

# HOW TO TRANSFORM PATIENT SAFETY AND SAVE HEALTHCARE SYSTEMS



### 3 GOOD HEALTH AND WELL-BEING



## 17 PARTNERSHIPS FOR THE GOALS



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At the time of the publication, Dr Boehme was appointed to  
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# Patient Safety in Numbers

Before the start of the pandemic, **1 in 10** patients were harmed while receiving hospital care (WHO).

Unsafe care results in over **3 million** deaths each year worldwide (WHO).

The social cost of patient harm is **US\$1–2 trillion** a year. Eliminating harm could boost global economic growth by over 0.7% a year. This adds up to more than US\$ 29 trillion, or about 36% of current global output over a decade (OECD).

The risk of healthcare associated infections in low- and middle-income countries is **20 times higher** than in high-income countries (Commonwealth).

**4 in 100** people die from unsafe care in the developing world (WHO).

According to available estimates, approximately **20%** of all-cause global deaths are due to sepsis, disproportionately affecting neonates, pregnant or recently pregnant women, and people living in low-resource settings (Global Sepsis Alliance).

**US\$383.7 billion:**

The forecasted cost to the global economy by 2022 due to patient safety issues (G20).

Unsafe care disproportionately impacts low- and middle-income countries, where **134 million** adverse events occur in hospitals every year, contributing to 2.6 million deaths (WHO).

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\*This work was done when Catharina Boehme was CEO at FIND.  
At the time of the publication, Dr Boehme was appointed to Cabinet Chief at the World Health Organization.





HRH Prince Khalid bin Bandar bin Sultan Al Saud

## FOREWORD

In March 2019 the Kingdom of Saudi Arabia had the honour of hosting the fourth global ministerial summit on patient safety. The event was attended by over 1500 global health experts from around the world. It was organised in cooperation with WHO and the governments of Japan, Germany and the United Kingdom.



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Both patient safety and health workers' safety are fundamental for building resilient healthcare systems and a sustainable world economy.”

The aim of the Ministerial Summit was to identify scalable and sustainable solutions to the challenge of ensuring patients are kept safe when they are often at their most vulnerable. The summit concluded that if we are to deliver Universal Health Coverage and Sustainable Development Goal (SDG) 3 to meet United Nations SDG targets by 2030, we need better collaboration to improve and promote patient safety globally.

Patient safety has a high priority in Saudi Arabia, as the safety of our patients and health workers means the safety of our societies and economies now and for the years to come. This is why for Saudi Arabia's G20 Presidency under the theme, 'Realising Opportunities for the 21st Century', the Kingdom made global health and patient safety a central tenet of the Presidency by putting people empowerment at its centre.

With the unprecedented COVID-19 pandemic sweeping across the world, global health has become an even more critical area for international cooperation. Therefore, it was essential that this year's G20 Presidency had a robust health track. Given that the Kingdom of Saudi Arabia had created a national patient safety centre to take forward new policies that put the patient at the

heart of the healthcare system, this year's G20 Presidency introduced, for the first time, 'Patient Safety' onto the G20 agenda. This approach has also been central in supporting the goals and values of Saudi Arabia's Vision 2030 goals and its three main pillars – a vibrant society, a thriving economy and an ambitious nation – with the overarching goal of making the Kingdom an exemplary and leading nation in all aspects.

The op-eds by distinguished leaders of the global health and economic community in this report demonstrate why we must carry forward the importance of promoting the health and well-being of our patients and health workers to next G20 and G7 Presidencies that include the Italian G20 Presidency and the UK G7 Presidency in 2021. A year after the Jeddah Global Ministerial meeting, and in the midst of this pandemic, it has become even clearer that both patient safety and health workers' safety are fundamental for building resilient healthcare systems and a sustainable world economy.

The Kingdom of Saudi Arabia is committed to continue to play its part in improving patient safety and global health security in this challenging period for all citizens around the world.



Jeff Surges

## INTRODUCTION

COVID-19 has shone a light on the challenges facing millions of patients and frontline health workers around the world.

Before the start of the pandemic, 1 in 10 patients were harmed while receiving hospital care according to the World Health Organization (WHO)<sup>1</sup>. Since then, further challenges have emerged that contribute to patient and health worker harm, including increased infection rates, overcrowded facilities and limited access to personal protective equipment (PPE).

Furthermore, the socio-economic consequences of COVID-19 continue to devastate communities. On a macroeconomic scale, the pandemic has left G20 economies with a deficit of USD 12 trillion, exceeding the 2008 economic crisis entirely. To build back our economies stronger and better than before, we need to proactively identify and prevent risks, care for the mental and physical wellbeing of global health workers and ensure patient safety is at the forefront of the global healthcare agenda.

To this end, the WHO, the Organisation for Economic Co-operation and Development (OECD) and the G20 have joined together with civil-society organisations around the world to address the challenges facing patient and health worker safety and to discuss how the leadership of policymakers, existing digital health solutions and best practices across care settings can help move us towards a world free of preventable patient and health worker harm.

In 2019, the G20 Presidency, under the auspices of

the Kingdom of Saudi Arabia, placed patient and health worker safety at the heart of the national agendas of G20 governments. This work was further supported by the WHO, who, on World Patient Day 2020<sup>2</sup>, issued a charter on health worker safety dedicated to the millions of health workers fighting COVID-19 across the globe.

Outside of healthcare, industries such as aviation and nuclear energy serve as success stories when it comes to safety and reinforce the notion that more can be done. In aviation, an individual has a 1 in a million chance of being harmed while travelling on a plane, whereas the chance of a patient experiencing harm in healthcare is 1 in 300. These numbers alone demonstrate a clear need for coordinated action to address safety in healthcare while providing hope for what's possible if we commit ourselves to change.

All of this lends itself to the need for fast, coordinated and effective solutions to address patient and health worker safety, including digital health technology. Technological innovations will undoubtedly pave the way for global economic recoveries while at the same time mitigating – and ultimately preventing – harm to health workers and patients.

What's more, transforming institutional and global care delivery to achieve 'Zero Harm' demands systemic and cultural change across healthcare

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The G20's inclusion of patient safety as a central tenet of the 2020 G20 summit and the WHO's charter on patient safety shows that, globally, we are uniting around a shared vision of patient and health worker safety.”

organisations. This will only be achieved through continual learnings that prevent safety events and near misses from happening again and through programs that prioritise health worker safety.

At RLDatix, we are committed to building digital health and patient safety tools to help achieve the United Nations Sustainable Development target by 2030. For more than three decades, we have been a trusted ethical patient safety and risk management software and services provider for organisations across G20 countries, including the United Kingdom, the United States, the Kingdom of Saudi Arabia, Australia, Canada and Denmark.

RLDatix's Communication and Optimal Resolution (CANDOR) program helps hospitals and health systems respond to harmful events and is supported by robust software for proactive interventions with patients, families and affected health workers. It prioritises the importance of responding in a principled manner following a harm event by engaging patients and families, caring for caregivers, learning from incidents and revising organisational policies and procedures to ensure institutional changes take place to prevent future harm.

The G20's inclusion of patient safety as a central tenet of the 2020 G20 summit and the WHO's charter on patient safety shows that, globally, we are uniting around a shared vision of patient and health worker safety.

This report brings together an elected group of experts from across International Organisations, G20 Governments, The Global Health Community and Civil Society to address the challenges that patients and health workers have faced and are currently facing amidst the COVID-19 pandemic. It demonstrates how the safety of patients and health workers is inexorably linked to all global health challenges including infectious and non-communicable diseases.

What this report makes abundantly clear is that without acknowledging the safety challenges that patients and health workers face, reopening our societies, growing our economies and improving the resiliency of healthcare systems will be more challenging than ever. The time to change is now.

<sup>1</sup> See: [www.who.int/news-room/photo-story/photo-story-detail/10-facts-on-patient-safety](https://www.who.int/news-room/photo-story/photo-story-detail/10-facts-on-patient-safety), accessed March 2021.

<sup>2</sup> See: [www.who.int/docs/default-source/world-patient-safety-day/health-worker-safety-charter-wpsd-17-september-2020-3-1.pdf?sfvrsn=2cb6752d\\_2](https://www.who.int/docs/default-source/world-patient-safety-day/health-worker-safety-charter-wpsd-17-september-2020-3-1.pdf?sfvrsn=2cb6752d_2), accessed March 2021.

# PART I

## PATIENT SAFETY



Dr. Tedros Adhanom Ghebreyesus

### CHAPTER 1

## THE ROLE OF PATIENT SAFETY, AND UNIVERSAL HEALTH COVERAGE BY 2030?

Universal Health Coverage (UHC) – the notion that all people should be able to receive the health services they need without suffering financial hardship – is at the heart of the World Health Organisation’s ambitions for a healthier world. That is why we have set ourselves a target of 1 billion additional people benefitting from UHC by 2023.

As we push health authorities to expand access to a full spectrum of essential services, we must interweave the foundational principle of health, to first do no harm. Far from being straightforward, providing safe and quality care is now a bigger barrier to good health in most countries than lack of access to care.

Patient safety impacts every health system, irrespective of design and capacity, although the prevalence of harm varies between countries. Unsafe care disproportionately impacts low- and middle-income countries (LMICs), where 134 million adverse events occur in hospitals every year, contributing to 2.6 million deaths. Half the global burden of patient harm originates in primary and ambulatory care, with as many as four out of ten patients facing safety lapses. This may account for over 6% of hospital bed days and more than 7 million admissions in OECD countries alone. It is estimated that up to 80 percent of harm in primary care settings can be avoided.

There is no doubt that improving patient safety must be a priority for health systems, which

presents us with a pressing question: how do we achieve UHC that delivers broad-based services without compromising on safety and quality? The answer is not simple, but neither is this an insurmountable problem. A holistic, coherent, communities-centred approach to care is needed, with investment that focuses on dismantling existing structures, cultures and behaviours within health systems that harm patients and waste resources.

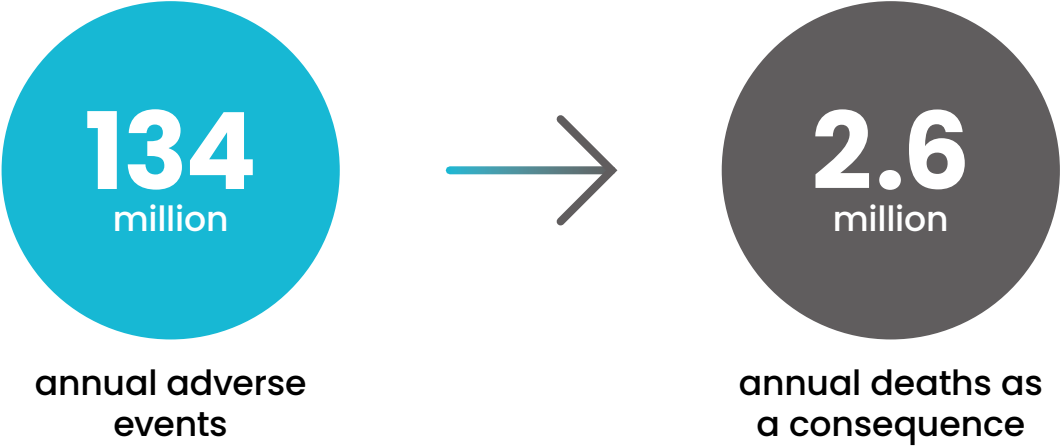
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There is no doubt that improving patient safety must be a priority for health systems”

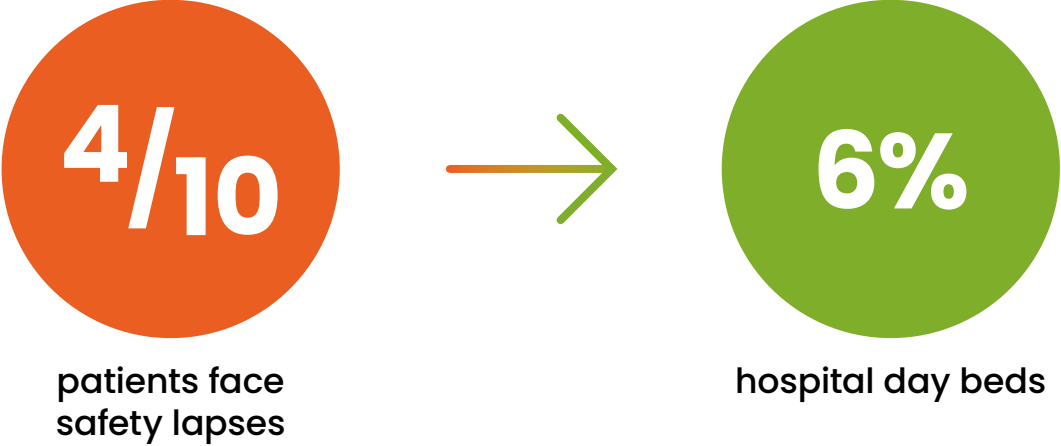
A holistic approach requires patient safety to be embedded as a priority at all points of care. Every layer of healthcare provision contains a certain degree of inherent risk, and thus any



LMICs



OECD



effort to achieve UHC and ensure provision of a full spectrum of essential services – across health promotion and prevention, treatment, rehabilitation, and palliative care – needs to be built on a strong foundation of patient safety. While gaps in primary care represent a major burden, patient safety is of critical importance throughout the whole continuum of care. By extension, to make sustainable improvements, interventions are required at all governance levels and all levels of healthcare provision, through a system-wide approach. Moreover, strategies and interventions should not only be aimed at reduction of harm, but should also strongly emphasise risk management to prevent occurrence of harm.

Community engagement as a means of building trust between service users and providers is another essential dimension of patient safety and, by extension, of the delivery of UHC. If health services are seen to cause harm, patients, their

families and communities lose trust in the system and the utilisation of health services declines, undermining efforts to improve access and expand coverage. Empowering and engaging patients, families and communities in shared decision-making and in their own care is an essential way of maintaining trust in the system as a whole.

To make the case for health authorities to prioritise patient safety, it is important to spotlight the financial returns related to investment in safe, quality care. The available evidence suggests that 15% of hospital expenditure can be attributed to treating safety failures in OECD countries. Unsafe and poor-quality care imposes costs of US\$ 1.4 trillion to 1.6 trillion each year in lost productivity in LMICs. The total cost of avoidable admissions to hospitals from long-term care facilities in 2016 was almost US\$ 18 billion, equivalent to 2.5% of all spending on hospital inpatient care or 4.4% of all spending on long-term care. It is also important





to recognise that, while many patient safety interventions do not necessarily require significant financial investment, improvement will depend on a commitment from leaders to continuously monitor and engage key stakeholders in order to ensure that change is made at the level of point of care.

Everybody has a role to play to take this agenda forward in the coming decade. Policymakers and leaders at the organisational and the institutional level need to define patient safety as a policy objective, establish institutional mechanisms and a regulatory environment, set strong accountability systems and ensure efficiency and alignment with other critical policy objectives within the broader UHC context. Healthcare providers must strive to provide safe and effective care at the highest possible standards and to meet the needs of patients, their families and communities, as well as to be open and transparent, to learn continuously from errors and successes, to engage in teamwork and to be good communicators.

Patients and families are the co-producers of health. They have critical roles and responsibilities in identifying their own needs and preferences, and in managing their own health with appropriate support from service providers and healthcare leaders. The role of professional associations, academic and research institutions and civil society organisations is crucial in supporting different dimensions of patient safety improvement strategies and interventions. These include raising awareness, managing knowledge, and generating evidence to contribute to information decision-making and capacity-building. While it is important to recognise the differences in roles and responsibilities of the various stakeholders, it is equally important to recognise the strong connections between them and the fact that only collective and coordinated efforts will ensure reduction of harm in healthcare.



In May 2019, the World Health Assembly adopted a landmark resolution on 'Global Action on Patient Safety', calling for WHO Member States and international stakeholders to recognise patient safety as a priority in health sector policies and programmes, making it an essential component for strengthening health systems in order to progress towards UHC. To achieve this, we must work together towards improving patient safety and towards a vision of zero patient harm in healthcare.

In an effort to keep up momentum, WHO has established 'A Decade of Patient Safety 2020–2030', a flagship global initiative to encourage actions for improving patient safety at the global, regional, and national levels. The initiative recognises the central role of patient safety in UHC and its linkage with components across health systems, and with disease-specific, health and clinical programmes to reduce patient harm and improve health outcomes at the point of care.

UHC and high quality, safe care are inextricably linked – we will not achieve one without also striving for the other. Unsafe care increases costs, reduces efficiency, and directly compromises health outcomes and patient perceptions, leaving health systems across the world with large bills and wary service users. Working together, between countries and within them, we each have a role to play in improving patient safety and quality of care, whether as patients, healthcare workers, service providers or policy makers. The world will not achieve UHC unless and until patient safety is embedded into every aspect of care.

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Everybody has a role to play to take this agenda forward in the coming decade.”

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Dr. Abdulelah Alhawsawi

## CHAPTER 2

# ZERO HARM: IS IT REALISTIC OR JUST A DREAM?

“When eating an elephant, take one bite at a time”

Creighton Abrams

## THE RECURRING CONVERSATION

**Me:** “Our goal in healthcare should be ‘Do No Harm’. Zero Harm should be our True North.”

**Hospital X Executive:** “Unfortunately, Zero Harm is unachievable. According to the literature, an average of 10% of patients are harmed in healthcare.”

**Me:** “How many patients do you see a day in your hospital (both inpatients and outpatients)?”

**Hospital X Executive:** “About 2,000 patients.”

**Me:** “According to the literature, 200 of your patients are harmed daily. Can you please give me the names of the 200 patients you will harm today?!”

## The ‘What’ of Zero Harm

The Joint Commission Centre for Transforming Healthcare’s most important mission is to help healthcare organisations reach Zero Harm. In healthcare, ‘Zero Harm’ can be defined as zero harm (any kind of harm) to patients. In other words: zero patient deaths; zero healthcare-associated infections (HAI); zero healthcare-associated conditions; zero episodes of overuse; zero missed opportunities to provide effective care; and zero patient safety events of any kind. Mark Chassin, President and CEO of the Joint Commission believes that the definition should go beyond focusing only on patients and also include zero injuries to caregivers<sup>1</sup>.

The way we define Zero Harm has contributed to making it a very high mountain to climb. When we view Zero Harm as an ‘all-or-none’ goal, it gives the impression to many that any harm that happens to any patient, at any point in time, is considered a failure, in other words, that Zero Harm is unattainable. This takes us back to idea the idea that “When eating an elephant”, we should “take one bite at a time”. If we break Zero Harm down into smaller pieces for each patient, *we can achieve a number of Zero Harms each day*. Here’s an example: imagine that a clinical unit has 20 patients. At the beginning of each 12-hour shift, there is an opportunity to achieve

<sup>1</sup> See: [centerfortransforminghealthcare.org/assets/4/6/MA18\\_ipc\\_reprint.pdf](https://centerfortransforminghealthcare.org/assets/4/6/MA18_ipc_reprint.pdf), accessed October 2020.

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If we as providers view the goal of Zero Harm goal not just from our perspective as Healthcare Workers (HCW) but as family members, convincing many in healthcare about the need to strive for Zero Harm becomes a much easier task.”

40 out of 40 Zero Harms, which could be 80 out of 80 Zero Harms chances each day. If we add *co-production* principles here, which means dividing the responsibility for Zero Harm between healthcare professionals on one end, and patients/families on the other end, we can increase the likelihood of achieving as many Zero Harms as possible. On a practical level, this could mean that the floor nurse with 5 patients discusses the Zero Harm goal with each of her 5 patients. At the beginning of each shift, there can be a pledge that both the nurse and the patient and/or the family commit to. The

medical team should also be fully committed to this during their daily morning rounds, as well as overnight whilst on call. Such a mindset could help us achieve as many Zero Harm opportunities as possible, which would boost the morale of staff, empower patients, and have a spill-over effect that could encompass more patients, more shifts, more clinical units, and more hospitals. Based on this patient-centric definition of Zero Harm, we have managed to break down that big elephant into small edible pieces.





The ‘Why’ of Zero Harm

Many people in healthcare believe that the goal of Zero Harm is unrealistic. People who doubt the Zero Harm concept cite a variety of reasons for their position. They may think that:

- 1 The complexity of healthcare systems makes it almost impossible to reach Zero Harm.
- 2 Asking for Zero Harm is like asking for perfection from healthcare workers (HCW), and no one is perfect.
- 3 Comparing healthcare to other industries, like aviation or nuclear, is naïve.
- 4 Demanding Zero Harm from HCW could lead to them avoiding certain complex cases, a practice known as ‘Defensive Medicine’ (antagonists here believe that Zero Harm as a goal could in fact potentially harm patients).
- 5 Striving to reach Zero Harm will drive costs up, and many healthcare facilities wouldn’t be able to afford it.

The problem is that the rationale for these objections is one-sided. It brings up only the angle of HCW, in other words, it is physician-centric or nurse-centric. I have been practising medicine for almost 20 years, and I’ve yet to meet a patient who wants to be harmed. Patients and their families not only don’t want patients to be harmed (Patient Safety), but also expect healthcare to treat them effectively (Quality) and treat them with dignity (Patient Experience).

I have 2 children: a 16-year-old son (Yousef), and a 10-year-old daughter (Farah). As a father, the thought of them being harmed in a hospital is completely unacceptable to me. If it is unacceptable for me to have my children harmed in healthcare, it should be unacceptable for me to have any patient harmed anywhere. If we as providers view the goal of Zero Harm goal not just from our perspective as HCW but as family members, convincing many in healthcare about the need to strive for Zero Harm becomes a much easier task.

Zero Harm is not only achievable: it is also a moral and ethical responsibility in the case of every patient, in every clinical unit, at all times. The



aviation industry has concluded that Zero Harm is a realistic objective. If it had not done so, imagine how many more aeroplane crashes we would have each day. No industry is free from accidents, but high reliability organisations (HRO) like aviation, nuclear, oil and gas, have decided that Zero Harm is an everyday goal, and that is why their safety track records are extraordinary, with relatively very few accidents and very little harm compared to healthcare.

The ‘How’ of Zero Harm

Now that we have defined Zero Harm in a patient-centric way, it definitely feels more feasible. The question is: has any healthcare organisation achieved Zero Harm before?

Organisations that are leading the way to Zero Harm:

- 1 **Nationwide Children’s Hospital, Columbus, OH:** This is one of the national patient safety leaders in the U.S. committed to Zero Harm. In 2009, it established an innovative programme called ‘Zero Hero’, which focuses on everyone in the organisation, from the board and senior executives to frontline clinicians and employees. ‘Zero Hero’ prioritises patient safety, making it the responsibility of everyone to reach and maintain Zero Harm. Nationwide Children’s Hospital is one of the early pioneers in the U.S. to publicly highlight the goal of Zero Patient Harm<sup>2</sup>.

2 See: [www.nationwidechildrens.org/impact-quality](http://www.nationwidechildrens.org/impact-quality), accessed 2 April 2020.



- 2 Memorial Hermann Health System (MHHS), Southeast Texas:** MHHS is comprised of 17 hospitals located in southeast Texas. As part of its commitment to becoming a high reliability organisation (HRO) with a genuine interest in serving its patients, MHHS has dramatically reduced HAI in many hospitals, and achieved Zero Harm in 78 of their hospitals, which means a minimum of 12 months with zero HAI or other harmful events. All this great work culminated in the National Quality Forum (NQF) and The Joint Commission naming MHHS the 2012 recipient of the John M. Eisenberg Patient Safety and Quality Award at the National Level<sup>3</sup>.

These are just examples of the many clinical units that managed to achieve Zero Harm, showing an overall commitment to patient safety that starts with the leadership and extends to all healthcare professionals. This kind of environment in the presence of a learning culture and empowered patients will result in a transformed safety culture and more Zero Harm achievements throughout healthcare.

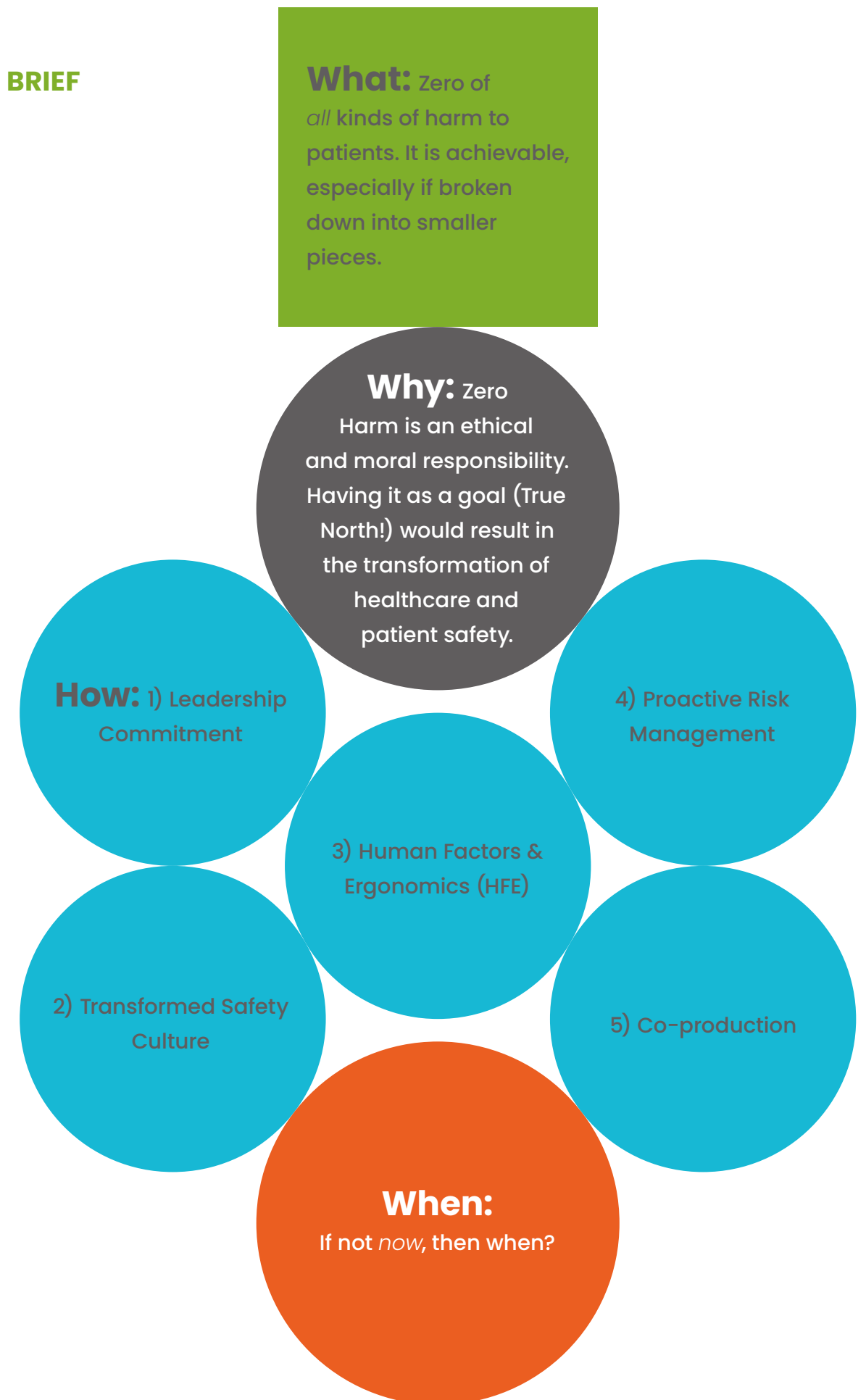
### The recipe for Zero Harm is:

- 1 Leadership Commitment:** Starting from the governing body, all the way down the senior executives. Leaders must walk the talk, which means impactful leadership safety walkarounds, a just culture, and 'safety huddles' (meetings to focus on the patients most at risk).
- 2 Transformed Safety Culture:** All the industries that have transformed safety and made great progress towards Zero Harm share one thing in common: a robust safety culture. Such a culture views safety as an everyday priority. Safety is integrated into procurement, clinical pathways, hiring decisions, employee appraisal, and promotions. In other words: safety in all policies and procedures.
- 3 Human Factors and Ergonomics (HFE):** HFE is defined as: "the understanding of the interactions among humans and other elements of a system, and the profession that applies theoretical principles, data and methods to design in order to optimise human well-being and overall system performance;". Because of the complexity of healthcare, the human-human interface and the human-technology interface are both potential sources of risk and of subsequent medical errors by HCW. The rapid pace of evolution in health technology, coupled with the complex-adaptive nature of the healthcare system, makes it timely that each hospital has FTE Human Factors Engineers who could really transform clinical risk management and help us get closer to Zero Harm.
- 4 Proactive Risk Management:** The 'reactive' nature of risk management in healthcare, would not help us reach Zero Harm, because we would be always be several steps behind to recognise and prevent the next risk. *If we want to reach zero harm, Here are the questions that a clinical risk manager should ask him/herself:* 1- What went wrong yesterday? 2- What went right yesterday? And more importantly, 3- What could go wrong today? How can it be prevented?
- 5 Co-production:** Zero Harm can only be reached if both HCW at one end and patients/ families at the other collaborate and complement one another's efforts. There are 3 types of coproduction: 1) Co-Design: before care delivery; 2) Co-Delivery: during care delivery; and 3) Co-Assessment: after care delivery.

### The 'When' of Zero Harm

If not now, then when?! Our patients deserve it, our healthcare workers are capable of delivering it, and our healthcare system's sustainability is dependent on it.

### IN BRIEF



<sup>3</sup> See: [www.psqh.com/news/high-reliability-memorial-hermann-health-systems-it-network-a-case-study/](http://www.psqh.com/news/high-reliability-memorial-hermann-health-systems-it-network-a-case-study/), accessed 19 February 2013.



Guy Ryder

## CHAPTER 3

# SAFE STAFF SAVE LIVES: THE CASE FOR HEALTH WORKER SAFETY AND HEALTH

Health workers are the backbone of every health system. Without them there is no healthcare. Protecting their health and safety is fundamental and will benefit workers, patients and society.

The protection of workers is at the core of the International Labour Organisation's (ILO) mandate, laid down in its constitution since 1919. Yet despite the significant progress made over the past 100 years, almost 3 million workers are still dying every year, either at work or due to their work. An additional 374 million workers suffer from non-fatal occupational accidents annually<sup>1</sup>. This is an unacceptable and avoidable human tragedy.

Occupational safety and health needs to be a higher priority on the policy agenda. This was underlined in the ILO Centenary Declaration for the Future of Work<sup>2</sup>, adopted unanimously by the ILO's 187 Member States in 2019 and stating that safe and healthy workplaces are fundamental to decent work. In September 2020, G20 Labour and Employment Ministers acknowledged the vital importance of occupational safety and health during the COVID-19 pandemic and committed to implementing policies to ensure that workers stay safe at work<sup>3</sup>.

All workers must be protected. And health workers in particular have played an essential role during the COVID-19 crisis, responding to the call of duty with determination and dedication. They need adequate protection to be able to do their jobs safely.

However, across the world it has become apparent that health systems, faced with a pandemic of this scale, have not been fully able to protect their health workers. Even in some high-income countries with high levels of health expenditure, health workers have lacked sufficient provision of personal protective equipment<sup>4</sup>.

For weeks, citizens worldwide came out on the streets to express their gratitude to health workers for their courageous, hard work in fighting COVID-19 and keeping patients safe. But applause is not enough. Increasingly, health workers have been forced to the streets themselves to raise awareness of over-burdened health systems and poor working conditions. They are demanding investments in

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Citizens worldwide came out on the streets to express their gratitude to health workers for their courageous, hard work in fighting COVID-19 and keeping patients safe. But applause is not enough.”



1 ILO. Safety and health at the heart of the future of work. Geneva, 2019. See: [www.ilo.org/wcmsp5/groups/public/---ed\\_protect/---protrav/---safework/documents/publication/wcms\\_678357.pdf](http://www.ilo.org/wcmsp5/groups/public/---ed_protect/---protrav/---safework/documents/publication/wcms_678357.pdf), accessed October 2020.

2 ILO: ILO Centenary Declaration for the Future of Work. Geneva, 2019.

3 G20 Labour and Employment Ministers. Ministerial Declaration. Virtual Meeting, 10 September 2020. See: [g20.org/en/media/Documents/G20SS\\_Labour\\_And\\_Employment\\_Ministerial\\_Declaration\\_EN.pdf](https://www.g20.org/en/media/Documents/G20SS_Labour_And_Employment_Ministerial_Declaration_EN.pdf), accessed October 2020.

4 ILO: Sectoral Brief: COVID-19 and the health sector. Geneva, 2020 [www.ilo.org/wcmsp5/groups/public/---ed\\_dialogue/---sector/documents/briefingnote/wcms\\_741655.pdf](http://www.ilo.org/wcmsp5/groups/public/---ed_dialogue/---sector/documents/briefingnote/wcms_741655.pdf) accessed October 2020.



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The UN high-level Commission on Health, Employment and Economic Growth has highlighted the urgent need for sustainable investment in health systems, and investment in strong health workforces that can do their jobs under decent working conditions.”

health services as well as pay rises in recognition of the vital role they play in society and to make up for years of ‘pay erosion’ in the health sector.

On a daily basis, health workers experience heavy workloads, long hours and sometimes violence and harassment in the workplace. They also encounter a range of other occupational risks including biological, chemical, physical, ergonomic and psychosocial hazards. We need to step up our efforts to protect and support them with concrete measures that address these risks. National programmes for occupational safety and health for health workers have proven to be effective in implementing systematic and comprehensive emergency preparedness strategies to address these issues<sup>5</sup>.

Protecting health workers also means providing them with social protection coverage, as well as employment injury benefits in case of occupational accidents or illness, and ensuring access to healthcare for themselves and their families. The gender dimension of healthcare needs to be further tackled.

Women make up more than 70% of the global health and social workforce. In some occupational

groups, including nursing and personal care, that rises to 90%. Women in the health and social work sectors tend to be engaged in lower-skilled, lower-paid jobs, within the professional hierarchy, contributing to a gender pay gap of 26% on average in high-income countries and 29% on average in upper-middle-income countries<sup>6</sup>. They are often exposed to violence and harassment at work and, in addition, are likely to shoulder the burden of unpaid care work, including taking care of children or elderly family members. It is estimated that while women’s contribution to healthcare accounts for nearly 5% of global GDP, almost half of their contribution is, in fact, unpaid and unrecognised<sup>7</sup>.

Attention has to be paid to care workers in residential and home care. These are often female migrant workers, who in many countries have been neglected and overlooked for many years. Severe staff shortages and deficits of decent work have contributed to the high prevalence of COVID-19 in elderly care homes and in home care<sup>8</sup>.

The longstanding structural problems in already overburdened and underfunded public health systems in many countries have been exposed vividly by the COVID-19 crisis. It has been

<sup>5</sup> See for example: WHO-ILO Global framework on national occupational health programs for health workers (2010); [GB.309/STM/1/2](#), appendix II.

<sup>6</sup> ILO: ILO Monitor, 2nd edition: COVID and the world of work. Geneva: ILO, 7 April 2020.

<sup>7</sup> ILO: A quantum leap for gender equality: for a better future of work for all, Geneva, 2019.

<sup>8</sup> ILO: Sectoral Brief COVID-19 and care home workers, Geneva, 2020. See: [www.ilo.org/wcmsp5/groups/public/---ed\\_dialogue/---sector/documents/briefingnote/wcms\\_758345.pdf](http://www.ilo.org/wcmsp5/groups/public/---ed_dialogue/---sector/documents/briefingnote/wcms_758345.pdf), accessed October 2020.

### Worldwide annually

workers die at or due to their work

3  
million

374  
million

non-fatal work accidents

recognised that the health and care sectors have been struggling because of limited resources and the implementation of cost-saving measures. The UN High-level Commission on Health, Employment and Economic Growth – which included the ILO, WHO and OECD – has highlighted the urgent need for sustainable investment in health systems, and investment in strong health workforces that can do their jobs under decent working conditions. It calls for a paradigm shift so that the role of the health sector in economic development and employment creation is recognised.

In the recovery phase of the COVID-19 pandemic we will need to focus on a human-centred approach that respects human and labour rights, while also supporting businesses. There is now global momentum for investing in increased health employment and decent work in the health sector.

### We need to

- 1 Improve** the working conditions of health workers, both because they deserve better, and because there is clear evidence that decent working conditions have a positive impact on the quality of care – including patient safety – while also contributing to the retention of skilled and motivated staff<sup>9</sup>;
- 2 Invest** in sectors of the economy which generate employment, strengthen resilience and add social value. Investing in health systems and the health workforce should be at the forefront of any such strategy;
- 3 Develop** policies and measures through dialogue with governments, and with employers’ and workers’ organisations. Our experiences show that practical and sustainable solutions to complex challenges can be best found when all those concerned work together.

There is consensus that health worker safety benefits patient safety. However, the protection of health workers should not be seen only as a means to this end. Anchored in the Universal Declaration of Human Rights and in many international labour standards, the right to safe and healthy workplaces must be secured for all health workers, just as it must be secured for all workers.

<sup>9</sup> ILO: TMIEWHS: Improving employment and working conditions in health services, Report for discussion [www.ilo.org/wcmsp5/groups/public/---ed\\_dialogue/---sector/documents/publication/wcms\\_548288.pdf](http://www.ilo.org/wcmsp5/groups/public/---ed_dialogue/---sector/documents/publication/wcms_548288.pdf).





Dr. Rafael Mariano Grossi

## CHAPTER 4

# HOW CAN WE IMPROVE RADIATION SAFETY IN HEALTHCARE?

The key to improving radiation safety in medicine lies in understanding that this is a broad and multi-faceted issue where international organisations and other interested parties will have to work together to achieve results for the patients' benefit while ensuring the safety of health workers.

The International Conference on Radiation Protection in Medicine: Setting the Scene for the Next Decade was organised by the International Atomic Energy Agency (IAEA), co-sponsored by the World Health Organisation (WHO), hosted by the Government of Germany in the city of Bonn in 2012, and attended by more than 500 participants. Following the Conference, the IAEA<sup>1</sup> and WHO<sup>2</sup> issued a joint position statement, the Bonn Call for Action. It provides a decade-long global roadmap for strengthening radiation protection in medicine, highlighting ten main actions and related sub-actions in this area that are identified as essential over the following decade, and on which all parties are encouraged to take action.

## THE BONN CALL FOR ACTION: TEN MAIN ACTIONS IDENTIFIED

- 1 **Enhance** the implementation of the principle of justification;
- 2 **Enhance** the implementation of the principle of optimisation of protection and safety;
- 3 **Strengthen** manufacturers' role in contributing to the overall safety regime;
- 4 **Strengthen** radiation protection education and training of health professionals;
- 5 **Shape** and promote a strategic research agenda for radiation protection in medicine;
- 6 **Increase** availability of improved global information on medical exposures and occupational exposures in medicine;
- 7 **Improve** prevention of medical radiation incidents and accidents;
- 8 **Strengthen** radiation safety culture in healthcare;
- 9 **Foster** an improved radiation benefit-risk-dialogue;
- 10 **Strengthen** the implementation of safety requirements globally.

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In cooperation with other organisations including WHO, the IAEA develops and promotes international safety standards, guidance documents and accurate dosimetry to enhance radiation protection and safety.”

In 2017, midway through the decade set out in the Bonn Call for Action, the International Conference on Radiation Protection in Medicine: Achieving Change in Practice was organised by the IAEA and co-sponsored by WHO and the Pan American Health Organisation (PAHO) and convened to review actions taken and developments since the 2012 Bonn conference. More than 500 participants from

<sup>1</sup> See: [www.iaea.org/sites/default/files/17/12/bonn-call-for-action.pdf](http://www.iaea.org/sites/default/files/17/12/bonn-call-for-action.pdf), accessed 28 September 2020.

<sup>2</sup> See: [www.who.int/ionizing\\_radiation/medical\\_radiation\\_exposure/BonnCallforAction2014.pdf?ua=1](http://www.who.int/ionizing_radiation/medical_radiation_exposure/BonnCallforAction2014.pdf?ua=1), accessed 28 September 2020.

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Education and training of health professionals is an important aspect of the IAEA's work to help Member States keep patients and health workers safe.”

97 countries and 16 international organisations agreed that although work has intensified in the area of radiation protection in medicine in response to the Bonn Call for Action, more needs to be done. To achieve real improvement, actions are needed, not only at the international level (by organisations and professional bodies), but also at the national level, healthcare facility level and individual level. With the 'Bonn Call for Action decade' running out, new, more intense efforts will be required.

### Actions by the IAEA

The IAEA is mandated to accelerate and enlarge the contribution of atomic energy to peace, health and prosperity throughout the world. In cooperation with other organisations including WHO, the IAEA develops and promotes international safety standards, guidance documents and accurate dosimetry to enhance radiation protection and safety in medical uses of radiation.

The IAEA assists Member States in putting in place the measures needed to ensure that medical radiation equipment is installed and operated



IAEA 2019

48  
regional and  
national courses

32  
online webinars

with  
10,000  
participants

under safe conditions. To have an adequate radiation safety infrastructure, a country needs appropriate governmental, legal and regulatory frameworks for safety<sup>3</sup>. Among the responsibilities of each government are: establishing an independent regulatory body with the necessary legal authority, competence and resources; establishing requirements for education, training, qualification and competence in protection and safety for all persons engaged in relevant activities; and the formal recognition of qualified experts.

Education and training of health professionals is an important aspect of the IAEA's work to help Member States keep patients and health workers safe. In 2019, the IAEA held 48 regional and national training courses and workshops relating to the radiation protection of patients. These events, held

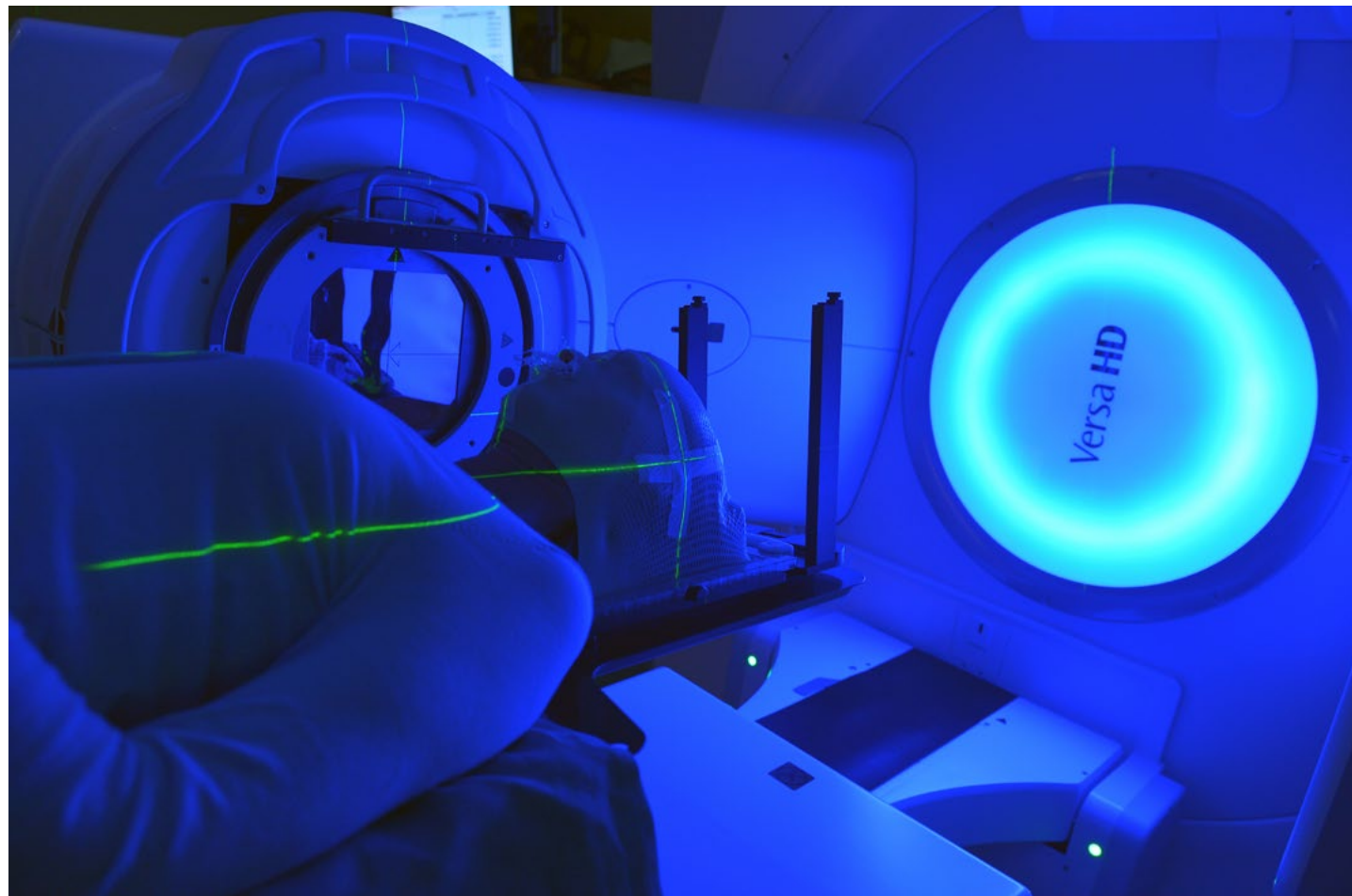
in countries around the world, brought together 1,450 participants. In addition, the IAEA Radiation Protection of Patients (RPOP) website<sup>4</sup> – which attracts more than 500,000 page views annually – had 10,000 total registrations for e-learning courses in 2019 on radiation protection for patients and health workers. There were also 32 online webinars, with experts on the topic reaching out to 10,000 registered participants. The IAEA also awards many fellowships every year to young health professionals and regulators, enabling them to learn about the safe use of radiation in medicine in other countries and supporting scientific visits by senior professionals to study specific techniques.

The IAEA has developed online databases and learning systems in this area, including the Safety in Radiation Oncology (SAFRON) incident learning

<sup>3</sup> International Atomic Energy Agency, Governmental, Legal and Regulatory Framework for Safety, IAEA Safety Standards Series No. GSR Part 1 (Rev. 1), IAEA, Vienna (2016).

<sup>4</sup> See: [www.iaea.org/resources/rpop](http://www.iaea.org/resources/rpop), accessed 28 September 2020.





The accurate positioning of the patient on a daily basis in radiotherapy is fundamental to safely treat the patient. To aid this positioning, health professionals use a laser, a light field, markers, electronic coordinate systems, and sometimes an immobilisation device using an individually fitted mask. (Photo: D. Calma/IAEA)

system<sup>5</sup>. This is voluntary, anonymised and aims to provide health professionals in Member States with opportunities to learn from events that have happened in radiotherapy around the world. Another example is the Information System on Occupational Exposure in Medicine, Industry and Research – Interventional Cardiology (ISEMIR-IC), which facilities can use to optimise occupational radiation protection in interventional cardiology (an area where health professionals in attendance can be at risk of receiving non-trivial occupational exposures)<sup>6</sup>.

The IAEA/WHO Network of Secondary Standards Dosimetry Laboratories (SSDLs) provides

comparison and calibration services to designated SSDLs in Member States<sup>7</sup>, which are in turn responsible for calibrating dosimetry equipment for hospitals. This ensures that hospitals have access to dosimetry measurements that are traceable to the International System of Units (SI). Approximately 15,000 calibrations are provided through the SSDL Network each year, allowing hospitals to ensure they are meeting therapeutic and diagnostic dosimetry standards. Global harmonisation of dosimetry is essential to ensuring the accuracy of dose, and the IAEA has been central to the development of international codes of practice in this area<sup>8</sup>. The IAEA organises an International Symposium on Standards, Applications and Quality Assurance in Medical Radiation Dosimetry (IDOS) every 8–10 years. These meetings, the most recent of which was held in 2019 with more than 420 attendees, foster a unique opportunity for scientific exchange between laboratory scientists, dosimetry experts and clinical medical physicists.

5 See: [www.iaea.org/resources/rpop/resources/databases-and-learning-systems/safron](http://www.iaea.org/resources/rpop/resources/databases-and-learning-systems/safron), accessed 28 September 2020.

6 See: [www.iaea.org/resources/rpop/resources/databases-and-learning-systems/isemir-ic](http://www.iaea.org/resources/rpop/resources/databases-and-learning-systems/isemir-ic), accessed 5 October 2020.

7 International Atomic Energy Agency (2018), SSDL Network Charter: The IAEA/WHO Network of Secondary Standards Dosimetry Laboratories – Second Edition, IAEA, Vienna.

8 International Atomic Energy Agency (2000), Absorbed Dose Determination in External Beam Radiotherapy: An International Code of Practice for Dosimetry Based on Standards of Absorbed Dose to Water, Technical Reports Series No. 398, IAEA, Vienna.

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IDOS meetings foster a unique opportunity for scientific exchange between laboratory scientists, dosimetry experts and clinical medical physicists.”

For more than 50 years, the IAEA/WHO postal audit service for radiotherapy dosimetry has provided verification of beam calibrations to hospitals in Member States<sup>9</sup>. More than 1,100 dosimeters are mailed to participants globally each year. In the radiotherapy process, the accuracy with which the prescribed dose can be realistically delivered is not only influenced by reference dosimetry, but also by technological, clinical and radiobiological considerations<sup>10</sup>. Several audit methodologies have been developed, tested and disseminated by the IAEA in order to encourage health professional teams to prioritise safety and seek continuous quality improvement in their practice<sup>11</sup>.

The International Basic Safety Standards for radiation protection and safety of radiation sources states that the fundamental safety objective of protecting people, both individually and collectively, from harmful effects of ionising radiation has to be achieved without unduly limiting the conduct of

activities that give rise to radiation risks. There are enormous benefits to individual patients, as well as to the global population, from using radiation in medicine. Using radiation in medicine saves lives. It makes it possible to detect non-communicable diseases such as cardiac and neurological disorders. It also aids in the assessment of communicable/infectious diseases, like tuberculosis, making it possible to start treatment in a timely manner and avoid complications and the further spread of infection in the population. Radiation is also an essential component in the treatment and palliation of cancer. Ionising radiation has been used in medicine for more than 100 years. A strong safety culture and meticulous quality control<sup>12</sup> are universal prerequisites to using these complex procedures in healthcare, and to maximising the associated benefits while minimising the associated risks.

9 J. Izewska et al, '50 Years of the IAEA/WHO postal dose audit programme for radiotherapy: What can we learn from 13756 results?' *Acta Oncologica*, 59.5, (2020), pp. 495–502.

10 International Atomic Energy Agency, Accuracy Requirements and Uncertainties in Radiotherapy, IAEA Human Health Series No. 31, IAEA, Vienna, 2016.

11 See: [www.iaea.org/publications/13563/ssdl-newsletter-issue-no-70-june-2019](http://www.iaea.org/publications/13563/ssdl-newsletter-issue-no-70-june-2019), accessed 28 September 2020.

12 International Atomic Energy Agency, International Labour Office, Pan American Health Organisation, World Health Organisation, Radiation Protection and Safety in Medical Uses of Ionizing Radiation, IAEA Safety Standards Series No. SSG-46, IAEA, Vienna, 2018.



# PART II

## NATIONAL PATIENT SAFETY



Professor Konrad Reinhart



Dr. Abdulelah Alhawsawi



Dr. Imrana Malik

### CHAPTER 5

## SEPSIS, A LEADING CAUSE OF PREVENTABLE DEATHS AND DISABILITY – A CALL TO ACTION

Sepsis is a life-threatening condition that arises when the body's response to an infection injures its own tissues and organs. It can be a life-changing and disability-inducing event, resulting in a considerable financial burden for healthcare systems<sup>1</sup>. An estimated 11 million people die each year from sepsis, with 38 million surviving<sup>2</sup>.

Many survivors experience persistent health problems, including new or worsened physical, cognitive and/or psychological impairments. These impairments can lead to a loss of work, prolonged nursing care, and an overall increased

risk of death<sup>3</sup>. According to available estimates, approximately 20% of all-cause global deaths are due to sepsis, disproportionately affecting neonates, pregnant or recently pregnant women, and people living in low-resource settings.

<sup>1</sup> HC. Prescott, TJ. Iwashyna, B. Blackwood et al., 'Understanding and Enhancing Sepsis Survivorship. Priorities for Research and Practice' *American journal of respiratory and critical care medicine*, 200.8 (2019), pp.972–981; TG. Buchman, SQ. Simpson, KL. Sclarretta, et al., 'Sepsis Among Medicare Beneficiaries: The Burdens of Sepsis, 2012–2018', *Critical Care Medicine*, 48.3,(2020), pp. 276–288.

<sup>2</sup> KE Rudd, SC. Johnson, KM. Agesa, et al., 'Global, regional, and national sepsis incidence and mortality, 1990–2017: analysis for the Global Burden of Disease Study' *The Lancet*, 395, (2020), pp.200–211.

<sup>3</sup> CY Huang, R. Daniels, A. Lembo, et al., 'Life after sepsis: an international survey of survivors to understand the post-sepsis syndrome' *Int J Qual Health Care*; 31.3, (2017), pp.191–198.

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Sepsis mortality and morbidity should be viewed through a patient-safety lens, with efforts to prevent sepsis seen as efforts to promote patient safety.”

The burden of sepsis

Worldwide, the majority of sepsis-related mortality is found among low, low-middle and middle-income countries (LMICs)<sup>4</sup>. Given that patient safety is defined as the absence of preventable harm to a patient during the process of healthcare provision, sepsis mortality and morbidity should be viewed through a patient-safety lens, with efforts to prevent sepsis seen as efforts to promote patient safety<sup>5</sup>.

Sepsis is also a major health concern in high-income countries (HICs). Each year, more than 1.7 million people in the United States of America develop sepsis, with nearly 270,000 adult Americans dying as a result and US\$ 62 billion being spent on sepsis-related healthcare costs as a result<sup>6</sup>. Estimates for the burden of sepsis in Europe, extrapolated from the incidence and death rates in Sweden, suggest that 3.4 million cases and more than 640,000 deaths occur annually.

Sepsis contributes significantly to preventable mortality, because it is the final common pathway to death for severe infectious diseases. This is true for highly transmissible infections such as

seasonal influenza and dengue viruses, as well as for pathogens of even greater public health concern, like coronavirus, avian and swine influenza, Ebola and yellow fever viruses. As a result, WHO has acknowledged that critically ill patients with severe COVID-19 infection are at a high risk of developing and dying from sepsis. Indeed, patients with severe COVID-19 infection can exhibit the myriad manifestations that characterise sepsis, such as vasodilatory shock, acute kidney injury, coagulation abnormalities, and multi-organ dysfunction, including respiratory failure resulting in Acute Respiratory Distress Syndrome<sup>7</sup>. In addition to infectious causes, sepsis can often arise as a complication of injuries and non-communicable diseases.

Table 5.1 shows the lives lost by infectious diseases (i.e., sepsis) in comparison with other major global threats to mankind. It contradicts the notion (This perception was based on the dramatic decrease of the mortality rates by infectious diseases in HICs such as the USA during the 20th century<sup>8</sup>) that the war against infectious diseases has been won and that the book of infectious diseases can therefore ultimately be closed.

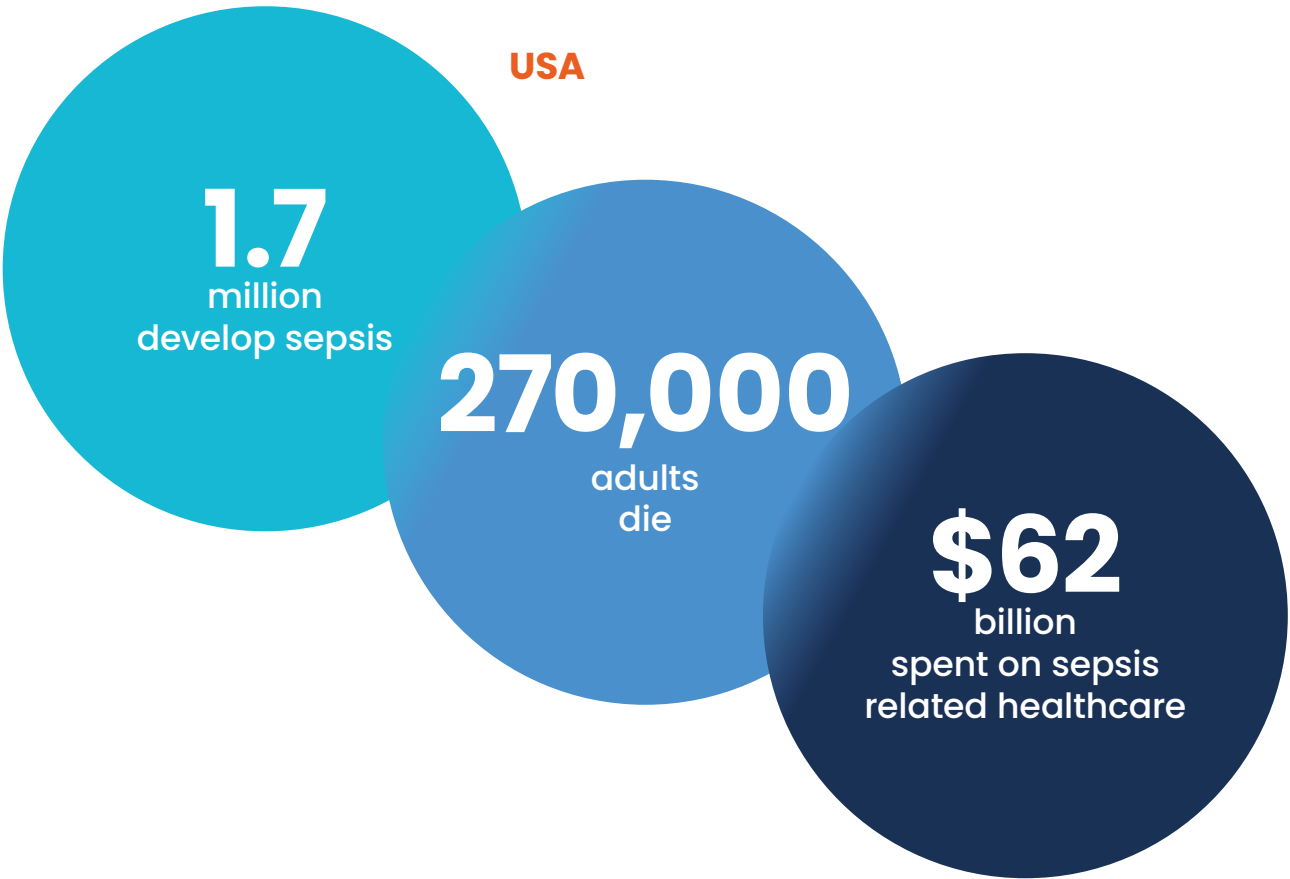


TABLE 5.1

Cause of death	Number of deaths	Time period
Sepsis	11 million	2017
HIV	0.69 million	2019
COVID-19	Over 1 million	10 months (in 2020)
Hunger	7.6 million	2018
War*	0.75 million	1945-2000
Cancer	9.6 million	2019

\*Average number per year as a result of wars and conflicts since the end of World War II

4 Ibid.  
5 L. Slawomirski, A. Auraaen and N. Klazinga (2017), ‘The economics of patient safety: Strengthening a value-based approach to reducing patient harm at national level’, *OECD Health Working Papers*, No. 96, OECD Publishing, [Paridx.doi.org/10.1787/5a9858cd-en](https://doi.org/10.1787/5a9858cd-en)  
6 See: [cdc.gov/sepsis/](https://cdc.gov/sepsis/), accessed October 2020.  
7 S. Richardson, et al., ‘Presenting Characteristics, Comorbidities, and Outcomes Among 5700 Patients Hospitalized With COVID-19 in the New York City Area’ *Jama*, 323, (2020), pp2052-59.  
8 Armstrong, Gregory L. et al Trends in Infectious Disease Mortality in the United States During the 20th Century. *Jama* 281.1, (1999),pp 61-66.

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Improved approaches to sepsis will save the lives of many patients... approaches targeted only at COVID-19 risk falling short of reducing the current and future burden of sepsis due to all causes.”

### Important milestones in the fight against sepsis



## Global Sepsis Alliance

In 2012, the Global Sepsis Alliance (GSA) launched the World Sepsis Declaration and the World Sepsis Day Movement<sup>9</sup>. In 2012, sepsis was not only inadequately addressed on the WHO website, but was also absent from the US Centre for Disease Control and Prevention (CDC) and all other national CDC websites. Likewise, sepsis was not represented in the Global Burden of Disease Report, except in respect to neonatal sepsis. From 2014, the GSA, in collaboration with its 100-plus member organisations, lobbied for a resolution on sepsis by the World Health Assembly (WHA). Finally, in 2017, with the strong support of the German Government and several other WHO Member States, the 70th WHA adopted a historic resolution aiming to improve the ‘prevention, diagnosis and clinical management of sepsis’<sup>10</sup>. This was a quantum leap in the fight against sepsis.

9 See: [www.worldsepsisday.org/declaration](http://www.worldsepsisday.org/declaration), accessed October 2020.

10 See: [www.who.int/health-topics/sepsis/#tab=tab\\_1](http://www.who.int/health-topics/sepsis/#tab=tab_1), accessed October 2020.

### The WHA urged member states to:

- **Include** prevention, diagnosis and treatment of sepsis as part of national health systems, both in the community and in healthcare settings, according to WHO guidelines
- **Increase** public awareness of the risk of progressions to sepsis from infectious diseases, through health education (including on patient safety) to ensure prompt initial contact between affected persons and the healthcare system;
- **Develop** training for all health professionals about communicating with patients, relatives and other parties, including using the term ‘sepsis’ as a way of enhancing public awareness;
- **Promote** research aimed at innovative means of diagnosing and treating sepsis across the lifespan, including research for new antimicrobial and alternative medicines, rapid diagnostics tests, vaccines and other important technologies, interventions and therapies;
- **Engage** further in advocacy efforts to raise awareness of sepsis, in particular through supporting existing activities held in Member States every year on 13 September (World Sepsis Day).

### Furthermore, the resolution requested the WHO Director-General to:

- **Develop** WHO guidance including guidelines, as appropriate, on prevention and management of sepsis;
- **Support** Member States to define appropriate standards and establish the necessary guidelines, infrastructure, laboratory capacity, strategies and tools for reducing the incidence of, mortality from, and long-term complications of sepsis;

- **Collaborate** with other organisations in the United Nations system (partners, international organisations and relevant stakeholders) in enhancing access to quality, safe, efficacious and affordable types of treatments for sepsis, and infection prevention and control, reducing immunisation – particularly in developing countries – while taking into account relevant existing initiatives.





The well-established effectiveness of quality improvement initiatives to prevent and treat sepsis-related mortality can be reduced if sepsis and septic shock are recognised and treated within a timely manner (i.e., within one hour of septic shock and within three hours of sepsis). For example, each delay in delivering the sepsis treatment bundle was associated with an increase in mortality in a large cohort in New York State (NYS), where mandates for sepsis were established in 2018<sup>11</sup>. Additionally, data from NYS between 2015–2019 showed that sepsis hospital mortality in adult patients increased from 32% to 22%<sup>12</sup>. Similar positive effects have also been demonstrated in NYS for children and shown in other countries including the United Kingdom and the Republic of Ireland<sup>13</sup>.

Encouragingly, the WHA resolution led to an increased number of countries and regions promoting systematic approaches to sepsis awareness, prevention and intervention, including

the United Kingdom, the USA, Canada, Brazil, Mexico, the Republic of Ireland, Spain, the Kingdom of Saudi Arabia, the United Arab Emirates, Sudan, Uganda, Nigeria, Malawi and Kenya. On World Sepsis Day 2019, the governments of Australia, France and Sweden announced national sepsis campaigns.

However, on a global level, the progress in actually implementing national plans has been slow. To date, less than 10% of WHO Member States have implemented adequate national strategies to combat sepsis. Not surprisingly, despite its remarkably high incidence, sepsis remains practically unknown to the public in most parts of the world.

11 CW. Seymour, F. Gesten, HC. Prescott et al., ‘Time to treatment and mortality during mandated emergency care for sepsis’ *The New England Journal of Medicine*, 37.6 (2017), pp. 2235–2244.  
12 See: [www.health.ny.gov/diseases/conditions/sepsis/](http://www.health.ny.gov/diseases/conditions/sepsis/), accessed October 2020.  
13 See: [www.hse.ie/eng/about/who/cspd/ncps/sepsis/resources/national-sepsis-report-2018.pdf](http://www.hse.ie/eng/about/who/cspd/ncps/sepsis/resources/national-sepsis-report-2018.pdf), accessed October 2020.



Bringing the fight against sepsis to the next level

On the occasion of the launch of the Global Sepsis Report on World Sepsis Day 2020, Dr. Tedros, the Director-General of the World Health Organisation reminded the international community that it is now *imperative* to address the burden of sepsis in both HICs and LMICs. Dr. Tedros also stated that preventing and fighting sepsis contributes to the achievement of the Sustainable Development Goals Developed by the United Nations. Dr. Tedros also stated that ‘research and policymakers must be ready to forge partnerships to stimulate funding and help place sepsis more firmly on the list of critical health conditions to target in the pursuit of universal health coverage’<sup>14</sup>.

Improved approaches to sepsis will save the lives of many patients, including those suffering from COVID-19. In contrast, approaches targeted only at COVID-19 risk falling short of reducing the current and future burden of sepsis due to all causes.

14 See: [www.who.int/publications/i/item/9789240010789](http://www.who.int/publications/i/item/9789240010789), accessed October 2020.





Annette Kennedy

## CHAPTER 6

# PATIENT SAFETY VS HEALTHCARE WORKERS' SAFETY: ZERO-SUM GAME? THE CASE FOR SAFE NURSING RATIOS

In economic theory, a zero-sum game occurs when gains for one person cause losses for another in an identical amount. If we look at patient safety versus healthcare worker safety as a zero-sum game, we are saying that we cannot ensure patient safety without negatively impacting healthcare worker safety, and vice versa. However, evidence has shown, over and over again, that patient safety and healthcare worker safety is a win-win situation.

As we improve healthcare worker safety, patient safety improves as well. This year, the World Health Organisation chose 'Health Worker Safety: A Priority for Patient Safety' as its theme for World Patient Safety Day.

The International Council of Nurses (ICN)'s position statement on evidence-based safe nurse staffing<sup>1</sup> highlights the evidence that having an appropriate number of nurses available, with a suitable mix of education, skills and experience, reduces the duration and intensity of healthcare interventions, prevents deterioration in patients' health and can be cost effective. The statement also cites evidence that safe staffing results in reduced adverse events, reduced hospital readmissions, a decreased risk

of nosocomial complications and decreased length of hospital stay, as well as increased patient satisfaction<sup>2</sup>.

In 2019, the ICN and the Saudi Patient Safety Centre published a *White Paper on Nurse Staffing Levels for Patient Safety and Workforce Safety*<sup>3</sup>. This important report brought together evidence from a wide range of sources, covering different countries and contexts, all showing that having safe staffing levels is the most cost-effective approach to bringing about improvements in patient safety and quality of care.

A team of independent researchers from the University of Pennsylvania's Centre for Health

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Safe staffing results in reduced adverse events, reduced hospital readmissions, a decreased risk of nosocomial complications and decreased length of hospital stay, as well as increased patient satisfaction.”

Outcomes and Policy Research, in collaboration with the Queensland University of Technology, were commissioned to evaluate the impact of a policy establishing minimum nurse-to-patient ratios in 27 public hospitals in Queensland, Australia. The research found that increased nurse staffing was associated with improvements in outcomes for both patients and nurses in the adult medical and surgical wards where increased ratios were applied. The staff survey showed positive changes as a result of nurse-to-patient ratio policy, including improved “time to complete necessary care” and “time to detect patient changes”, better job satisfaction, and less burnout, as well as lower mortality and readmission rates as well as decreased length of stay<sup>4</sup>.

Let us look at patient safety and healthcare worker safety through the lens of the ongoing COVID-19 pandemic. In many countries, the pandemic has put a large amount of pressure on healthcare systems, increasing workloads for nurses and other healthcare workers. A recent article in *The New York Times* showed the impact this has on patients, stating that the odds of surviving the virus could depend on where a patient is treated. In under-staffed, under-resourced hospitals in New York,

hundreds of patients languished while waiting for care, while in privately-funded medical centres in the same city, patients had access to care, ventilators and other life-saving resources<sup>5</sup>.

In fact, the pandemic has highlighted the lack of investment in health systems and the added pressure this puts on nurses, as well as the devastating impact on patient outcomes. Even before the pandemic, the world was facing a global shortage of 6 million nurses<sup>6</sup>, and nurses around the world were experiencing unsustainable workloads and inadequate pay. When the personal risks of work are too high and when workloads created by the demands of the health system and staff shortages become too heavy, nurses and other healthcare workers are more likely to leave their jobs, resulting in further weakening of health systems.

1 See: [www.icn.ch/sites/default/files/inline-files/PS\\_C\\_%20Evidence%20based%20safe%20nurse%20staffing\\_1.pdf](http://www.icn.ch/sites/default/files/inline-files/PS_C_%20Evidence%20based%20safe%20nurse%20staffing_1.pdf), accessed October 2020.

2 LH Aiken, W. Sermeus, KV Heede, et al., 'Patient safety, satisfaction, and quality of hospital care: cross sectional surveys of nurses and patients in 12 countries in Europe and the United States', *British Medical Journal* 44 (e1717), (2012), pp. 1-14.

3 See: [www.icn.ch/sites/default/files/inline-files/WHITE%20PAPER%20on%20Nurse%20Staffing%20Levels%20For%20Patient%20Safety%20and%20Workforce%20Safety\\_1.pdf](http://www.icn.ch/sites/default/files/inline-files/WHITE%20PAPER%20on%20Nurse%20Staffing%20Levels%20For%20Patient%20Safety%20and%20Workforce%20Safety_1.pdf), accessed October 2020.

4 ICN (2020). Nurses: A Voice to Lead – Nursing the World to Health, p.49. Available at [2020.icnvoicetolead.com/wp-content/uploads/2020/03/IND\\_Toolkit\\_120320.pdf](https://2020.icnvoicetolead.com/wp-content/uploads/2020/03/IND_Toolkit_120320.pdf), accessed October 2020.

5 B. Rosenthal, et al., 'Why Surviving the Virus Might Come Down to Which Hospital Admits You', *The New York Times*. 1 July 2020. Available at [www.nytimes.com/2020/07/01/nyregion/coronavirus-hospitals.html](https://www.nytimes.com/2020/07/01/nyregion/coronavirus-hospitals.html), accessed October 2020.

6 WHO, ICN, Nursing Now (2020) State of the World's Nursing Available at: [www.who.int/publications/i/item/nursing-report-2020#:~:text=The%20State%20of%20the%20world's,education%2C%20jobs%2C%20and%20leadership](https://www.who.int/publications/i/item/nursing-report-2020#:~:text=The%20State%20of%20the%20world's,education%2C%20jobs%2C%20and%20leadership), accessed October 2020.



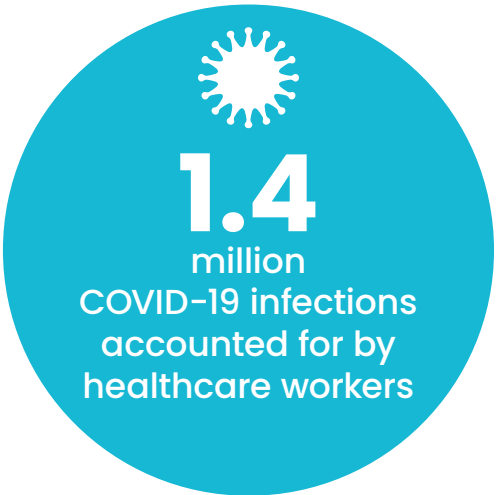
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The pandemic has highlighted the lack of investment in health systems and the added pressure this puts on nurses, as well as the devastating impact on patient outcomes.”

One well-publicised issue is the lack of personal protective equipment for healthcare workers. Unfortunately, the number of healthcare workers contracting the virus is testimony to this lack of resources. In July, WHO reported that over 1.4 million of COVID-19 infections were accounted for by healthcare workers<sup>7</sup>, and over 10,000 health workers in Africa had been infected with COVID-19 so far<sup>8</sup>. It is clear that if nurses and other health workers are not protected from an infectious disease like COVID-19, then patients will be at risk in the very place they come to get better.

Inadequate preparedness of countries for a pandemic causes avoidable morbidity and loss of life. Frontline workers have already learned these lessons from previous pandemics like SARS, H1N1 and Ebola. During these times of great stress, the majority of nurses do not turn away from their duty to their patients. In fact, one systematic review of nurses’ experiences of working in acute care hospital settings during a respiratory pandemic<sup>9</sup> showed that “nurses, regardless of the circumstances, felt a great sense of professional duty to work during a pandemic”. However, they also worried about “the need to prioritise resources and patient needs in a time where they had to ration and deny services to some patients”. The same study concluded that without proper support for mental and physical stress, “nurses

WHO July 2020



are likely to experience substantial psychological issues that can lead to burnout and loss from the nursing workforce”.

The pandemic has also shown exactly how important safe staffing is in the management of critically ill patients. The ICN has warned that the substitution of less qualified cadres of healthcare workers for Registered Nurses needs to be treated with caution, as the evidence suggests that this can result in poorer patient outcomes and lower cost-effectiveness<sup>10</sup>.

Over the years, research by Dr. Linda Aiken and her colleagues has emphasised the importance of nurse-to-patient ratios and their effect on patient satisfaction, outcomes, and even mortality, as well as on burnout and job dissatisfaction in nurses<sup>11</sup>.

Safe working environments are another important aspect of both health worker safety and patient safety. Certain key elements in the workplace can strengthen and support the workforce and in turn have a positive impact on patient outcomes

and organisational cost-effectiveness. These include (among many others): professional recognition; adequate and timely compensation; equal opportunity and fair treatment; access to adequate equipment; a healthy work-life balance; employment security and work predictability; opportunities for professional training, development and career advancement; and safety from harm.

The ICN is deeply concerned about the serious threat to the safety of patients and quality of healthcare resulting from insufficient numbers of appropriately trained nurses. Sadly, the COVID-19 pandemic has brought these issues to the forefront, and they can no longer be ignored.

We must follow the recommendations of the *State of the World’s Nursing report* to:

- Invest in the massive acceleration of nursing education – faculty, infrastructure and students – to address global needs, meet domestic demand, and respond to changing technologies and advancing models of integrated health and social care;
- Create at least six million new nursing jobs by 2030, primarily in low- and middle-income countries, to offset projected shortages and redress the inequitable distribution of nurses across the world; and
- Strengthen nurse leadership – for both current and future leaders – to ensure that nurses have an influential role in the formulation of health policy and in decision-making, in order to contribute to the effectiveness of health and social care systems<sup>12</sup>.

12 See: [www.who.int/publications/i/item/nursing-report-2020#:~:text=The%20State%20of%20the%20world's,education%2C%20jobs%2C%20and%20le](http://www.who.int/publications/i/item/nursing-report-2020#:~:text=The%20State%20of%20the%20world's,education%2C%20jobs%2C%20and%20le), accessed October 2020



7 See: [www.dw.com/en/coronavirus-latest-who-says-health-workers-account-for-10-of-global-infections/a-54208221](http://www.dw.com/en/coronavirus-latest-who-says-health-workers-account-for-10-of-global-infections/a-54208221), accessed October 2020.  
8 See: [www.afro.who.int/news/over-10-000-health-workers-africa-infected-covid-19](http://www.afro.who.int/news/over-10-000-health-workers-africa-infected-covid-19), accessed October 2020.  
9 R. Fernandez et al., ‘Implications for COVID-19: a systematic review of nurses’ experiences of working in acute care hospital settings during a respiratory pandemic’, *International Journal of Nursing Studies* (2020).  
10 C. Duffield, et al., ‘Nursing staffing, nursing workload, the work environment and patient outcomes’, *Applied Nursing Research*, 24.4, (2020), pp. 244–255.  
11 L. Aiken et al., ‘Hospital Nurse Staffing and Patient Mortality, Nurse Burnout, and Job Dissatisfaction’, *JAMA*. 288.16, (2002) pp.1987–1993.



Dr. Guenther Jonitz

## CHAPTER 7

# HOW THE CHANGE IN CULTURE IN THE HEALTHCARE SYSTEM WILL IMPROVE PATIENT SAFETY

Patient safety is the leading issue in healthcare. It increases as medicine progresses and becomes more complex, but decreases as working conditions for caregivers worsen. Mainly experienced as a threat, it is in fact a chance and an invitation to rethink our processes of care and our systems. The magic bullet is culture. Are we able to talk about what should not have happened? Can we be open to discussion and learning?

What is patient safety culture (PSC)? "The safety culture of an organisation is the product of individual and group values, attitudes, perceptions, competencies, and patterns of behaviour that determine the commitment to, and the style and proficiency of an organisation's health and safety management"<sup>1</sup>. Its central role is proven by many scientific studies. Jeffrey Braithwaite et al published a major review in 2017, based on 2,049 relevant articles<sup>2</sup>. It found a consistently positive association between culture and outcomes across multiple studies, settings and countries.

In 2020, the OECD published an overview of 24 countries<sup>3</sup>. 20 of the 24 countries surveyed use at least one PSC tool broadly within their health

system. 75% of all surveyed countries (18 out of 23) indicated that they had plans to initiate or expand existing work on PSC. The effect in real life was also shown by Tuffolotti et al.<sup>4</sup>. Drawing on data from 137 English acute trusts (or hospital systems) for the period 2012–14, they used multivariate regression models to test whether mortality rates, taken from the Summary Hospital-level Mortality Indicator, were lower in hospitals that had higher levels of openness among staff members, a measure derived from the NHS National Staff Survey. Adjusted for hospital operating capacity, their results showed that a one-point increase in the standardised openness score was associated with a 6.48% reduction in hospital mortality rates.

- 1 V. F. Nieva and J. Sorra, 'Safety culture assessment: a tool for improving patient safety in healthcare organizations', *BMJ* 12.2. (2003).
- 2 J. Braithwaite et al. 'Association between organizational and workplace cultures, and patient outcomes: systematic review', *BMJ* 7.11 (2017).
- 3 K. de Bienassis et al. (2020), 'Culture as a cure: Assessments of patient safety culture in OECD countries' *OECD Health Working Papers*, No. 119. Available [www.oecd-ilibrary.org/social-issues-migration-health/culture-as-a-cure\\_6e1a6eae-en](https://www.oecd-ilibrary.org/social-issues-migration-health/culture-as-a-cure_6e1a6eae-en), accessed October 2020.
- 4 V. Tuffolotti and D. Stuckler, 'A Culture of Openness Is Associated with Lower Mortality Rates Among 137 English National, Health Service Acute Trusts', *National Library of Medicine* 38.5 (2019): 844–850.

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You must choose between fear or safety.”

**Don Berwick**, speaking at the first Ministerial Summit on Patient Safety (London, 2016)

## OECD 2020

20/24

countries  
use one PSC tool in  
their healthcare  
system

18/23

countries  
plan to  
initiate/expand work  
on patient safety  
culture (PSC)

The tools are usually based on the AHRQ's 2014 Hospital Survey on Patient Safety Culture<sup>5</sup>, on the Safety Attitudes Questionnaire of the University of Texas<sup>6</sup> or on the Manchester Patient Safety Framework<sup>7</sup>. The OECD report gives an excellent overview. By the way, if you ask caregivers, they will admit that organisations based on openness and trust are good places to work and care.

The kinds of statements that result are essential and potentially painful: 'People support one another in this unit', 'We have enough staff to handle the workload', 'Staff in this unit work longer hours than

is best for patient care', 'Staff feel like their mistakes are held against them', 'Mistakes have led to positive changes here', 'When an event is reported, it feels like the person is being written up, not the problem'... (statements drawn from AHRQ SOPS Hospital Survey, TM).

What are the obstacles? First, there is cognitive dissonance. Psychology is important. We are all re driven by the impulse to help and to do more good than harm. This intrinsic motivation gives caregivers strength in even the most extreme situations.

5 See: [www.ahrq.gov/sops/index.html](https://www.ahrq.gov/sops/index.html), accessed October 2020.

6 J. Sexton et al., 'The Safety Attitudes Questionnaire: psychometric properties, benchmarking data, and emerging research', *BMC Health Service Research*, 63.4, (2006).

7 See: [improve.bmj.com/improve\\_post/manchester-patient-safety-framework-mapsaf/](https://improve.bmj.com/improve_post/manchester-patient-safety-framework-mapsaf/), accessed October 2020.



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Patient care is a deeply humanistic assignment and trust is essential.”

The 'clinical mentality' is described as follows:

“First, the aim of the practitioner is not knowledge but action. Successful action is preferred, but action with very little chance for success is to be preferred over no action at all. Second, the practitioner is likely to have to believe in what he is doing in order to practice—to believe that what he does good more than harm, and that what he does makes the difference between success and failure rather than no difference at all. He is himself a placebo reactor who is developing faith in his remedies and so modifying his behavior toward his patient.”<sup>8</sup>.

This attitude, if not accompanied by reflection

and self-reflection, can lead to behaviour where individuals react negatively against unwanted effects. What gives caregivers power can also make them blind. To accept that errors or mistakes have happened is a challenge because it is perceived as a personal failure, so that the caregiver feels like a 'second victim'.

This normally leads to the 'blame game' where scapegoats are sought in place of analysing causes for errors. Complexity and distortion are also major contributions to unsafe care and bad PSC. An absence of support in the case of errors and harm promotes the notion of caregivers as 'second victims'.

8 E. Freidson, *The Profession of Medicine*, (Chicago: University of Chicago Press, 1970), p168.



### PSC needs action and support on three levels:

- 1 Individually**, it takes courage and the right attitude to speak up. As patient safety means 'first do no harm' it should not be novel for physicians working to the principles of medical ethics. It is part of medical professionalism.
- 2 Organisationally**, it takes leadership. Role models are needed and structural prerequisites are essential. Morbidity and mortality conferences should be an ordinary occurrence (with everybody making proposals for cases) alongside critical incident reporting systems, including root cause analyses. The urgent need for safe working conditions (in the sense of having at least enough trained human capacity) was addressed by the International World Patient Safety Day September 2020 by WHO<sup>9</sup>. And interdisciplinary teamwork might be key not only for PSC.

- 3 Politically**, PSC must also be executed by avoiding threats, creating cooperation (like the Ministerial Summits on Patient Safety which have been held since 2016<sup>10</sup>, and the Global Patient Safety Network by WHO) and providing support – including financial support – for patient safety. Training for groups of caregivers is essential, although resources are scarce.

Patient care is a deeply humanistic assignment and trust is essential. If we cannot speak up and talk, we will repeat mistakes. Professionalism is needed, and safe and humane systems provide safe and humane working conditions for caregivers. Safety culture is essential to be able to learn from errors and mistakes. PSC can be measured and the results enhance our activities, taking us towards safer and better care<sup>11</sup>.

Start now – improve daily. Re-discover the primary virtues of healthcare.

9 See: [www.who.int/campaigns/world-patient-safety-day/2020](http://www.who.int/campaigns/world-patient-safety-day/2020), accessed October 2020.

10 See: [www.who.int/patientsafety/policies/ministerial-summits/en/](http://www.who.int/patientsafety/policies/ministerial-summits/en/), accessed October 2020.

11 Van Vegten et al, 'Patient Safety Culture in Practice – Experiences and Lessons Learnt by University Hospital Zurich' in P. Waterson (ed.) *Patient Safety Culture: Theory, Methods, Application*. (Farnham: Ashgate Publishing, 2014).







Marisol Touraine



Dr. Philippe Duneton

## CHAPTER 8

# HOW INNOVATION IN R&D FOR TACKLING HIV, TB AND MALARIA CAN BENEFIT THE PATIENT AND HEALTHCARE WORKER IN THE FUTURE

Innovation means both using existing tools in new ways and developing new products and approaches. In many instances, innovation is about finding the means to simplify and increase access to safe, effective, high-quality and affordable critical health products for the benefits of patients and health workers.

This has been at the heart of Unitaid's mandate for the last fifteen years: to identify new health solutions with the potential to alleviate the burden of HIV/AIDS, tuberculosis, malaria and cervical cancer, as well as HIV co-infections such as hepatitis C.

But beyond the scope of those specific diseases, Unitaid is pushing forward game-changing approaches which have a transformative impact on health systems. Through its contribution to health systems streamlining and strengthening, Unitaid's work is supporting the global drive toward universal health coverage and the Sustainable Development Goals.

The COVID-19 pandemic raises unprecedented health challenges and highlights the need for a coordinated response and a political commitment from all countries. As health systems are disrupted, it is essential to prevent and reduce risks, errors and harm to patients accessing healthcare, and to ensure that healthcare workers have safe working conditions and the training, pay and respect they deserve. Patient safety needs to be at the cornerstone of health systems and stands as a key driver to achieve universal health coverage.

Building on the lessons learnt from the fight against HIV/AIDS, tuberculosis and malaria, Unitaid believes that innovation plays a crucial role in improving patient safety for all. In fact, innovation helps to

prevent and reduce risks, errors and harm, while health products which are simpler and easier to administer change the lives of patients and health workers, in low-income and high-income countries alike.

## Innovation makes access to healthcare easier and safer for all

According to WHO, 4 out of 10 patients are harmed during primary and ambulatory healthcare. The most detrimental errors are related to diagnosis, prescription and the use of medicines. Innovation can make a huge difference and transform the way diseases are prevented, diagnosed and treated: it can help health products become more effective, more affordable, easier to administer, simpler, and better adapted and tolerated.

Better diagnostic tools can save vital time in treatment, reduce adverse diagnostic events and limit unnecessary drug exposure. With efficient diagnostics systems, healthcare workers can save precious time and focus on patients' treatment and follow-up. Rapid tests can be incorporated into local healthcare centres, and even into remote, low-resource environments, to provide same-day results. They replace the weeks- or even months-long ordeals of transporting specimens to central laboratories for processing, a time-lag that very often costs lives.

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Through its contribution to health systems streamlining and strengthening, Unitaid's work is supporting the global drive toward universal health coverage and the Sustainable Development Goals.”

Similarly, devices to measure vital signs, such as blood oxygen levels, help identify children who require urgent care. Unitaid is supporting a project for introducing pulse oximeters so that frontline health workers in low-resource settings can diagnose the multiple causes of febrile disease in children and treat or refer them appropriately.

When antimalarial drugs are mistakenly given to fever patients who do not have malaria, resistance to these drugs grows in communities. Simple and affordable triage tools allow health workers to diagnose and treat fevers that are not associated with malaria, thereby reducing the risk of antimicrobial resistance. Innovations in medicines can reduce side-effects, shorten protocols and as such reduce exposure to treatment.

Injectable artesunate has been a gamechanger in addressing severe malaria in children, more effective than the alternative (quinine). With an estimated 22.5% reduction in relative mortality, injectable artesunate has proven to be better tolerated by children, with fewer severe side effects, as well as being far simpler for health workers to administer. Based on Unitaid's joint work with the Global Fund (investment case period 2021-2023), we estimate that injectable artesunate can save an additional 150,000 lives relative to quinine.



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**Innovations in medicines can reduce side-effects, shorten protocols and as such reduce exposure to treatment.”**

Historically, treatment for multi-drug resistant tuberculosis has been long, expensive and often ineffective, with side effects often including hearing loss, depression or psychosis, as well as reduced kidney function. According to the latest Global Tuberculosis Report, the global treatment success rate for MDR-TB remains low, at just 56%. New treatments for MDR-TB, including those evaluated in a project supported by Unitaid, are expected to improve treatment outcomes significantly, with the potential to save an additional 20,000 lives in the next 3 years. Innovation in formulations and delivery systems improve adherence, prevent misuse as well as inappropriate doses.

Formulations also dramatically improve children's quality of life, protecting them from health threats and allowing health workers or parents to administer medicines more easily. For example, Unitaid and its partners have introduced child-friendly medicine for tuberculosis. Previously, health workers or parents had to split, cut and mash up adult tuberculosis treatments. Not only can this be complicated, it also places the child at risk of being given inappropriate doses, which would be dangerous and ineffective. As of today, and funded by Unitaid, more than 1 million treatment courses of the fruit-flavoured treatment that comes in the correct dose have been procured in 116 countries.

Long-acting delivery systems for medicines are changing the way some diseases are managed. Safe and effective daily oral medicines are available to prevent and treat major diseases, but when they are not taken consistently, treatments fail and illness can spread. Poor adherence can also lead to an increase in antimicrobial resistance. Long-acting technologies offer a simpler way of administering medicines that frees patients from daily pills, makes it easier for them to start and stay on treatment, and reduces the burden on health

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Unitaid puts the patient at the centre of its work and develops solutions that look beyond one single disease.”

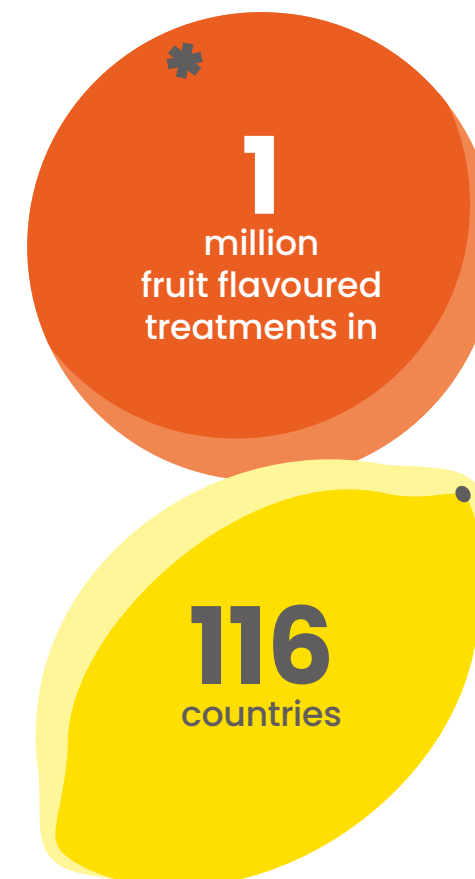
systems. In places where certain diseases are stigmatised, long-acting medicines can provide people with a more discreet treatment. Unitaid is investing in speeding up the development of long-acting versions of medicines for low- and middle-income countries.

### The benefits of innovation in the regulation of health products

A lack of quality-assured health products for use in low- and middle-income countries delays progress towards global health targets and puts populations at risk.

The WHO Prequalification Programme (WHO PQ) is a global innovation to facilitate access to medicines and diagnostics that meet a unified standard of quality, safety and efficacy. Set up in 2001, it was created with a view to ensuring that products selected and procured by the United Nations (UN) have a guaranteed level of effectiveness and efficiency. As support from the international community grew, the programme quickly became a reference point for procurement beyond the UN (as demonstrated by the Global Fund). Today, the programme is widely recognised for having made an enormous contribution in terms of accelerating and increasing access to critical quality-assured products that are affordable and adapted for markets in low- and middle-income countries. Unitaid has supported the prequalification programme since 2006. We have witnessed the tangible benefits of this programme to public health in low- and middle-income countries. It facilitates capacity-building and collaboration between regulators, accelerates access to urgently-needed medical products through the collaborative procedure for national registration, and contributes to market sustainability and lower prices by increasing fair competition among quality products. It is estimated that WHO PQ enables access to quality-assured products to around 400 million additional people and a large donor-funded market of about US\$ 3.5 billion of quality, safe and efficacious products.

### Unitaid





In the same vein, innovative ways of assessing innovations in the context of urgent needs for new therapeutic solutions can help accelerate market entry without compromising patient safety. For example, Unitaid supports the Expert Review Panel which works on a risk-based approach to time-limited procurement of specific products. The review focuses on products with high public-health impact that are a priority for the Global Fund and Unitaid and have yet to undergo stringent regulatory assessment.

Finally, the lack of access to necessary health products creates a vacuum that is too often filled by substandard and falsified products. WHO has identified this issue as one of the urgent health challenges for the next decade, given that more than 1 in 10 medicines in low- and middle-income countries are estimated to fall into this category. Simple and affordable innovations for health product can increase their tracking in supply chains. Innovative mobile tools can also support patient awareness on this issue and improve reporting systems.

### Simpler, closer, safer: a paradigm shift to place the patient at the centre

Greater patient involvement is the key to safer care. According to WHO, engaging patients can reduce the burden of harm by up to 15%, saving billions of dollars each year. Thanks to new treatments and diagnostics, patients become empowered and are able to monitor their health and develop better adherence to treatments. This also translates into fewer visits to health centres and creates efficiencies for both patients and health workers. For example, Unitaid supported the introduction of HIV self-testing kits, which offer a discreet and convenient way to test, with the potential to reach individuals in need of HIV testing services who may not otherwise seek a test. Self-testing can be done in private, requires no special training, and serves as an entry point to HIV care and prevention. Overall, self-testing can help link more people living with HIV to treatment and address the testing gap in HIV.

Building on similar projects, Unitaid puts the patient at the centre of its work and develops

solutions that look beyond one single disease. We are convinced that this integrated approach will transform health systems and dramatically improve their effectiveness in combatting diseases. It is also a safer approach for patients, as potential interactions can be easier to spot and prevent. Multi-platform diagnostics are supporting this approach.

Innovation also enables task-shifting without compromising patient safety, offering a viable solution for improving healthcare and contributing to universal health coverage targets. Simpler mobile devices and tools reduce the hazards of manipulation and interpretation. They facilitate delegation, allowing tasks to be moved, where appropriate, to less specialised health workers. Task-shifting can make more efficient use of the human resources available. By accessing better and simpler tools, health workers are empowered, and tasks usually done by doctors can be delegated to nurses or community workers.

Innovation plays a key role in alleviating the burden on health systems by allowing decentralisation of care to take it as close as possible to the patient and making the patient a dynamic player in the system. Innovation has both a direct and indirect impact on patients, health workers, and the health system. We can expect future innovations, and especially artificial intelligence, to contribute even more to the fluidity of care and the protection of all, thus playing a pivotal role in achieving patient safety.

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Innovation plays a key role in alleviating the burden on health systems.”

Through its multiple ripple effects, innovation has a direct impact on patient safety: patients have a better and safer access to healthcare, today's patients and tomorrow's patients can be protected, and healthcare workers' tasks are made easier and safer.

Weston Kandawasvika, with his wife, Patience Mbeve, takes a HIV self-test. (Photo © Eric Gauss / UNITAID)





# PART III

## THE POLITICS OF PATIENT SAFETY ON THE GLOBAL STAGE



Rt Hon. Jeremy Hunt MP

### CHAPTER 9

## PATIENT SAFETY GOVERNANCE: ROLE OF G20 HEALTH MINISTERS IN PATIENT SAFETY

*"You have to understand, Secretary of State, that in healthcare we harm ten percent of patients."*

Quite a statement for a brand new Minister to hear, especially one responsible for their country's healthcare system. But that was exactly what I was told in my first few months as the UK's Secretary of State for Health back in 2012.

I had recently been promoted into the role and like many Ministers in similar positions, and even more Presidents and Prime Ministers around the world, had no medical background. So this shocked me. Research published shortly after this incident found that nearly 4% of hospital deaths in the UK were classified as normal. That was about 150 people per week. How did more people not know about this? Why wasn't it treated with the same sense of urgency as it would be if another industry accidentally killed that many people a week? And what could be done to reduce that number?

The fact that the general public weren't clamouring for answers to those questions is why the first thing politicians can do to promote patient safety is raise awareness of it. Patient safety itself is a little-known term outside the medical and policy-making worlds. Most people, if asked, tend to think of health and safety issues and then switch off. But keeping patients safe is the most fundamental part of healthcare and the reason many people become doctors or nurses. And when the World

Health Organisation (WHO) estimates that there are 2.6 million avoidable deaths a year, it is obviously an area that needs more attention, more research and more focus.

WHO

**2.6**  
million  
avoidable  
deaths annually

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No doctor or nurse goes into medicine to harm patients. They all feel passionately about giving the best care they can. So rather than fight you, most will welcome the fact that you want to help them reduce the number of errors that occur.”

So politicians must use the power of their office to highlight the problem. Drawing attention to the negative aspects of healthcare, particularly in a country like the UK where the NHS is a revered institution, doesn't come naturally to politicians. I know many are worried that they will alienate medical professions. But in my experience, nothing could be further from the truth. No doctor or nurse goes into medicine to harm patients. They all feel passionately about giving the best care they can. So rather than fight you, most will welcome the fact that you want to help them reduce the number of errors that occur.

To help highlight the problem, but also to ensure people working in the NHS themselves knew how their hospital or their unit was doing on safety, I initially focused on transparency. If we could highlight where care needed to improve, then patients would benefit from safer services. The most profound and impactful change was the introduction of an independent rating system – via the Care Quality Commission (CQC) – for hospitals, care homes and GP practices.

Although it can be a traumatic experience for the staff involved when the CQC says a hospital is



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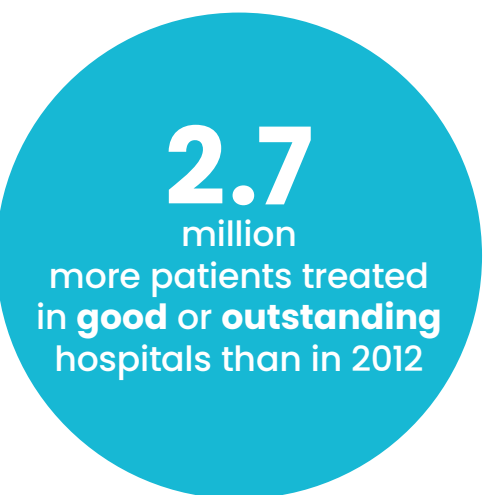
inadequate or when it is put into special measures, the results are often transformational. A renewed focus on patient care, sometimes alongside new management, and much greater attention to what truly matters can turn around even the most poorly performing hospital. And at the end of my time in office in 2018, 2.7 million more patients were being treated in good or outstanding institutions than at the start in 2012.

Alongside reform of the CQC I focused on transparency of the data on avoidable harm. The Learning from Deaths programme introduced reporting and data collection requirements for those patients who died as a result of problems with their care. I also expanded the remit and reach of the Healthcare Safety Investigations Branch so that patient safety investigations into maternity deaths could spread learning and best practices around the NHS. Increased transparency definitely helps to improve patient safety. So I would encourage all Health Ministers to pull whatever levers you have to introduce more of it into the system. It may be difficult initially for some involved to be confronted with the truth about how safe or otherwise their patients are, but in the end everyone benefits from knowing where to focus help.

It took me a long time to recognise though that transparency and a renewed focus on patient safety could only get you so far. Ultimately

Most importantly, Ministers should do all they can to remove blame from the system.”

UK 2018





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Profile-raising, increased transparency, legal reform, and empowering great leaders. Those are the main things politicians can do to improve patient safety.”

promoting patient safety is about culture change. And culture change is incredibly hard to introduce from the top down. But there are some things Ministers can do.

Most importantly, they should do all they can to remove blame from the system. Mistakes in healthcare, as in all walks of life, will happen. That is only human. But what we do when they occur shows whether we are prepared to learn from those errors or just accept that these things happen. Addressing the blame culture sounds like a nebulous concept, but what I now know is that much of it starts with the legal and regulatory framework in which medical professionals operate.

In the UK, for instance, our current compensation system actively incentivises confrontation when something goes wrong. To access compensation, families of patients killed or harmed have to prove gross negligence on the part of the medical professional involved. No professional wants that on

their record and so the shutters often go up. Rather than get to the heart of what happened so that they can learn from it, the system sets them against their former patient. In countries like Sweden, this doesn't happen. The bar for compensation is lower as people have to prove that the harm was avoidable rather than negligent. The amounts on offer are lower too, but I think that's worth it if it means families are able to get what they deserve quickly, without excessive legal fees, and the professionals involved can openly share what went wrong to stop similar mistakes happening again.

Secondly, Ministers need to empower the leaders within their healthcare systems who understand the importance of patient safety and let them get on with it. Use the newly available data and transparency on patient safety you've introduced and find the amazing leaders in your healthcare organisations. Help them spread what they are doing that is different from what everybody else is doing. Far better to have a respected doctor tell

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Ministers need to empower the leaders within their healthcare systems who understand the importance of patient safety and let them get on with it.”

poorly performing hospitals how they turned things around than a politician come and lecture them on the same subject. Instead, work with leading experts to operationalise what has made them a success so that it can be shared across the system. If necessary, give them funding and space to do this. One of the best examples of this in the UK is the amazing Getting it Right First Time programme led by orthopaedic surgeon Professor Tim Briggs CBE. What started as Tim looking at variations in performance data and sharing this with colleagues is now a national clinician-led programme that has saved countless lives and also saved the Trusts who have adopted its methods more than £50 million.

Profile-raising, increased transparency, legal reform, and empowering great leaders. Those are the main things politicians can do to improve patient safety. But in truth the profound cultural change required is very difficult to achieve quickly. That is why I've carried on working on patient safety issues since leaving office. Cultural change in large organisations takes time. But reducing avoidable harm and the number of avoidable deaths is no less pressing now than it was when I was Health Secretary.

The WHO quantifies the scale of the problem as 5 avoidable deaths every minute. Some may worry that the scale of the challenge is too daunting. To them I simply offer a saying Aristotle, first told to me by my good friend Dr. Abdulelah Alhawsawi: the problem is not aiming too high and missing your target, but aiming too low and hitting it.





Alan Donnelly

## CHAPTER 10

## BREAKING SILOS: THE ROLE OF POLICYMAKERS IN THE GLOBAL HEALTH DEBATE

The World Health Organisation (WHO)'s decision to launch a Global Patient Safety Day (GPSD) in 2019 was a very welcome initiative. In 2020, because of the impact of COVID-19 on health and care workers, the second GPSD was dedicated to the safety of frontline caregivers.

Why is this so important? Well, the debate on global health security has too often been conducted amongst health scientists and academics, and is largely segmented into disease silos. This tends to push the multilateral debate on health into meetings of Government Chief Medical Officers and from time to time, Health Ministers.

The G20 Health and Development Partnership (G20HDP) was created by a group of organisations who recognised that this approach resulted in the resilience of health systems being pushed down the political agenda. The partnership targeted the G20 Heads of Government in 2017, with the intention of elevating health to the top of the political agenda.

Our approach has been to demonstrate the link between healthy citizens and a strong, healthy economy. We have proactively engaged with Finance Ministers and Heads of Government to ensure that they understand that spending on strengthening health systems must be treated as essential national investment where the return on that investment can be properly measured.

Patient and healthcare worker safety is at the heart

of strengthening health systems and it resonates with politicians across the political spectrum. A focus on patient safety allows us to break down the disease silos, and it allows us to take the excellent work of our health scientists and academics and engage with a much wider range of key decision makers, including the Finance Ministers who have to budget for the health security of their citizens.

During the COVID-19 pandemic, patient and healthcare worker safety has never been more visible, never more critical. The countries with inadequate pandemic preparedness and weak health systems are paying a massive human and economic cost for a lack of strategic investment. This is clearly not confined to low- and middle-income countries (LMICs), with some of the wealthiest G20 countries having seen their populations and their economies devastated.

Last year, the G20HDP urged the Japanese Prime Minister, as President of the G20, to host the first ever joint meeting of Health and Finance Ministers, and this was held in Osaka June 2019. This year, we urged the Saudi Presidency to repeat this initiative and to the KSA government's credit, a full Finance and Health Ministers virtual meeting was convened.

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During the COVID-19 pandemic, patient and healthcare worker safety has never been more visible, never more critical.”

The significance for strengthening health systems cannot be underestimated. The narrative in their final communiqué explicitly referred to health spending as investment, and it recognised that without a resilient health system, human capital and long-term prosperity is significantly weakened.

The Saudi Government also placed the development of sustainable person-centred health systems at the centre of their health track. The Presidency recognised that this is a prerequisite in delivering universal health coverage. Given that

a person-centred health system must guarantee patient safety, it is a welcome development that this year the Saudi government have ensured that patient safety has also been part of its G20 health track. Next year's Italian presidency is expected to keep patient safety on the G20 agenda.

But how do we turn solemn declarations on health security and patient safety into concrete action? The COVID-19 pandemic has forced organisations out of their disease silos to cooperate in the promotion and development of diagnostics,





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The COVID-19 pandemic has forced organisations out of their disease silos to cooperate in the promotion and development of diagnostics, therapeutics and vaccines.”

therapeutics and vaccines. It has also led to governments participating in new initiatives to ensure that capacity is built to manufacture and distribute these new medicines, vaccines and tests, particularly to vulnerable communities around the world. Given the increasing sale of sub-standard and counterfeit medicines in LMICs, and its impact on patients, the scaling up is essential at this time .

The pandemic has also placed a spotlight on some other significant aspects of patient safety. Given the need for social distancing, there is a serious concern amongst the medical community, including in the UK, that people with other health challenges are not seeking medical help or diagnosis. This represents a serious health challenge, particularly amongst ageing communities.

Last year, during the Japanese G20 Presidency, the issue of ageing and health was on the agenda. The Japanese recognised that with a rapidly ageing and declining population they were having to turn to digital health solutions. This pandemic demonstrates that we need to speed up the deployment of digital technology in the health system. Doctors being able to communicate virtually with their patients in their homes could significantly improve patient safety.

Furthermore, there are too few trained medical professionals – particularly nurses – around the world. This gap must be filled, and virtual education and training can play an important role in ensuring caregivers and health professionals have the tools to properly care for their patients. Linked to



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This year's UK G7 Presidency and Italy's G20 Presidency must prioritise antimicrobial resistance, with politicians understanding the warning health scientists and researchers have been giving us for several years.”

this is the need for a common, accurate means of measuring incidents of patient harm, with a system where the patient, the patient's family and the healthcare worker are supported through these traumatic situations.

Systems also need to accurately record health issues faced by health professionals in the treatment of their patient, such as the incidents of infection, mental health, violence and general occupational health matters. With accurate data it is increasingly possible to identify trends and gaps in patient care, and the challenges faced by caregivers.

WHO has developed some toolkits to support health professionals in the delivery of safe care, particularly in regions with weak health systems. The toolkit approach is valuable and should be expanded. In order to do that, I strongly support the creation of a Global Patient and Healthcare Worker Safety Fund.

Such a Fund could continue advocacy to keep this issue on the agenda of political leaders, and it could help to develop the online training and toolkits to assist healthcare workers to deliver much safer care. This is a gap not presently supported by governments or philanthropy. Perhaps the legacy initiative of the Saudi G20 Presidency could be the creation of this new fund?

A growing threat to patient safety is the rise of antimicrobial resistance. Drug-resistant pathogens pose a threat to humans, animals and plant life. However, WHO and the International Atomic Energy Agency (IAEA) have expressed deep concern over the inappropriate and over-use of antibiotics. This is a key area where the silos must be broken down. This year's UK G7 Presidency and Italy's G20 Presidency must prioritise this issue, with politicians understanding the warning health scientists and researchers have been giving us for several years.

The G20HDP has created a group drawn from our partners in public-private partnerships, academia and the private sector to help shape practical public policy initiatives that will help politicians and key decision makers halt this hidden pandemic. This year has changed the entire nature of global health security discourse. It is leading to deeper cooperation between the leaders of the global health community and to a recognition that sustainable growth is linked directly to the health of a country's population. Investing in health is a matter of national security and, most significantly of all, is about person-centred healthcare, where the security of the patient and the healthcare worker is paramount and central to universal health coverage.



Francesca Colombo



Katherine De Bienassis

## CHAPTER 11

## THE LEADING EDGE: THE ROLE OF GOVERNANCE, LEADERSHIP, AND CULTURE IN IMPROVING PATIENT SAFETY

The COVID-19 pandemic is a global health crisis which has caused unprecedented human and economic consequences, and it has shown safety vulnerabilities in our health systems, but it is not the first deadly, infectious disease in our healthcare settings. Before COVID-19, health systems and policymakers were already battling hospital-acquired infections from other, potentially deadly, agents, including drug resistant bacteria.

While the danger of patient safety events, like that of hospital-acquired infections, may have been under the radar of public consciousness, COVID-19 has made evident to a wider, global audience the continued vulnerability of healthcare delivery systems, bringing home the real risk of patient harm. Beyond the safety of patients, the safety of staff is crucially at stake.

Despite the challenges, the COVID-19 crisis has highlighted opportunities for leveraging synergies in, for example, hygienic measures that dually improve COVID-19 outcomes and drive patient safety improvements.

### Patient harm imparts a high financial cost

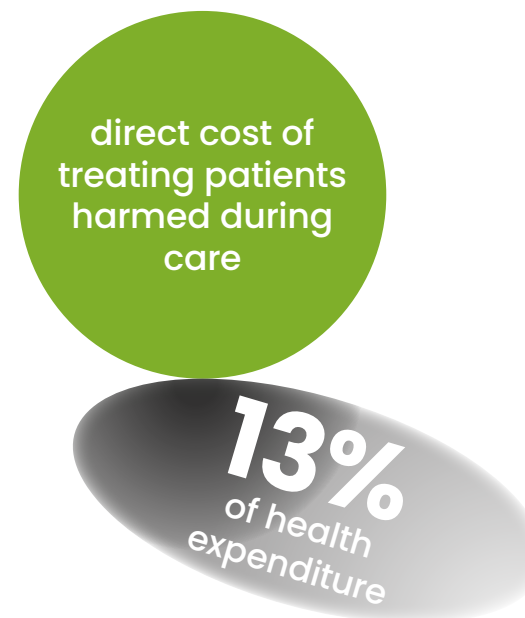
Poor safety comes at a price. In developed countries, the direct cost of treating patients who have been harmed during their care approaches 13% of total health expenditure. Excluding safety lapses that may not be preventable, total costs amount to just over 1% of OECD countries' combined economic output<sup>1</sup>.

Beyond being a major source of inefficiency and waste in health systems, the health burden of patient harm hampers economic growth and social welfare. While implementing and maintaining

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Beyond being a major source of inefficiency and waste in health systems, the health burden of patient harm hampers economic growth and social welfare.”

### developed countries



efforts to improve safety is not free, clinical, organisational, and system-level interventions have been shown to generate a good return on investment when implemented individually, and these benefits increase further when implemented as part of an overarching national strategy.

Governments, health systems, and providers have a duty to protect patients and the public from harm. Improving on the status quo will require policymakers to further assess how safety strategies, programmes, and interventions can be implemented to generate the best return on investment across their systems. Underpinning such strategies must be a robust culture of patient safety.

### Improving safety culture to improve patient outcomes

Improved models of patient-safety governance and investments in improving patient safety culture have a substantial and lasting impact on patient safety outcomes. Governance, leadership and culture are key for both improving patient safety and controlling COVID-19. Moreover, a positive culture around patient safety results in increased transparency, trust, and in higher levels of shared responsibility, along with improved confidence in organisational and national safety initiatives. Safety culture also relates to the way safety issues are dealt with in healthcare organisations, including how medical errors are communicated or the way interactions between employees or across hierarchies take place. High-reliability organisations, including those in the aviation and energy sectors, have offered a roadmap on how to create safety governance regimes based on organisational culture, including feedback and learning. The impact on healthcare would be substantial. A growing body of research has found that positive patient safety culture is associated with a number of benefits, including better health outcomes and patient experience, as well as improved organisational productivity and staff satisfaction.

Achieving this impact requires leadership: an overarching culture of safety needs to be instilled across the health system. Policymakers and healthcare leaders already have at their disposal many of the tools they need to improve safety culture and outcomes. These include, for example,

<sup>1</sup> See: [www.oecd.org/health/patient-safety.htm](http://www.oecd.org/health/patient-safety.htm), accessed October 2020.



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The COVID-19 crisis has highlighted the importance of a flexible health system and workforce as a way to rapidly increase intensive care unit capacity, implement safety policies in nursing homes, and mobilise personnel for tracking personal contacts.”

safety standards, routine reporting for internal improvement, inspections and review boards for self-regulation or peer-to-peer learning, and ongoing training of professionals. However, these tools need to be appropriately activated and continually improved.

An important element of safety culture is the creation of environments where patients and caregivers are at the centre of every action and activity. Commitment on the part of leadership

and management is crucial to establishing and maintaining a safe, people-centred environment. Leaders play a key role in driving organisational priorities by setting examples, fostering communication and creating enabling atmospheres for raising concerns, as well as leveraging incentives with the aim of creating safe, people-centred care. In tandem, good safety governance should include patient perspectives on the design, implementation and execution of efforts to improve safety.



Safety governance should also expand beyond the hospital. COVID-19 has dramatically shown that other sectors, including long-term and primary care, are extremely vulnerable to adverse safety events, and are too often neglected. Evidence from several OECD countries suggest that an important share of COVID-19 deaths has been in long-term care (LTC) residents<sup>2</sup>. Even before the COVID-19 crisis, healthcare-associated infections were common in LTC, accounting for, on average, 3.8% of deaths among LTC facility residents in OECD countries in 2016–17<sup>3</sup>. If health systems are to continuously improve their safety governance functions, then extending and strengthening safety governance outside hospitals must become a priority.

As many patient safety issues are related to infections, patient safety and COVID-19 prevention measures can – and should – reinforce each other. The COVID-19 crisis has illustrated the importance of strong patient safety cultures in maintaining safe, effective healthcare environments in times of emergency, and there are signs that progress is being made. In a recent survey of OECD countries, 75% of those countries surveyed (18 out of 23) indicated that there were plans in their country to initiate or expand existing work on patient safety culture<sup>4</sup>. Health systems with more positive patient safety cultures are more resilient and adaptive to changing circumstances, such as the rapidly evolving COVID-19 crisis.

### A holistic look at patient safety

Patient safety and the safety of healthcare workers are fundamentally interconnected. The COVID-19 crisis has brought renewed attention to the occupational hazards of healthcare workers, with countries facing staffing shortages, a lack of appropriate training, and shortages of personal protective equipment. The crisis has highlighted the importance of a flexible health system and workforce as a way to rapidly increase intensive care unit capacity, implement safety policies in

nursing homes, and mobilise personnel for tracking personal contacts. However, to date, analysis of the economic impact of patient safety has largely not included the costs of safety issues that impact health workers. These relate to staff leave, turnover, and productivity. Improving staff safety not only improves patient outcomes, it also improves the bottom line for health systems.

### Moving forward

The current pandemic has highlighted the need for strong and resilient safety governance and culture. This requires investments and leadership, and a focus on patient- and worker-centredness, and must extend beyond the hospital to ensure safety in long-term care and ambulatory care settings. A culture of patient safety is a fundamental component of efforts to pivot towards learning-based health systems built on risk mitigation. Policies to create the conditions conducive to good patient safety are essential for driving healthcare improvement. Efforts should seek to improve both patient and worker safety simultaneously, given the indelible relationship between staff working environments, patient safety, and occupational safety.

COVID-19 has challenged the capacity of governments, health systems, and healthcare providers to work quickly and in a coordinated manner to address a substantial threat. While the degree of success has varied across countries, systematic changes are possible if the necessary willpower and sense of urgency are present. Reducing the harm caused by COVID-19 and by adverse safety events is an achievable and necessary objective which could bring significant health and economic returns.

<sup>2</sup> See: [www.oecd-ilibrary.org/social-issues-migration-health/health-at-a-glance-europe\\_23056088](http://www.oecd-ilibrary.org/social-issues-migration-health/health-at-a-glance-europe_23056088), accessed November 2020.

<sup>3</sup> See: [www.oecd-ilibrary.org/social-issues-migration-health/health-at-a-glance-2019\\_4dd50c09-en](http://www.oecd-ilibrary.org/social-issues-migration-health/health-at-a-glance-2019_4dd50c09-en), accessed November 2020.

<sup>4</sup> K. de Bienassis et al. (2020), ‘Culture as a cure: Assessments of patient safety culture in OECD countries’ *OECD Health Working Papers*, No. 119. Available at: [www.oecd-ilibrary.org/social-issues-migration-health/culture-as-a-cure\\_6ee1aeae-en](http://www.oecd-ilibrary.org/social-issues-migration-health/culture-as-a-cure_6ee1aeae-en), accessed October 2020.

# PART IV

## PATIENT SAFETY 3.0



Dr. Giuseppe Ruocco

### CHAPTER 12

## HUMAN FACTORS **ENGINEERING** **AND PATIENT SAFETY**

2017 saw the introduction of a great novelty in the practice of collecting information about adverse events and near-misses in Italy. Law 24 created the National Observatory of Good Practices on Safety in Health. Set up by the National Agency for Regional Health Services (AGENAS – itself established in 1993 as a non-economic public body, subject to the supervision the Ministry of Health), it collects regional data about the causes, extent, frequency and financial burden of potential disputes.

The same law also made the National Institute of Health (Istituto Superiore di Sanità – ISS) responsible for the management of clinical guidelines, so as to offer a clear indication of the clinical pathways to be followed in the health sector in order to reduce the occurrence of adverse events. The new structure established by Law 24 provided for the collaboration of various entities to create synergies able to enhance patient safety and quality of care in Italy. Patient safety is indeed a domain where multi-disciplinarity and the involvement of all actors in the system is not just an asset, but also a need.

Risk Management and patient safety are part of the activities related to a wider area defined as Clinical Government, which places the needs of citizens at the centre of the planning and management of health services, enhancing the role of health workers and their responsibility promoting quality of care. For this reason, Law 24 drew attention to the relevance of the collection of data about adverse events and near-misses, but also to the implementation of preventative actions,

allocating their management to the Good Practices Observatory. The study of near misses occurring not only in hospitals, but also in the welfare and social health facilities, will indeed contribute to improvement, focusing as it will not only on acute illness, but on extending the field of observation to the various levels of the national healthcare system.

### Italy's experience

Italy's Italian National Public Health System (NPHS) offers 40 years of experience to draw on in the area of patient safety. During the COVID-19 pandemic, we are checking how the NPHS deals with the dramatic changes that have come about, aiming to increase its resilience to epidemiological changes, as well as to economic, social and cultural ones. Only a systemic approach to patient safety management can be successful and sustainable.

In Italy, national and regional Authorities are working closely with medical and nursing associations to define documents and guidelines for a more



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Patient safety is indeed a domain where multi-disciplinarity and the involvement of all actors in the system is not just an asset, but also a need.”

efficient use of human resources in healthcare and are also fostering integration between different health professionals. The National Public Health Service has launched a very detailed programme to address the main risks in the care sector. Actions are being developed in priority areas with the aim of creating an “organisation with a memory” that can learn from mistakes and improve.

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Italy's Italian National Public Health System (NPHS) offers 40 years of experience to draw on in the area of patient safety. Only a systemic approach to patient safety management can be successful and sustainable.”

### Key priorities in the NPHS programme

- **Monitoring and analysing** of sentinel events reported through the 'Information System for Monitoring Errors in Healthcare' (SIMES);
- **Organising audits** to analyse serious adverse events (via a Crisis Unit);
- **Setting up regional compliance** and LEA

(Livelli Essenziali di Assistenza – Essential Levels of Healthcare);

- **Formulating recommendations** for Preventing Sentinel Events;

- **Drawing up guidance** so that citizens, patients and users can be actively involved in the design of healthcare pathways, patient journeys and best practices for safety and quality.

**Monitoring and analysis of sentinel events reported through the 'Information System for monitoring errors in healthcare':** Surveillance of the most serious events (so-called sentinel events – adverse events of particular seriousness which cause death or serious harm to the patient and which reduce the patient's trust in the NPHS) was strongly recommended by WHO. This constitutes an important public health action, offering an indispensable tool for the prevention of such occurrences and for the promotion of safe treatments. Surveillance, which began experimentally in the early 2000s, has seen a progressive increase in both the number and quality of reports. The number of sentinel events on 31 December 2019 was 7,913 (as cumulative data from 2005–2018). There is still an underestimation of major events because the reporting lies with healthcare operators, but the increased number of reports shows the development of a safety culture among the healthcare staff.

**On-site visits through the Crisis Unit:** The Ministry of Health – in fulfilment of its health protection duty and using its supervisory power – carries

out on-site visits via the Ministerial Crisis Unit, in collaboration with experts from the National Institute of Health (ISS) and experts from AGENAS. The purpose is to collect useful information for understanding the processes that led to an adverse event and the deeper causes and organisational factors that contributed to event at a system level. Visits also aim to indicate to the region and to facilities where the event occurred what actions should be taken to avoid reoccurrence. The Italian Healthcare System is oriented towards change; these visits are therefore an occasion to learn, through interdisciplinary debate among different health professionals. At the end of each visit, the Ministry draws up a document containing the proposed improvement actions for the relevant organisation, to reduce the probability that similar risk situations occur again. Since 2016, 29 visits have been made through the Crisis Unit (also known as a 'National Task Force'), along with 40 ordinary visits not related directly to a specific event.

### Regional compliance with minimal quality standards and verification through the LEA questionnaire:

Each year the Ministry of Health evaluates implementation at the regional level of the tools that have been suggested for promoting quality and safety of care. Specific indications are used to measure compliance with the surgical safety checklist, allowing the reporting of sentinel

events to be measured against Ministerial recommendations. These indicators and the related standards are updated every year on the basis both of results obtained in previous years and innovations introduced at national level in the field of patient safety. Since 2009, there has been a progressive improvement in the implementation of Ministerial Recommendations and in the incidence of sentinel events. For the regions, performance against the relevant indicators affects their share of funding.

### Recommendations for preventing sentinel events:

The Directorate-General for Health Planning in the Ministry of Health has (in collaboration with experts from Regions and Autonomous Provinces and other stakeholders) developed 19 recommendations or specific documents with the aim of offering tools provide for preventing adverse events, and of promoting responsibility among healthcare actors, including fostering system change. The Recommendations will be reviewed and updated by the Directorate-General for Health Planning, in collaboration with the Regions and Autonomous Provinces, AGENAS, the Italian Pharma Authority (AIFA), the ISS, the Coordination of Regions and Autonomous Provinces for the Safety of Care – Sub Area Clinical Risk, scientific societies and other stakeholders. With the goal of improving patient safety, the Ministry of Health last month issued 19





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Accurate knowledge of drug therapy is essential to ensure patient safety and prevent errors, not only in hospital, but also in the wider community, and especially in transitions of care.”

recommendations about the safe handling of solid oral dosage forms and the proper management of oral drug therapy. These are designed to be used in cases where it is not possible to administer drugs intact and when the administration of drugs has not been set up by a pharmacy.

#### Guidance and indications on the prevention of errors in drug therapy during treatment transitions:

Pharmacological reconciliation is one of the best strategies for ensuring good quality of care: the WHO considers reconciliation one of the most effective strategies for ensuring good quality and safety of care for patients. In Italy, reconciliation has been included among the criteria and accreditation requirements that Regions and Autonomous Provinces are required to ensure for their patients. Accurate knowledge of drug therapy is essential to ensure patient safety and prevent errors, not only in hospital, but also in the wider community, and especially in transitions of care (patient hospitalisation, discharge, and transfer between departments of the same structure or to other health facilities). In transitions of care, in fact, the patient's therapy can be modified and, in particular, the active ingredient, dosage, pharmaceutical form and route or frequency of administration can be changed. New prescriptions can be introduced or medicines previously suspended previously can be reintroduced; these decisions, if not supported by an accurate medical history, can harm patients. Indications have been developed on the prevention of errors in drug therapy during treatment transitions. In the

period February 2017–August 2018, the Ministry of Health launched a project to detect discontinuities during the transition between settings with the aim of detecting the discontinuity situations in the transition between different settings. More precisely, the project focused on the transfer of elderly patients from their homes to a protected healthcare facility (Residenze Sanitarie Assistenziali – RSA) and on oncology patients discharged from hospital and vice versa, and the guidelines were subsequently revised.

### Human Factors Engineering (HFE)

The recent Italian experience of remodeling the NPHS to adapt it to new upcoming scenarios began with reorganising the health workforce.

### Reorganising the health workforce

In 2012, Law 189 came into force, covering many aspects of the organisation of Italy's Public Health System. In particular, it provided for **the creation at regional level of a structure whereby different specialist medical residents can work together** in cooperation with other health professionals.

In 2015, **a new law and new guidelines regarding the training of health professionals** was adopted for specialist medical schools.

Finally, the Ministry of Health **increased scholarships available at General Practitioner residency programmes by 10%.**

According to the international debate on education and training on patient safety, one of the main areas in which educational systems must invest energies and attention is the training given to new generations of healthcare professionals. Healthcare students and residents show great interest in promoting patient safety and understand the importance of providing safe and high-quality healthcare. New, younger generations in all professional sectors are more open-minded, allowing the improvement of habits not yet completely structured.

However, it has also been shown that if young health workers do not receive adequate training in patient safety, their inexperience and lack of knowledge in technical and non-technical skills mean they are more exposed to risky behaviours that negatively affect patients. To improve the training of students and residents in all healthcare environments, WHO developed and launched the 'Multi-professional Patient Safety Curriculum

Guide' in 2011. Here, WHO has included human factors and ergonomics in the patient safety curriculum at medical schools and has defined them as key disciplines to understand human performance in complex systems and critical situations, emphasising the interactions between human being and the other components of the environment that can produce breakdowns.

Taking the Multi-professional Patient Safety Curriculum Guide as its starting point, the Tuscany Region decided to start working on the introduction of patient safety training and the disciplines of human factors and ergonomics into university curricula and for those training in all healthcare profiles. This was achieved via the Centre for Clinical Risk Management and Patient Safety (GRC)–WHO Collaborating Center in Human Factor and Communication for the Delivery of Safe and Quality Care, with the collaboration of the International Ergonomics Association (IEA) and the University of Florence.





## Ergonomic factors

The term 'Ergonomics', generally refers to what is called physical ergonomics, or the relationship between postural/physical strength and worktools/ workstations. Ergonomics has been characterised by attention to the interactions between human beings, technologies and organisation in environments both in work and in daily life more generally. More recently, and according to the International Ergonomics Association, ergonomics (or what we might term human factors) has been defined as "the scientific discipline concerned with the understanding of the interactions among humans and other elements of a system, and the profession that applies theoretical principles, data and methods to design in order to optimise human well-being and overall system performance". As Carayon et al. have pointed out<sup>1</sup>, Human Factors and Ergonomics (HFE) approaches could contribute to patient safety by focusing on a number of specific aspects.

### Patient Safety: what should Human Factors and Ergonomics (HFE) focus on?

- **Usability** of technology, including the design of usable and safe medical devices and health IT;
- **Understanding** and identification of the mechanisms of human error through a systems approach, applying the Vincent and colleagues adapted Reason's Swiss Cheese model<sup>2</sup>;
- **Identification** of performance obstacles that may endanger patients by making it difficult for clinicians to perform tasks and procedures safely;
- **Enhancement** of resilience in the system, that is, "the ability of systems to anticipate and adapt to the potential for surprise and failure"<sup>3</sup>;
- **Commitment** to maintaining 'situational awareness' by ensuring that within organisations it becomes standard practice for staff to carefully examine their operations, looking for anomalies, real and possible errors<sup>4</sup>.

1 P. Carayon, A. Xie and S. Kianfar, 'Human factors and ergonomics as a patient safety practice', *BMJ Qual Saf.* 23.3 (2014), pp. 196–205.

2 C. Vincent, S. Taylor-Adams, N. Stanhope, 'Framework for analysing risk and safety in clinical medicine', *BMJ* 11;316 (1998), pp. 1154–57.

3 DD. Woods and E. Hollnagel, 'Prologue: Resilience engineering concepts' in: E. Hollnagel, DD Woods DD and N. Leveson (eds.) *Resilience engineering—concepts and precepts*. (Hampshire, UK: Ashgate 2006).

4 S. Bagnara, O. Parlangeli and R. Tartaglia, 'Are hospitals becoming High Reliability Organizations?' *Appl Ergon* 41.5 (2010), pp. 713–718.



In Italy, the Italian Society for Ergonomics and Human Factors promotes (among other topics) interventions and research for improving safety and quality in healthcare. It works in collaboration with the Centre for Clinical Risk Management and Patient Safety (Tuscany Region) – WHO Collaborating Centre in Human Factors and Communication for the Delivery of Safe and Quality Care. The approach to safety and quality that the Centre GRC promotes, both regionally in its role as regional body and internationally as a WHO CC, is that of applying HFE principles to enable a deep understanding of complex systems and of designing and implementing interventions focused on the multiple interactions between human beings (healthcare workers) and their environment (healthcare structures) to improve safety and outcomes<sup>5</sup>.

During the COVID19 outbreak, for instance, it emerged that several of the key organisational issues that health systems had to face were related to HFE and the safety culture. During the crisis, the main activities of the health services were forced to rapidly adapt to new and unknown scenarios and HFE tools have been able to provide our healthcare systems with some easy-to-realise solutions for supporting healthcare workers' cognitive overload, and to cope with the

for need improved communication, teamwork and situational awareness<sup>6</sup>.

In this framework and from a risk management perspective, a paradigm shift is needed in order to understand adverse events and develop accident-prevention strategies. The focus must move from the search for active error, to uncovering the latent errors that are generally grounded in the organisation rather than in frontline operator skills and competences. Human error thus becomes the consequence of failures in the system resulting from organisational choices and from inappropriate decisions that may have not considered the cognitive and physical limits of the operators, rather than being the direct and main cause of the hazard. Health systems have a number of characteristics that make them very different from other high-risk contexts.

### How health systems differ from other high-risk contexts

- In a hospital, there are **more numerous and more frequent adverse events** and the occurrence of adverse events show far **more variety in form and location** than in traditional

5 T. Bellandi et al., 'Human Factors and Ergonomics in Patient safety Management', in P. Carayon (ed.), *Handbook of Human Factors and Ergonomics in Health Care and Patient Safety*, (Oxford: Taylor & Francis Ltd., 2017).

6 S. Albolino, G. Dagliana, M. Tanzini et al., 'Human factors and ergonomics at time of crises: the Italian experience coping with COVID-19' *International Journal for Quality in Health Care* (2020).



High Reliability Organisations (HROs), where vulnerability tends to be localised;

Events usually involve few operators and affect few people, and hospitals are very rarely affected by catastrophes (epidemics, for example, are uncommon);

Hospitals are characterised by high human being density, with a high variability of the people inside holding both active and passive roles. Unlike traditional HROs, **hospitals are characterised by a preponderance of people having a more or less passive role**;

Hospitals are also systems where there are designated victims, i.e. the patients. At variance with what happens in traditional HROs, an operator in a hospital is very seldom the victim of an adverse event where he or she plays an active role;

Very often, adverse events become immediately manifest. Even when technology is employed, barriers and defences against unsafe acts are weak, when they are present at all. In hospitals, unsafe acts are often not preventable. Instead, they require repair actions to be undertaken and executed in an emotional atmosphere. **Healthcare systems have to cope with human beings, who are the most changing and dynamic systems in nature.** Patients continuously introduce unpredictable variability that makes it nearly impossible to establish standard procedures, clear and effective communication strategies, or error-free operations;

The organisation of any two hospitals is never alike. The unpredictability of the dynamics of human beings means that the organisation is continuously forced to change and assume different shapes. **Hospitals have to become systems that quickly adapt themselves to individual needs** within various cultural scenarios. Such a situation is very uncommon in traditional HROs, and, indeed, is sometimes carefully avoided in order to remove possible conflicts and ambiguities;

Decision-making processes in hospital are increasingly characterised by negotiation and emotion. The patient may intervene in the decision process bringing in a new element of variability. Healthcare professionals are usually highly motivated and well prepared, but, like every human being, they are subject to fatigue, emotions, and cognitive overload.

Alongside these general characteristics of healthcare settings, it is important to pay attention to the particular qualities of individuals settings in order to apply effective patient safety strategies to different clinical areas<sup>7</sup>.



The regional Centre for Clinical Risk Assessment (GRC) aims to construct a shared vision for safety by sharing of experiences and by developing collaborative projects for patient safety.”

### WHO Collaborating Centre in Florence

Since 2016, Italy has hosted one of the WHO Collaborative Centres (WHO CC) in the field of safety and quality of care, the WHO CC in Human Factor and Communication for the Delivery of Safe and Quality Care. The WHO CC has its headquarters in Florence (Tuscany Region) and is connected to the regional Centre for Clinical Risk Management, and to Patient Safety Centre (Gestione Rischio Clinico - GRC), a clinical governance structure instituted in 2003 by the Tuscan regional council. The GRC now enrolls professionals of different disciplines (public health, clinical risk management, industrial design, human factors, organisation studies, communication science, law, psychology, and international relations). The GRC promotes

a culture of safety through active and cross-disciplinary learning, looking at adverse events and errors and promoting initiatives and best practices for improving quality and safety in healthcare settings. The GRC aims to construct a shared vision for safety by sharing of experiences and by developing collaborative projects for patient safety. The Centre proposes international, national and regional standards and recommendations for operational contexts and supports the effective measurement of critical process and measures.

After several years of collaboration with WHO on theme of patient safety and following participation in and international collaborative project for the implementation of WHO patient safety campaigns in Italy and also in less developed countries, the regional Centre (GRC) was appointed WHO Collaborating Centre and to date it is in its second 4-year mandate.

### The main activities of the WHO Collaborating Centre (WHO CC)

- 1 To **host a platform for sharing knowledge** at the global level (Global Knowledge Sharing Platform for Patient Safety - GKPS) in order to improve patient safety and quality of care and to collect and share lessons from reporting, learning about patient safety incidents so that safety practices can be applied for risk prevention. GKPS also aims to share knowledge and training about reporting and learning systems on patient safety, connecting key stakeholders involved in the implementation of safety practices.
- 2 To **support WHO in the development of methods and solutions** relating to human factors and communication in order to improve the safety and quality of care, offering training courses and teaching materials on these topics for the basic and continuous training of health workers and for the education of caregivers and patients.

3 To **support the integration of safety and quality objectives into health policies and strategies** and collaborate with WHO in supporting Member States through international cooperation projects and cultural exchange. The WHO CC contributes to the implementation of collaborative interventions for safety and quality improvement and to projects for strengthening the most fragile health systems around the world via shared planning, the exchange of safety practices and experiences and the creation of professional networks. These activities are conducted in collaboration with the Global Health Centre of the Tuscany Region<sup>8</sup> with the aim of integrating elements of safety and quality of care into international cooperation projects.

4 To **promote an approach to safety and quality of care based on Human Factors and Ergonomics (HFE)** as an innovative way of understanding complex systems – such as those in healthcare settings – and to promote a systemic approach. The aim is to develop a deeper understanding of the organisational dynamics that may contribute to making healthcare systems safer or potentially more risky.

An emphasis of Human Factors and Ergonomic (HFE) will improve patient safety by focusing on the particular complexities of healthcare settings. The WHO's Collaborative Centres (WHO CC) offer a practical model for the kind of multidisciplinary approach that can make a real difference.

7 C. Vincent and R. Amalberti R, *Safer Healthcare. Strategies for the Real World* (New York City: Springer, 2016).

8 The Global Health Center (GHC) is a multidisciplinary facility of the Tuscany Region that coordinates actors in the Tuscany Regions international health cooperation network and promotes international activities in regional local health services. See: [www.centrosaluteglobale.eu/about-us/](http://www.centrosaluteglobale.eu/about-us/), accessed October 2020.





Dr. Catharina Boehme

## CHAPTER 13

# THE ROLE OF TESTING IN MINIMISING DIAGNOSTIC ERRORS AND IMPROVING PATIENT SAFETY AND THE SAFETY OF HEALTHCARE WORKERS

Testing has a crucial role to play in minimising diagnostic errors, improving patient safety and improving the safety of healthcare workers. Delayed, missed or incorrect diagnoses can lead to negative patient outcomes, loss of productivity, loss of income and, in extreme cases, death, as well as exacerbating mistrust in healthcare systems<sup>1</sup>. Historically, diagnostic errors have received less attention than other types of errors such as procedural or medication errors<sup>2</sup>, yet diagnostic errors are more likely than other incidents to be associated with moderate or severe harm, or death<sup>3</sup>. This balance must be readdressed.

Diagnostic errors are defined as a missed opportunity to provide an accurate and/or timely explanation of a patient's health problems or to communicate that explanation to the patient<sup>4</sup>. Broadly speaking, there are two types of diagnostic error<sup>5</sup>. The first relates to system factors (for

example delayed test results) and the second to cognitive errors, including failures in perception, heuristics and bias by healthcare professionals (HCPs). Factors that can contribute to diagnostic errors include, but are not limited to: poor access to diagnostic tests (due to factors like a lack of

- 1 H. Singh and ML Graber, 'Improving Diagnosis in Health Care – The Next Imperative for Patient Safety' *The New England Journal of Medicine*, 73.26 (2015), pp. 2493–5.
- 2 Ibid.
- 3 N. Sevdalis et al., 'Diagnostic error in a national incident reporting system in the UK' *Journal of Evaluation in Clinical Practice*, 16.6 (2010), pp.1276–81.
- 4 See [iom.nationalacademies.org/Reports/2015/Improving-Diagnosis-in-Healthcare.aspx](http://iom.nationalacademies.org/Reports/2015/Improving-Diagnosis-in-Healthcare.aspx), accessed October 2020.
- 5 ML Graber, N. Franklin, and R. Gordon, 'Diagnostic error in internal medicine' *JAMA Internal Medicine* 165.13 (2005), pp.1493–9.

This work was done when Catharina Boehme was CEO at FIND.  
At the time of the publication, Dr Boehme was appointed to Cabinet Chief at the World Health Organization.

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The incidence of diagnostic error varies across disease areas, healthcare levels and assessment methods. However, the majority of studies support an overall rate of around 10–15% of cases.”

laboratory infrastructure or non-availability of high-quality tests)<sup>6</sup>; poor access to care (often linked to affordability); too few HCPs and specialists (often due to lack of training); communication issues (for example poor teamwork, lack of patient education); care coordination issues (for example the loss of test results, poorly documented records, and/or limited follow-up)<sup>7</sup>; availability of health informatics resources (for example, lack of access to the internet); cultural issues (for example, physician-centric systems and/or passive patients); and human factors (like workplace distractions/interruptions)<sup>8</sup>.

## Incidence of diagnostic error

The incidence of diagnostic error varies across disease areas, healthcare levels and assessment methods. However, the majority of studies support an overall rate of around 10–15% of cases<sup>9</sup>. Diagnostic errors can occur throughout the patient cascade, including at initial assessment, during performance and interpretation of diagnostic tests, as part of the follow-up and tracking of diagnostic information, and in referral-related communication and coordination, as well as in patient adherence and engagement<sup>10</sup>. As the first point of contact with the patient, diagnosis in primary care represents an especially high-risk area for errors<sup>11</sup>.

6 See: [www.who.int/patientsafety/topics/primary-care/technical\\_series/en/](http://www.who.int/patientsafety/topics/primary-care/technical_series/en/), accessed October 2020.

7 ML Graber ML, 'The incidence of diagnostic error in medicine' *The BMJ* 22.2 (2013).

8 H. Singh et al., 'The global burden of diagnostic errors in primary care' *The BMJ Quality and Safety* 26.6 (2017), pp. 484–94.

9 ML Graber ML, 'The incidence of diagnostic error in medicine' *The BMJ* 22.2 (2013).

10 See: [www.who.int/patientsafety/topics/primary-care/technical\\_series/en/](http://www.who.int/patientsafety/topics/primary-care/technical_series/en/), accessed October 2020.

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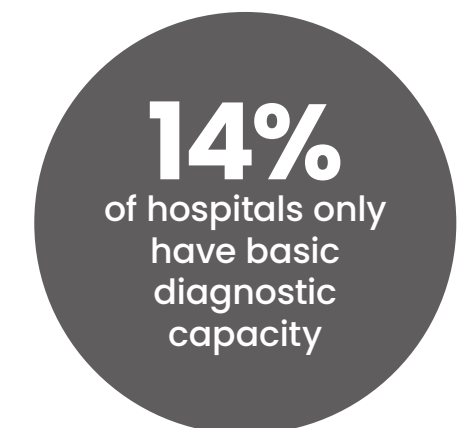
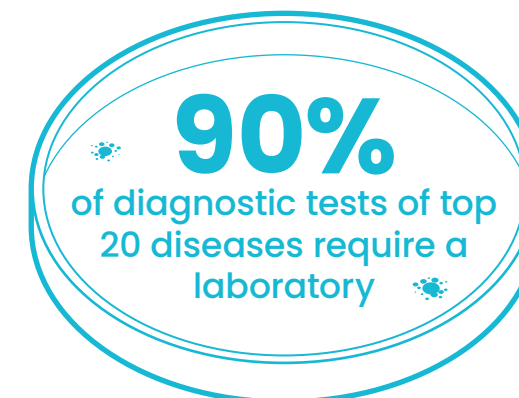
Delays in diagnosing cancer are common, with about 7% of abnormal test results not communicated to patients – the frequency of errors has been estimated to range from 2-12% of cases.”

Data from 3 studies in the US suggest a rate of outpatient diagnostic errors of circa 5% in adult patients, equating to circa 12 million US adults every year, with about half of these errors potentially being harmful<sup>12</sup>. Diagnostic errors often reflect complexities and vulnerabilities within healthcare systems, and there are therefore greater challenges in lower and middle-income countries (LMICS), where the process is further complicated by limited access to diagnostic testing resources, a paucity of qualified primary care providers and specialists, and pre-electronic recordkeeping systems<sup>13</sup>. The COVID-19 pandemic is likely to have increased the risk of diagnostic errors, due to the impact on capacity in healthcare systems, on the physical and psychological status of clinicians, and on staffing shortages and time pressures.

Cancer, infections and cardiovascular disease appear to be the leading areas in which harmful diagnostic errors occur in primary care<sup>14</sup>. Delays in diagnosing cancer are common, with about 7% of abnormal test results not communicated

to patients<sup>15</sup>; the frequency of errors has been estimated to range from 2-12% of cases<sup>16</sup>. Other infections that are commonly misdiagnosed include: viral infections, often misdiagnosed as bacterial, leading to unnecessary antibiotic use and potentially antimicrobial resistance<sup>17</sup>; malaria, often diagnosed as viral/bacterial due to presentation with fever<sup>18</sup>; tuberculosis, misdiagnosed in around 10% of cases due to failure to use basic diagnostics or to interpret test results correctly<sup>19</sup>; paediatric infections such as pneumonia, diarrhoea and meningitis, due to the non-specificity of presenting symptoms and a lack of trained healthcare workers to make diagnoses<sup>20</sup>; and premonitory symptoms of cardiovascular and metabolic diseases such as hyperglycaemia (10% cases unrecognised) and hypertension (only 45% of patients aware of their diagnosis), which are often missed<sup>21</sup>.

## LMICS



- 12 H. Singh, AN. Meyer and EJ. Thomas, 'The frequency of diagnostic errors in outpatient care: estimations from three large observational studies involving US adult populations' *The BMJ Quality and Safety* 23.9 (2014), pp. 727-731.
- 13 H. Singh et al., 'The global burden of diagnostic errors in primary care' *The BMJ Quality and Safety* 26.6 (2017), pp. 484-94.
- 14 See: [www.who.int/patientsafety/topics/primary-care/technical\\_series/en/](http://www.who.int/patientsafety/topics/primary-care/technical_series/en/), accessed October 2020.
- 15 H. Singh et al., 'Follow Up Actions on Electronic Referral Communication in a Multispecialty Outpatient Setting', *Journal of General Internal Medicine*, 169.12 (2009), pp. 1123-1129.
- 16 Raab SS, Grzybicki DM, Janosky JE, Zarbo RJ, Meier FA, Jensen C, et al. Clinical impact and frequency of anatomic pathology errors in cancer diagnoses. *Cancer*. 2005;104(10):2205-13.
- 17 H. Singh et al., 'The global burden of diagnostic errors in primary care' *The BMJ Quality and Safety* 26.6 (2017), pp. 484-94.
- 18 M. Anwar et al., 'Rapid diagnostic tests to improve treatment of malaria and other febrile illnesses: patient randomised effectiveness trial in primary care clinics in Afghanistan' *The BMJ Clinical Research Ed.* (2014).
- 19 L. Szczuka et al., 'Analysis of diagnostic errors and recommendations of diagnostic procedures in bacteriologically negative pulmonary tuberculosis', *Pneumonol Alergol Pol.* 66.1-2 (1998), pp. 17-23.
- 20 L. Liu et al., 'Global, regional, and national causes of child mortality: an updated systematic analysis for 2010 with time trends since 2000', *The Lancet* 379 (2012), pp. 2151-61.
- 21 CK. Chow, et al. 'Prevalence, awareness, treatment, and control of hypertension in rural and urban communities in high-, middle-, and low-income countries', *JAMA* 310.9 (2013) pp. 959-68;.



## The role of testing in minimising diagnostic errors

The high rate of diagnostic errors for many diseases with a high risk of error is due to a lack of quality diagnostics. Diagnostic errors may therefore be reduced through the development of new or improved diagnostic assays with higher performance versus existing diagnostics. This might, for example, include tests to distinguish bacterial from viral infections/malaria<sup>22</sup>, molecular/antigen tests for gonorrhoea (vs a syndromic approach)<sup>23</sup>, and a reliance on basic diagnostic techniques for tuberculosis<sup>24</sup>. Indeed, recently developed assay, such as in molecular diagnostics

and rapid diagnostic tests in tuberculosis, have the potential to reduce diagnostic errors for certain high-risk diseases.<sup>25</sup>

Recent technological developments have allowed the development of digital diagnostic support tools that have potential to reduce diagnostic errors<sup>26</sup>. Digital monitoring technologies and notification systems have been shown to improve the transmission of important diagnostic information to clinicians, preventing loss to follow-up<sup>27</sup>; and trigger algorithms, including computer based alert systems, that identify patients at high risk of diagnostic errors using electronic health record data, have been shown to improve

22 C. Escadafal, 'The good and the bad: using C reactive protein to distinguish bacterial from non-bacterial infection among febrile patients in low-resource settings' *BMJ Glob Health* 5.5 (2020).

23 C. Ferreyra et al., 'Developing target product profiles for Neisseria gonorrhoeae diagnostics in the context of antimicrobial resistance: An expert consensus' *PLoS One* 15.9 (2020).

24 T. Broger et al., 'Diagnostic accuracy of three urine lipoarabinomannan tuberculosis assays in HIV-negative outpatients', *Journal of Clinical Investigation* 130.11 (2020), pp. 5756–5764.

25 E. MacLean et al., 'Advances in Molecular Diagnosis of Tuberculosis', *Journal of Clinical Microbiology*, 58.10 (2020).

26 R. El-Kareh, O. Hasan, G.D. Schiff, 'Use of health information technology to reduce diagnostic errors', *The BMJ Quality and Safety* 22. 2 (2013), pp. 40–51.

27 H. Singh H et al., 'System-related interventions to reduce diagnostic errors: a narrative review', *The BMJ Quality and Safety* 21.2 (2012), pp. 160–170.



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The potential for quality diagnostic tests to reduce diagnostic errors can only be realised if patients and healthcare professionals (HCPs) have access to these tests.”

diagnostic accuracy<sup>28</sup>. Computerised support systems for clinical decisions can reduce clinician bias by prompting consideration of a variety of conditions that might be relevant to a patient's clinical presentation<sup>29</sup>, and these algorithms may be particularly effective in combination with point-of-care diagnostics<sup>30</sup>.

The potential for quality diagnostic tests to reduce diagnostic errors can only be realised if patients and HCPs have access to these tests. Currently, there are a number of overarching barriers to access to diagnostics, particularly in low-resource areas, where healthcare systems and laboratories have infrastructure weaknesses. These include, but are not limited to: the fact that more than 90% of current diagnostic tests for the top 20 diseases require a laboratory, yet only 1% of primary care clinics and 14% of hospitals have basic diagnostic capacity<sup>31</sup>; a general need for strengthening infrastructure, including education/training, in LMICs; and the development of rapid diagnostic tests that can be used at the point of care to increase access<sup>32</sup>. Regarding affordability and funding, there is a need for sustainable sources of domestic funding, a more transparent tendering process and decreased supply-chain costs. A

country-driven approach to generate market demand for affordable tests that are appropriate to the needs of the target population is key, as is the inclusion of diagnostic tests in national policies and guidelines in order to support uptake. Addressing these barriers will create a sustainable diagnostics ecosystem that can support quality diagnostic tests with the potential to reduce the frequency of diagnostic errors.

Diagnostic errors occur frequently and are often associated with severe harm to patients. Quality diagnostic assays and novel digital technologies have the potential to reduce the frequency of diagnostic errors, thereby improving patient safety. However, there is an underlying need to address persistent barriers that exist in accessing these diagnostics, particularly in low-resources areas, before their potential can be truly realised.

28 J. Abimanyi-Ochom et al., 'Strategies to reduce diagnostic errors: a systematic review', *BMC Medical Informatics and Decision Making* 19.1 (2019), p.174.

29 Ibid.

30 KG Pelle et al., 'Electronic clinical decision support algorithms incorporating point-of-care diagnostic tests in low-resource settings: a target product profile' *BMJ Global Health*, 5.2 (2020).

31 HH Leslie et al., 'Service readiness of health facilities in Bangladesh, Haiti, Kenya, Malawi, Namibia, Nepal, Rwanda, Senegal, Uganda and the United Republic of Tanzania' *Bulletin of the World Health Organisation*, 95.11 (2017), pp.738–48.

32 See: [apps.who.int/iris/bitstream/handle/10665/275867/9789241565653-eng.pdf?ua=1](https://apps.who.int/iris/bitstream/handle/10665/275867/9789241565653-eng.pdf?ua=1), accessed October 2020.





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# Conclusion and Recommendations

## The Future of Patient Safety: How can we Transform Patient Safety and Save Healthcare? Recommendations, Evidence

Despite tumultuous health events, both 2020 and 2021 will go down on record as years that remind us about the importance of empowering patients and healthcare workers nationally and globally across and beyond the G20. While COVID-19 continues to dominate our daily lives and political agendas, the current pandemic has focused its attention on the importance of guaranteeing the safety of healthcare workers, particularly if patients are to be kept safe.

Even before the pandemic outbreak, it is remarkable that Patient Safety was a prominent agenda item during the G20 Presidency under the

Kingdom of Saudi Arabia.

Last year was the WHO Year of Nurses and Midwives and, from an economic perspective the OECD has reported on the economics of Patient Safety for the first time. Last but not least, the WHO passed a Health Workers' Safety Charter that was supported by International Organisations and Member States across the world.

Since the establishment of the annual World Patient Safety Day (WPSD) in 2019 by the WHO, every 17 September the world is encouraged to mark the day by activities that raise awareness of the need



to continue to improve the safety of patients and healthcare workers worldwide.

This report has highlighted to us the challenges for patients and healthcare workers that span across industries and disease areas such as infectious diseases including COVID-19, HIV, TB and Malaria, plus non-communicable diseases such as sepsis.

The global challenges for patients and healthcare workers range across high-income and low- and middle-income countries and do not respect borders!

This report taught us that Patient Safety and healthcare workers' safety opens up discussions on gender-equality as, according to WHO, 70 per cent of the world's healthcare workers are women.

The report also highlights the interdependency between economic shocks, climate change and other socio-economic challenges, and the well-being of patients and their healthcare givers.

The valuable contributions made by thought-leaders, policymakers and experts in this report have shown us the diversity of issues related to patient safety spanning across occupational health and safety, digital innovations R&D and medical care.

The chapters have captured the importance and interdependence of patient safety in context of the COVID-19 crisis management and the building back better narrative. Empowering patients and healthcare workers are a central tenet of achieving Universal Health Coverage and the UN SDG3 targets by 2030. Technological disruptions such as existing and new digital health solutions need to be scaled up to promote stronger health systems and a safer environment for patients and healthcare workers.

This report also highlights some of the encouraging trends in patient safety and makes clear recommendations how the day-to-day safety of patients and healthcare workers worldwide can be improved, particularly by promoting best practice.

For the healthcare sector to behave more like other high-risk industries (such as aviation or nuclear power), and for its actors to move towards the

concept of HRO, we must reimagine and transform how we approach safety. To strengthen global health security, health systems must be resilient. The safety of patients and healthcare workers is at the heart of that improved resilience.

Over the past two decades since the ground-breaking report, 'To Err is Human', healthcare systems have made great progress on bridging the patient safety knowledge gap, but when it comes to the patient safety implementation gap, there is still room for improvement.

There is a significant opportunity to jointly develop policies and measures through dialogue with governments and with employers' and workers' organisations to develop practical and sustainable solutions to complex challenges when all that concerned work together.

The G20 Presidency of Italy in 2021 has taken the importance of Patient Safety on board and recognized that the improvement of care and safety for patients, nurses, doctors and healthcare workers is an important component in the "build back better" narrative.

Based on the author's contributions in this report, we recommend that the G7 and G20 Presidencies, the World Health Organization (WHO), the International Labour Organisation (ILO), the European Union (EU), the African Union (AU), the Organization of American States (OAS), the Association of South East Asian Nations (ASEAN) and the Arab League should systematically drive forward initiatives to build common tools that can be deployed to significantly reduce harm to both patients and carers.



# We recommend:

1

That the importance of patient safety and healthcare workers' safety should be **integrated into the health track of future G20 and G7 presidencies as a crucial component to build back better** and improve the resilience of healthcare systems and the sustainability of the global economy;

2

The **creation of a transparent system for accurate incident reporting and integrated metrics and dashboards** reflecting indicators of patient safety and health worker safety;

5

That as part of national pandemic preparedness plans and in tackling antimicrobial resistance, **healthcare workers are guaranteed access to personal protective equipment, the latest testing technology and are prioritized for vaccination**;

6

The promotion of measures that particularly address the health, welfare, personal safety and employment rights for healthcare workers especially that of **women, who make up of 90% of nurses worldwide**, in line with ILO standards;

The **development of a “blame free culture” through open communication channels** for health workers to encourage the reporting of adverse clinical incidents and promote a global benchmarking and learning system for work-related adverse events to health workers;

3

The **appointment of a Commissioner at a national level**, whose responsibility is to develop national programmes, to provide a policy framework for the safety of patients and health workers, and to promote safer health systems;

4

Include **healthcare workers' safety in the 14th General Programme of Work (GPW 14)** of the WHO;

7

To acknowledge the need to **establish a Global Fund for Patient Safety and Healthcare Workers' Safety** to act as a catalyst for change to support safety concerns in national health programs, learn from best practices globally, and guarantee the sustainability of its investments.

8

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The teams involved in creating this report have worked tirelessly in setting up this initiative and in compiling and delivering this report. We thank everyone for their collegiate efforts.

This report entirely represents the views and perceptions of its authors and the G20HDP team.

# Glossary

<b>AHRQ</b>	Agency for Healthcare Research and Quality
<b>CDC</b>	Centre for Disease Control and Prevention
<b>CQC</b>	Care Quality Commission
<b>GSE</b>	Global Sepsis Alliance
<b>HCW</b>	Healthcare workers
<b>HICs</b>	High-income Countries
<b>HFE</b>	Human Factors and Ergonomics
<b>HROs</b>	High Reliability Organisations
<b>IAEA</b>	International Atomic Energy Agency
<b>IEA</b>	International Ergonomics Agency
<b>ICN</b>	International Council of Nurses
<b>ILO</b>	International Labour Organisations
<b>LMICs</b>	Low- and Middle-income Countries
<b>LTC</b>	Long-term Care
<b>OECD</b>	Organisation for Economic Cooperation and Development
<b>PAHO</b>	Pan American Health Organisation
<b>PSC</b>	Patient Safety Culture
<b>SDG</b>	Sustainable Development Goal(s)
<b>WHO</b>	World Health Organisation





The G20HDP is an advocacy organisation that aims to ensure that G20 countries coordinate their health innovation strategies to tackle the growing burden of communicable and non-communicable diseases globally, to promote the delivery of the United Nations Sustainable Development Goals (SDGs) with a focus on SDG 3 “health and well-being for all”.

The G20HDP emerged as an informal coalition of like-minded organisations during the G20 Presidency in Germany in 2017, building on the objectives of SDG 17, “strengthening partnerships”. Our 22 partner organisations from across different sectors include product development partnerships; not-for-profit organisations; international organisations; public-private partnerships; health tech start-ups; the pharmaceutical industry; research institutions and academia. The Partnership is supported by a network of high-profile Global Ambassadors.

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