **48,218 samples**
collected in **88 countries** from **2007 - 2017**

Disability Adjusted Life Year (DALY)

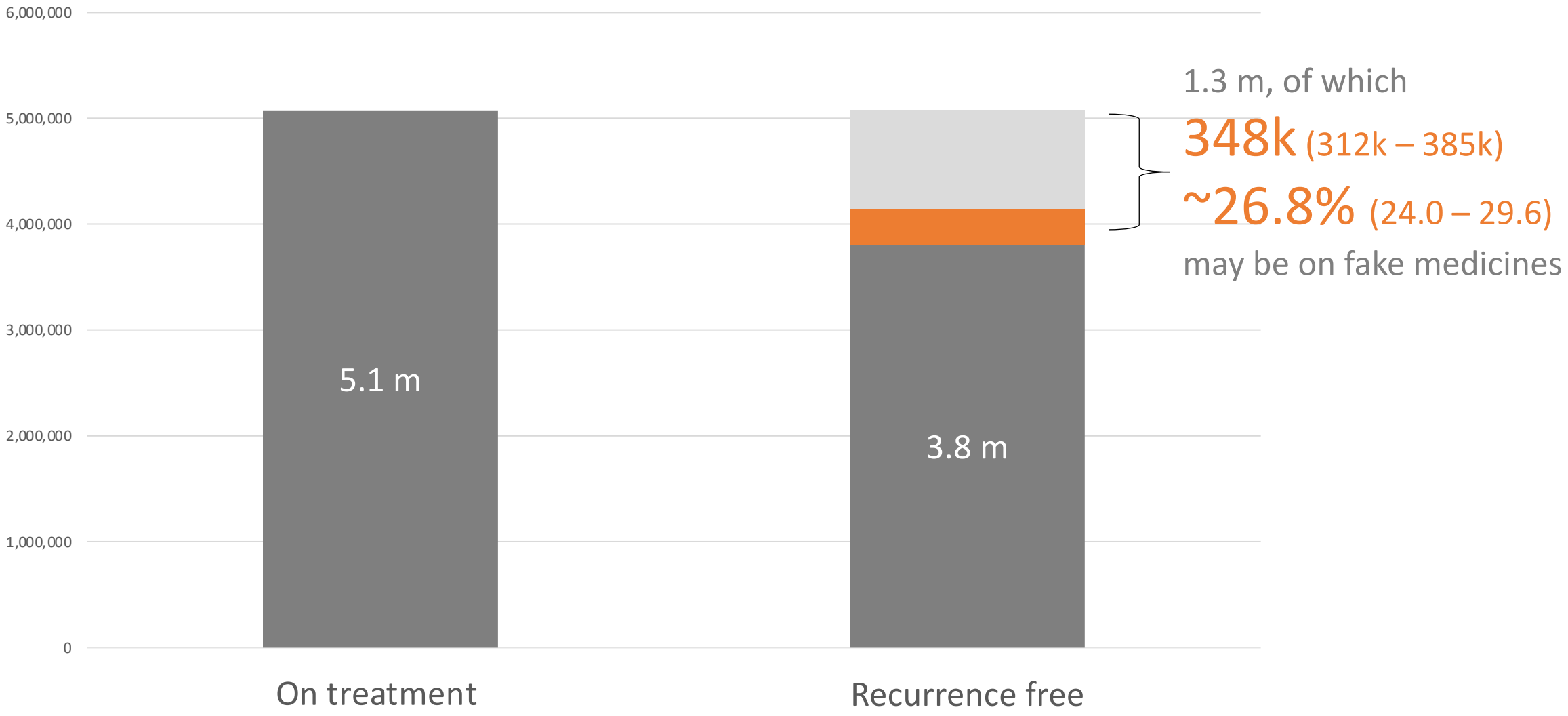
DALY = **Disability** + **Death**

YLD = Years of life Lost due to Disability (such as functional status)
YLL = Years of Life Lost due to premature death

Study Population, TB



Question 1: Prevalence of fake medicine exposure, TB



Question 2: Annual Human Harm, TB Fake Medicines

	Annual Harm	95% CI
DALYs		
Years of Life Lost	**7.8 m**	6.98 – 8.60
Years of life with Disability	**0.13 m**	0.11 – 0.14
Total DALYs	**7.91 m**	7.09 – 8.74
Deaths		
Drug-susceptible	**245,969**	220,271 – 271,667
MDR-TB	**8,703**	7,793 – 9,612
XDR-TB	**442**	396 – 489
Total Deaths	**255,115**	228,461 – 281,769

MEASUREMENT OPTIONS

Status Quo Measurement Options

Method of Measurement	Description	Relevance to Patient Safety
API Assessment	Direct assessment of the share of a drug's "active pharmaceutical ingredient"	There are now handheld devices that can be used to assess how "real" a drug is, these are still relatively expensive but can be used to conduct random "spot checks" of medicines This can be done at the point of purchase
Voluntary Error Reporting Systems	Self-reporting mechanisms to identify patient safety errors and enable healthcare providers & staff to submit patient safety incident reports	Self-reporting mechanisms can be used to directly identify patient safety errors by enabling healthcare providers & staff to submit patient safety incident reports. However, voluntary reporting strategies suffer from selection bias, particularly in contexts where patient safety culture is poor and there is fear of repercussion

Poll 6: What do you think are the most significant challenges to reporting safety events in Indian hospitals?

- No management support
- People do not think safety is a problem in the first place
- There are more significant issues
- Nothing would be done about it
- Fear of repercussion
- Other

Poll 7: If people don't voluntarily report adverse events, what measurement strategies do you think would be most useful to employ?

a) Chart review

b) Patient safety culture survey

c) Participant observation

d) Standardized patients

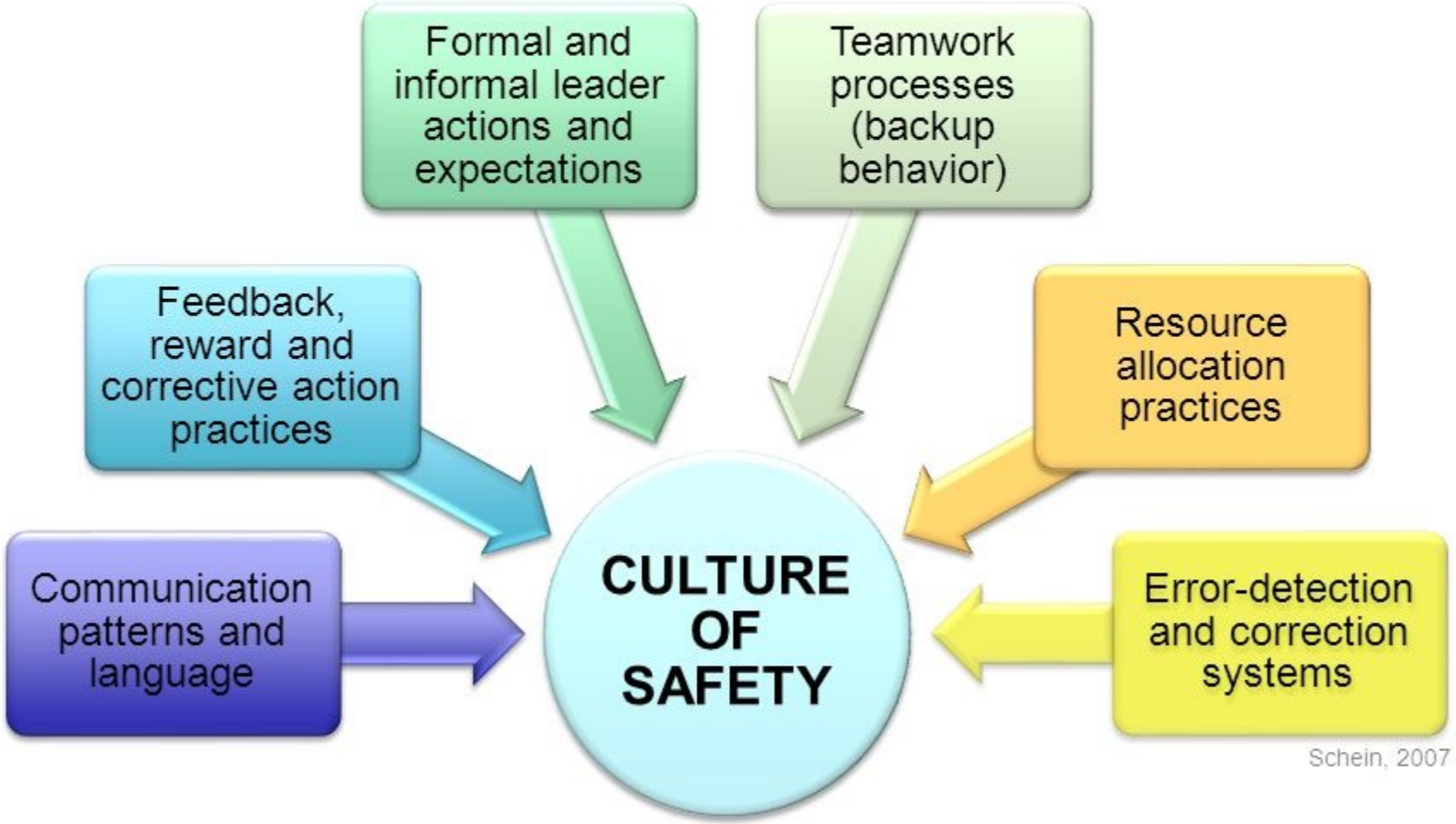
e) Other

Method of Measurement	Description	Relevance to Patient Safety
Patient Survey	Survey posed directly to patients (can be on any platform – phone, paper, oral, etc)	Useful to employ following patient-discharge – did the patient experience unexpected issues once they left the hospital? ”unexpected” may be hard to identify for patients, so use of “experience” or more objective questions Can also be used to assess functional status e.g. following surgery; deviation from expected recovery may help identify errors retrospectively
Participant Observation	Third party professionals “observe” the provider’s interaction with the patient. The provider’s diagnosis, treatment are compared against clinical guidelines.	As discussed in the session on effectiveness - participant observation can be used to assess many process measures relevant to patient safety, such as incorrect drug administration However, this method is subject to performance bias due to providers’ knowledge that they are being observed
Chart Reviews	Patient’s charts/discharge summaries are collected from providers. The provider’s diagnosis, treatment are compared against clinical guidelines.	Provides information on the process of care, which can be used to identify when/where/how, a safety incident, occurred during the care cascade. If documentation is adequate, can be used to determine the incidence and prevalence of adverse events. Nosocomial diseases, such as pneumonia can be identified if the patient did not have the disease on arrival
Standardized Patients	Patient actor visits the provider with specific symptoms & responds to the provider’s questions.	By definition, unsafe care causes harm to the patient. As a result it is not advised to use standardized patients to assess patient safety issues

Under-reporting & indirect measures of safety / culture

- At the organizational level, safety improvement is closely related to good management and the effective implementation of a safety culture.[27]
- A consistent and salient safety culture is a critical determinant of the success of safety interventions, and organizations can measure their safety culture over time using a validated instrument, the Hospital Survey on Patient Safety Culture.
- Organizations are unable to take on newly identified safety issues when they are still struggling to manage old ones whose solutions have not been sustainable because of culture issues.

Hospital Survey on Patient Safety Culture



	Method of Measurement	Description	Relevance to Patient Safety
Direct	**API Assessment**	Direct assessment of the share of a drug's "active pharmaceutical ingredient"	There are now handheld devices that can be used to assess how "real" a drug is, these are still relatively expensive but can be used to conduct random "spot checks" of medicines This can be done at the point of purchase
Direct	**Voluntary Error Reporting Systems**	Self-reporting mechanisms to identify patient safety errors and enable healthcare providers & staff to submit patient safety incident reports	Self-reporting mechanisms can be used to directly identify patient safety errors by enabling healthcare providers & staff to submit patient safety incident reports. However, voluntary reporting strategies suffer from selection bias, particularly in contexts where patient safety culture is poor and there is fear of repercussion
Indirect	**Safety Culture Surveys**	Survey posed to hospital staff involved with direct or indirect patient care (doctors, nurses, allied health professionals and managers/supervisors)	The patient safety culture survey (HSOPS) helps assess factors that contribute to developing a positive patient safety culture. These include strong, consistent leadership, better communication, blame free environments, interdisciplinary teamwork, incentives to report errors and dissemination of information and learning from errors.
Indirect	**Root Cause Analysis**	A process to help organizations understand why an unexpected death or known safety event occurred to identify & address the root causes	Root cause analysis can occur in the case of a known safety lapse – e.g. where a patient was given a harmful dose of a drug (to identify why this occurred) This can also be done in the case of an unexpected death e.g. through a "morbidity and mortality" conference to see if a safety lapse did occur that impacted the patient's state

Additional Considerations

- Some tools (e.g. retrospective chart review) are labor-intensive
- The adoption of platforms that make the routine assessment of errors more automatic can be costly (e.g. electronic health records) and still require active attention to ensure inputs are regular and accurate
- Screening tools (e.g. Patient Safety Culture Surveys and Voluntary Error Reporting Systems) cannot be reliably used for measuring incidence or prevalence of most safety problems.
- Estimates of certain types of error (e.g. diagnostic errors) often lack standardized and reliable guidelines, making it difficult to estimate harm or attribute blame
- Fear of retribution or punitive action often results in underreporting of patient safety errors

Addressing Unsafe Care & COVID-19

BREAKOUT SESSIONS: Group discussions, safety & COVID-19

GROUP 1: The minister of health has asked you to help investigate an unexpected increase in deaths in three rural hospitals. They are concerned that there have been serious lapses in safety protocol due to COVID-19. You have one month of full access to the facilities – what do you look at and why?

GROUP 2: You are the regional director of the WHO. Accurate reporting of death has been a significant issue during the pandemic. You are working to promote accurate reporting – what strategies would you employ and how might you draw on the patient safety literature to encourage countries to accurately report deaths?

GROUP 3: You are the chair of a large private hospital network; your ventilators are being used at capacity, at all times, for patients with COVID-19. What steps would you take to understand if this is leading to adverse events amongst your COVID-19 patients?

GROUP 4: You are the director of one rural hospital. You see an increase in adverse events experienced in your maternity ward due to the diversion of staff for COVID-19. What do you do, how do you prioritize the new COVID-19 patients' safety and also patients in need of more routine care?

GROUP 5: You are the head of a generally well-resourced intensive care unit. However, the volume of acute COVID-19 cases exceeds bed space and your staff are completely overworked. You know safety is becoming an issue – what three safety issues do track given your limited resources?

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To recap

- In the years since the IOM report's publication, it has become increasingly clear that safety issues are pervasive throughout health care and that patients are frequently injured as a result of the care they receive
- Medication errors have also been found to be one of the most common causes of harm; of which counterfeit and substandard medicines are a major contributor
- There are proven solutions to safety issues, but culture remains a significant barrier to accurate reporting
- At the organizational level, safety improvement is closely related to good management and the effective implementation of a safety culture
- Despite the high and harmful burden of unsafe care, there are many proven efforts to address safety & the MOHFW has prioritized the issue in India

Thank you!

#uniteforsafecare

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