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SYSTEM GOVERNANCE TOWARDS IMPROVED PATIENT SAFETY - KEY FUNCTIONS, APPROACHES AND PATHWAYS TO IMPLEMENTATION

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Executive summary

Box 1. Key Findings

1. There is no ideal patient safety governance model. It is more important that patient safety governance (a) complements overall health system governance and financing, and (b) aligns its individual components and functions.

2. The scope of patient safety governance should include all healthcare settings.

3. Safety governance should foster continuous learning from both harm and success. The focus should broaden from reacting to harm to risk assessment and management.

4. The basis of safety governance must be what is best for the patient, whose perspective should be included in the design, implementation and execution of governance models.

5. Governance should foster a culture of openness and trust among health professionals and regulators.

6. Safety governance should align with and influence other policy areas, notably data privacy/security policies and workforce preparedness.

7. Safety governance should encourage health care financing and investment that result in a better balance between costs made to address errors (failure costs) with costs to prevent errors (prevention costs). Likewise payment systems should reward good patient safety and punish poor patient safety.

8. Political leadership should include patient safety among the top priorities in its health policy agenda.

1. Patient safety is a critical policy issue. Safety failures can result in harm that profoundly affect patients and their family and carers. They also weigh heavily on the shoulders of healthcare professionals and leaders and exert unnecessary pressure on healthcare budgets. Previous OECD reports on the Economics of Patient Safety emphasised that safety failures are largely system failures. Strategies aiming to improve and strengthen patient safety must therefore take a systemic approach – and align with other policy measures. This also applies to governance of safety in health systems.

2. Safety governance refers to the approaches taken to minimise the risk for patient harm across an entity or system. It typically comprises steering and rule-making functions such as policies, regulations and standards. To date, governance has focused on the clinical level and the hospital setting, with limited oversight and control over safety in other parts of the health system. A need for a system-wide approach to safety governance is increasingly appreciated.

Legislation is the cornerstone of safety governance models, but stakeholder involvement can be strengthened

3. Safety governance is applied through a set of functions that are implemented across different levels of care and in specific parts of the health system. These functions comprise: defining roles and responsibilities establishing systems of measuring and monitoring safety, defining key accountabilities, ensuring capacity-building of personnel applying appropriate tools and strategies, and involving key stakeholders in safety governance and practice. Such key stakeholders include political leaders, boards of healthcare-providing organisations, health professionals, managers, administrators and, critically, citizens and patients.

4. All 25 countries that responded to a 2019 OECD Survey of Patient Safety Governance have enacted legislation that aims to promote patient safety. These practices include external accreditation and inspections of safety processes and outcomes.

5. Less emphasis is reported on involving key stakeholders in safety governance. In one quarter of responding countries, political leaders are not regularly informed on the patient safety in their health system. Furthermore, while legislation supports the involvement of patients in safety and quality decision-making processes, it is seldom implemented to its full potential in the development of safety strategies and programmes.

Strong safety governance models enable continuous learning

6. A key factor in patient harm is the complexity of modern health care. Strong safety governance models align the functions performed by different actors within a health system. This includes clear definition of roles and responsibilities, monitoring of safety and external accreditation. Evidence suggests an association between national safety standards and systems for measurement and monitoring of safety with performance indicators. This forms the basis for continuous feedback and learning, where monitoring of safety and performance indicators serve as corrective measures to existing practice.

There is no one-size-fits all in safety governance

7. The specific approach taken to safety governance is shaped to a large extent on the broader system governance model. Health systems with a national focus, e.g. Denmark, England, Sweden, have implemented more comprehensive and overarching safety governance models, for example enacting national-level legislation to ensure safety is implemented and aligned with other functions. In health systems characterised by more decentralised decision-making, e.g. Austria, Czech Republic and Switzerland, the safety governance seems also more fragmented.

8. The strength of safety governance, however, appears not to be dependent on the system governance model. In decentralised health systems with a high degree of fragmentation, the importance of developing a strategic oversight and common understanding of putting safety first is key to reducing patient harm across the system. Strategic oversight can be enabled by the establishment of a safety agency, for example the Canadian Patient Safety Institute and the German Federal Joint Committee, or a nation-wide safety strategy, as seen in Austria.

Political leadership and safety culture are key elements for reducing harm

9. The importance of leadership and culture in safety governance cannot be overstated. Leadership and political will to put patient safety on the national agenda have driven patient safety improvements

across the OECD. While consistent system-level efforts in monitoring and reporting have a direct effect on the quality of health care, political focus from central governments can enable sustainable funding and the resources needed for investing in safety. Targeted investments that balances prevention costs with costs of treating safety failures can reduce harm and further improve system efficiency.

10. Patient safety governance can be sustained if a culture that prioritises safety can be fostered. Involvement of key stakeholders, such as professional and patient associations, is a driver of patient safety culture. It is therefore crucial to raise public awareness, involve a wide range of interest parties and gain the support from professional associations that are implementing safety at each level of governance.

Safety governance is shifting towards trust, openness and learning from success

11. Cultures embodied with levels of trust, openness and learning are crucial for patient safety improvement. Yet, governance is ineffective if it fails to promote compliance. Finding the right balance between the two is the core compromise in safety governance.

12. Two-thirds of responding countries use financial incentives and penalties in safety governance, which makes pay-for-performance the least commonly implemented governance function. The less prominent role of financial incentives may reflect the negative effects penalties have on safety culture. Experience and evidence shows that the application of financial penalties can be counter-productive and inhibits openness and reporting of safety incidents.

13. Safety governance models are also moving away from punishment and shaming towards increased trust and openness. Trusting health professionals' ability and skills to provide safe care as well as report and learn from safety incidents when they occur is fundamental in safety culture. This new approach has paved the way for the development of several national safety strategies, where participation and involvement of key stakeholders has been essential, e.g. Norway, England and Ireland.

14. Learning from success as well as failures represents a paradigm shift in safety governance. The traditional approach in patient safety has focused on identifying the causes of harm. In complex adaptive systems like health, this approach is not sufficient. Building resilient health care systems is crucial, as is understanding system dynamics and interactions. A new approach, where learning from success is becoming equally important in enhancing patient safety, is increasingly being adopted.

15. Legislative barriers to sharing information still persist in some health systems, where data privacy regulations prevent effective reporting of data on safety processes and outcomes. Adequate data infrastructure is required to ensure the continuous measurement and monitoring of safety indicators feeding into a positive loop of learning and improvement. The systems' ability to also capture near-misses and situations where adverse events can be avoided, can create a robust basis for learning.

Résumé

Encadré 2. Messages clés

1. Il n'existe pas de modèle idéal de gouvernance de la sécurité des patients. Il est plus important que la gouvernance de la sécurité des patients (a) complète la gouvernance et le financement du système de santé dans son ensemble, et (b) aligne ses différentes composantes et fonctions.
2. La gouvernance de la sécurité des patients devrait s'étendre à tous les établissements de soins de santé.
3. La gouvernance de la sécurité devrait favoriser l'apprentissage continu, tant des dommages que des succès. L'accent devrait être mis sur l'évaluation et la gestion des risques plutôt que sur la réaction aux dommages.
4. La base de la gouvernance de la sécurité doit être ce qui est le mieux pour le patient, dont la perspective doit être incluse dans la conception, la mise en œuvre et l'exécution des modèles de gouvernance.
5. La gouvernance doit favoriser une culture d'ouverture et de confiance parmi les professionnels de la santé et les autorités réglementaires.
6. La gouvernance de la sécurité devrait s'aligner sur les autres domaines politiques et les influencer, notamment sur les politiques de sécurité et de protection des données privées et la préparation de la main-d'œuvre.
7. La gouvernance de la sécurité devrait encourager le financement des soins de santé et les investissements qui permettent un meilleur équilibre entre les coûts liés à la correction des erreurs (coûts de défaillance) et les coûts liés à la prévention des erreurs (coûts de prévention). De même, les systèmes de paiement devraient récompenser la bonne sécurité des patients et sanctionner la mauvaise sécurité des patients.
8. Les dirigeants politiques devraient inscrire la sécurité des patients parmi les principales priorités de leur programme de politique de santé.

16. La sécurité des patients est une question politique essentielle. Les défaillances en matière de sécurité peuvent entraîner des préjudices qui affectent profondément les patients, leur famille et les personnes qui les soignent. Elles pèsent aussi lourdement sur les épaules des professionnels et des responsables des soins de santé et exercent une pression inutile sur les budgets de santé. Les précédents rapports de l'OCDE sur l'économie de la sécurité des patients soulignaient que les défaillances en matière de sécurité sont en grande partie des défaillances du système. Les stratégies visant à améliorer et à renforcer la sécurité des patients doivent donc adopter une approche systémique et s'aligner sur d'autres

mesures politiques. Cela s'applique également à la gouvernance de la sécurité dans les systèmes de santé.

17. La gouvernance de la sécurité fait référence aux approches adoptées pour minimiser le risque de préjudice pour le patient dans une entité ou un système. Elle comprend généralement des fonctions de pilotage et d'élaboration de règles telles que des politiques, des règlements et des normes. Jusqu'à présent, la gouvernance s'est concentrée sur le niveau clinique et le cadre hospitalier, avec une surveillance et un contrôle limités de la sécurité dans d'autres parties du système de santé. La nécessité d'une approche de la gouvernance de la sécurité à l'échelle du système entier est de plus en plus reconnue.

La législation est la pierre angulaire des modèles de gouvernance de la sécurité, mais la participation des parties prenantes peut être renforcée

18. La gouvernance de la sécurité est appliquée par un ensemble de fonctions qui sont mises en œuvre à différents niveaux de soins et dans des parties spécifiques du système de santé. Ces fonctions comprennent : la définition des rôles et des responsabilités ; la mise en place de systèmes de mesure et de suivi de la sécurité ; la définition des principales responsabilités ; le renforcement des capacités du personnel ; l'application d'outils et de stratégies appropriés ; et l'implication des principales parties prenantes dans la gouvernance et les pratiques de sécurité. Ces acteurs clés comprennent les dirigeants politiques, les conseils d'administration des organismes de soins de santé, les professionnels de la santé, les gestionnaires, les administrateurs et, surtout, les citoyens et les patients.

19. Les 25 pays qui ont répondu à une enquête de l'OCDE sur la gouvernance de la sécurité des patients en 2019 ont tous adopté une législation visant à promouvoir la sécurité des patients. Ces pratiques comprennent l'accréditation externe et les inspections des processus et des résultats en matière de sécurité.

20. Il est fait état d'une moindre importance accordée à l'implication des principales parties prenantes dans la gouvernance de la sécurité. Dans un quart des pays ayant répondu, les dirigeants politiques ne sont pas régulièrement informés sur la sécurité des patients dans leur système de santé. De plus, si la législation favorise la participation des patients aux processus décisionnels en matière de sécurité et de qualité, elle est rarement mise en œuvre à son plein potentiel dans l'élaboration de stratégies et de programmes de sécurité.

De solides modèles de gouvernance de la sécurité permettent un apprentissage continu

21. La complexité des soins de santé modernes est un facteur clé du préjudice causé aux patients. De solides modèles de gouvernance de la sécurité permettent d'aligner les fonctions exercées par les différents acteurs au sein d'un système de santé. Cela inclut une définition claire des rôles et des responsabilités, le contrôle de la sécurité et l'accréditation externe. Les données disponibles suggèrent une association entre les normes de sécurité nationales et les systèmes de mesure et de surveillance de la sécurité avec des indicateurs de performance. Cela constitue la base d'un retour d'information et d'un apprentissage continus, où le suivi de la sécurité et les indicateurs de performance servent de mesures correctives aux pratiques existantes.

Il n'y a pas de solution unique en matière de gouvernance de la sécurité

22. L'approche spécifique adoptée en matière de gouvernance de la sécurité s'inspire dans une large mesure du modèle plus large de gouvernance du système. Les systèmes de santé à vocation nationale, par exemple le Danemark, l'Angleterre et la Suède, ont mis en œuvre des modèles de gouvernance de la sécurité plus complets et plus globaux, par exemple en promulguant une législation au niveau national pour garantir que la sécurité est mise en œuvre et alignée sur d'autres fonctions. Dans les systèmes de santé caractérisés par une prise de décision plus décentralisée, comme en Autriche, en République tchèque et en Suisse, la gouvernance de la sécurité semble également plus fragmentée.

23. La force de la gouvernance de la sécurité ne semble toutefois pas dépendre du modèle de gouvernance du système. Dans les systèmes de santé décentralisés et fortement fragmentés, il est essentiel de mettre en place une surveillance stratégique et une compréhension commune de la priorité à donner à la sécurité pour réduire les préjudices subis par les patients dans l'ensemble du système. La surveillance stratégique peut être rendue possible par la création d'une agence de sécurité, par exemple l'Institut canadien pour la sécurité des patients (Canadian Patient Safety Institute) et le Comité mixte fédéral allemand (German Federal Joint Committee), ou par une stratégie de sécurité à l'échelle nationale, comme on le voit en Autriche.

Le leadership politique et la culture de la sécurité sont des éléments clés pour réduire les dommages

24. L'importance du leadership et de la culture dans la gouvernance de la sécurité ne peut être surestimée. Le leadership et la volonté politique de mettre la sécurité des patients à l'ordre du jour national ont permis d'améliorer la sécurité des patients dans toute l'OCDE. Si les efforts constants déployés au niveau des systèmes en matière de surveillance et de notification ont un effet direct sur la qualité des soins de santé, l'orientation politique des gouvernements centraux peut permettre un financement durable et les ressources nécessaires pour investir dans la sécurité. Des investissements ciblés qui équilibrent les coûts de prévention et les coûts de traitement des défaillances en matière de sécurité peuvent réduire les préjudices et améliorer d'autant plus l'efficacité du système.

25. La gouvernance de la sécurité des patients peut être maintenue si l'on peut favoriser une culture qui donne la priorité à la sécurité. La participation des principales parties prenantes, telles que les associations professionnelles et de patients, est un moteur de la culture de la sécurité des patients. Il est donc essentiel de sensibiliser le public, d'impliquer un large éventail de parties intéressées et d'obtenir le soutien des associations professionnelles qui mettent en œuvre la sécurité à chaque niveau de gouvernance.

La gouvernance de la sécurité évolue vers la confiance, l'ouverture et l'apprentissage de la réussite

26. Des cultures incarnées par des niveaux de confiance, d'ouverture et d'apprentissage sont essentielles pour améliorer la sécurité des patients. Or, la gouvernance est inefficace si elle ne favorise pas le respect des règles. Trouver le bon équilibre entre les deux est le compromis fondamental de la gouvernance de la sécurité.

27. Deux tiers des pays ayant répondu utilisent des incitations et des sanctions financières dans la gouvernance de la sécurité, ce qui fait du paiement à la performance la fonction de gouvernance la moins couramment mise en œuvre. Le rôle moins important des incitations financières peut refléter les effets négatifs des pénalités sur la culture de la sécurité. L'expérience et les faits montrent que l'application de

sanctions financières peut être contre-productive et entraver l'ouverture et la notification des incidents de sécurité.

28. Les modèles de gouvernance de la sécurité s'éloignent également de la punition et de la honte pour s'orienter vers une confiance et une ouverture accrues. La confiance dans la capacité et les compétences des professionnels de la santé à fournir des soins sûrs ainsi qu'à signaler les incidents de sécurité lorsqu'ils se produisent et à en tirer des enseignements est fondamentale dans la culture de la sécurité. Cette nouvelle approche a ouvert la voie à l'élaboration de plusieurs stratégies nationales de sécurité, dans lesquelles la participation et l'implication des principales parties prenantes ont été essentielles, comme par exemple en Norvège, en Angleterre et en Irlande.

29. Tirer les leçons des succès comme des échecs représente un changement de paradigme dans la gouvernance de la sécurité. L'approche traditionnelle en matière de sécurité des patients s'est concentrée sur l'identification des causes des préjudices. Dans des systèmes adaptatifs complexes comme la santé, cette approche n'est pas suffisante. Il est essentiel de mettre en place des systèmes de soins de santé résilients, ainsi que de comprendre la dynamique et les interactions des systèmes. Une nouvelle approche, dans laquelle les enseignements tirés des succès sont tout aussi importants pour améliorer la sécurité des patients, est de plus en plus souvent adoptée.

30. Des obstacles législatifs au partage des informations persistent dans certains systèmes de santé, où la réglementation relative à la confidentialité des données empêche la communication efficace des données sur les processus et les résultats en matière de sécurité. Une infrastructure de données adéquate est nécessaire pour assurer la mesure et le suivi continus des indicateurs de sécurité, qui alimentent une boucle positive d'apprentissage et d'amélioration. La capacité des systèmes à saisir également les quasi-accidents et les situations dans lesquelles les événements indésirables peuvent être évités, peut créer une base solide pour l'apprentissage.

1 Introduction

31. The publication of *To Err is Human* (Kohn, Corrigan and Donaldson, 1999[1]) two decades ago signalled a new era in patient safety. The vexing numbers of harmful events and the impact on patients' lives and health systems led to the development targeted safety improvement strategies. Some of these were highly effective and inspired by principles from safety strategies applied in other high reliability industries. In parts of the United States, for example, central line associated bloodstream infections have fallen by 80% since the publication of To Err Is Human (Bion et al., 2013[2]) (Pronovost et al., 2016[3]).

32. Further progress in addressing healthcare-associated infections and patient safety outside of hospitals have been variable. Inconsistent implementation and practice of patient safety improvement strategies result in high frequency of adverse events (Bates and Singh, 2018[4]). Up to 10% of hospital admissions in high income countries lead to patient harm, the majority of which is deemed preventable. However, two-thirds of the burden of patient harm is carried by low-and middle income countries (Slawomirski, Auraaen and Klazinga, 2017[5]). Enforcing systematic implementation of safety improvement strategies therefore remain a global policy challenge and priority.

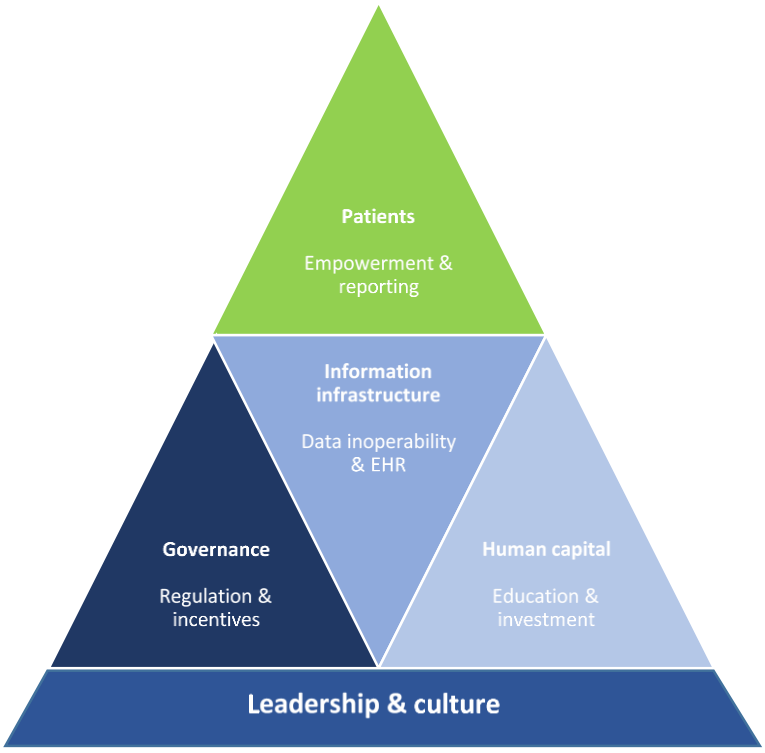
33. Patient safety is a central topic for academic research and debate, however, there has been a lack of arenas for academic researchers and patient safety experts to engage with political leaders and policy-makers. To fill this gap, the Global Ministerial Summits on Patient Safety has been organised on an annual basis since 2016. The OECD's background reports have been at the centre of the policy debates taking place at the Global Ministerial Summits.

34. Safety failures affect first and foremost patients, who are harmed from treatment that were intended to heal. Following a harmful event, the increased need for care can result in longer hospital stays, additional tests and procedures and re-admissions also consume considerable hospital resources. The 2017 OECD report on the Economics of Patient Safety quantified the economic burden that harm exerts on public hospital budgets to be up to 15%. (Slawomirski, Auraaen and Klazinga, 2017[5]). The report further made the economic case for investing in safety in order to prevent and reduce harm effectively and efficiently. Systematic implementation of system-level governance functions, such as safety standards linked to accreditation and professional education programmes, were identified as essential elements to improving safety.

35. In 2018, another OECD report explored the Economics of Patient Safety in Primary and Ambulatory Care. With more than 8 billion patient-provider encounters per year, primary and ambulatory care is the heart of healthcare provision. About half of the global burden of harm originates in primary care, however, the nature and consequences of harm is less severe than harm occurring in hospitals. The economic burden is estimated at 2,5 % of total health expenditure, but these numbers are expected to be underestimated due to the fragmented data infrastructure and reporting practices in primary care (Auraaen, Slawomirski and Klazinga, 2018[6]).

36. Both OECD reports emphasised the need for a system-wide approach to safety improvement, keeping safety at the centre of leadership, underpinned by an organisational culture conducive to safety. The 2018 report established four main elements of patient safety: investments into human capital, regulation, information infrastructure, and empowerment of patients underpinned by leadership and culture (Figure 1.1).

Figure 1.1. Taking a system approach to patient safety improvement



Source: (Auraaen, Slawomirski and Klazinga, 2018[6])

37. Previous Global Ministerial Summits' debates have emphasised the need for comprehensive governance approaches to ensure patient safety. Essential to safety improvement is to enhance the way safety is governed within health systems. Governance is key to achieving policy goals and affects directly the health system's capacity to overcome challenges. Good health policy is restructuring governance to skew health systems towards objectives like quality and safety (Greer et al., 2016[7]).

38. Patient safety *governance* deserves more attention from policy-makers to ensure safety initiatives have impact and are continuously evolving. Governance implemented by leadership can greatly contribute to the establishment of patient safety culture that is increasingly recognised as one of the most essential elements for ensuring patient safety. When it comes to the system-level safety governance, there is a notable gap in the literature which this report aims to fill.

39. In this report, patient safety governance refers to a wide range of steering and rule-making functions carried out by governments and decisions makers as they seek to achieve national health policy objectives (World Health Organization, 2019[8]). While system level governance is often narrowly associated with regulation and the resulting administrative burden or external oversight (Oikonomou et al., 2019[9]), this report takes a broad definition of governance by including functions like embedding safety in national or regional legislation, incorporating safety in educational and professional development, or enforcing continuous monitoring and reporting on patient safety (Box 1.1. Key concepts and definitions).

Box 1.1. Key concepts and definitions

Patient safety is the reduction of risk of unnecessary harm associated with health care to an acceptable minimum. An acceptable minimum refers to the collective notions of current knowledge, resources available and the context in which care was delivered and weighed against the risk of non-treatment or alternative treatment (World Health Organization, 2019[10]).

Patient harm is any unintended and unnecessary harm resulting from, or contributed to, by health care. This includes the absence of indicated medical treatment. Patient harm can be caused by specific incidents during care i.e. adverse events (i.e. medication errors, incorrect or delayed diagnosis, healthcare-associated infections) or cascade of events, which are individually innocuous but collectively result in harm (i.e. miscommunication, delays, errors or omissions).

Patient safety governance, in this report, refers to a wide range of steering and rule-making related functions carried out by governments and decisions makers as they seek to achieve the objective of patient safety (World Health Organization, 2019[8]).

Patient safety governance functions are defined as specific interventions, programmes or initiatives that are implemented to ensure safe care to patients, for instance, national safety standards, strategies to influence patient safety culture, external accreditation, or ongoing training as part of professional development. Patient safety governance functions are implemented to clearly define roles and responsibilities within the health systems, establish systems for measurement and monitoring, ensure key accountabilities, build capacity and skills of health workforce, involve stakeholders in formal decision-making processes.

System (macro)-level patient safety strategies are programs and initiatives that are best approached and implemented across the entire system. Implementation would typically require legislative or high-level policy levers, and often benefit from broad (societal level) public engagement. Examples include financing, pay for performance initiatives, or no-fault compensation schemes.

Organisational and institutional (meso)-level patient safety strategies are initiatives or practices that – while often aimed at particular clinical area or patient type – should be implemented across an entire health care organization or institution. Examples include clinical incident reporting, management systems, or hand hygiene initiatives.

Clinical (micro)-level patient safety strategies are practices that may span to organisations but are optimally initiated at practice level and managed within the clinical microsystem. This includes involvement of patients and their surrogates and administrative staff working with practitioners and patients. Examples of micro level strategies include catheter insertion bundles or surgical safety checklists.

40. Patient safety is the outcome of a comprehensive and strategic system-approach. Good safety governance consists of core elements that involves leadership, enables system learning and nurtures safety culture (Frankel et al. (2017[11]). Leadership across all levels of the health system contributes to the definition of values, expectations and capacities within the system to deliver safe care of high quality.

41. A learning health system is enabled by the development of systems for monitoring and reporting on safety processes and requires policy and institutional levers to be implemented in parallel (OECD, 2019[12]).Patient safety culture of trust and openness must be established in order for knowledge to be shared and accumulated in a blame-free environment that encourages collaboration and learning while welcoming the involvement of patients. (Braithwaite and Travaglia, 2008[13]; O'Connor and Paton, 2008[14];

Bates and Singh, 2018[4]).Governance can encourage the internalisation of new norms and values, thus, providing a motivation to engage in safe behaviour (Weaver et al., 2013[15]).

42. Governance can be structured according to at three levels: the clinical, organisational/institutional, and system level. Clinical level strategies are practices that may span organisations, but are optimally initiated and managed at the clinical level, e.g. catheter insertion bundles, surgical safety lists. On the organisational level, strategies or initiatives are often aimed at a particular clinical area or patient type but implemented across a health care organisation or institution e.g. clinical incident reporting, management systems. System level governance includes national or regional efforts to enhance patient safety, e.g. mandatory reporting of adverse events, safety standards linked to accreditation, national agency responsible for patient safety (Slawomirski, Auraaen and Klazinga, 2017[5]).

43. The body of research on safety improvements at the clinical and organisational level is rich and based on risk management theory, complex adaptive system theory as well as the emerging literature on resilience engineering. The literature is less comprehensive when it comes to the system level safety governance (Freeman et al., 2015[16])

44. This report aims to fill the gap in the literature by offering a system-level perspective on safety governance in the OECD:

- Chapter 2 introduces a framework for patient safety governance, building on existing knowledge on complex adaptive system theory, resilience engineering, safety management, and health system governance in order to apply existing theories on patient safety governance.
- Chapter 3 explores governance structures in other high reliability industries and their approach to risk management and responses to catastrophic events. The chapter further builds on experiences from other industries and draws parallels to health and finds that there are still things to be learnt from risk management and safety governance elsewhere, but healthcare is a very broad set of endeavours and has many unique features.
- Chapter 4 presents key findings from the 2019 OECD Survey in Patient Safety Governance. Adopting a whole-system approach, the chapter describes the functions that are implemented across OECD health systems, to what extent governance functions are aligned into safety governance models. This chapter further shares country experiences in developing and establishing safety governance models and brings perspectives and experiences from health systems outside of the OECD.
- Chapter 5 develops the conclusions of the paper. What can be done to improve safety governance in OECD countries?

2 Safety governance in health

Tailoring safety governance to health systems

45. Effective governance is context-sensitive and flexible (Healy, 2013[17]), there is no "one size that fits all''. In order to ensure compliance and legitimacy, governance has to be tailored to the strengths and characteristics of a specific system (Saltman, 2009[18]). Although patient safety in health care has drawn insights from other industries, governance strategies are not easily interchangeable. In low-complexity situations, interventions based on compliance and control of variability through activities like standardisation, are effective. Health care, however, is characterised by complexity, interdependency, and local context. Most importantly, the aim of health care is not to minimise cost but to maximise value – a fundamental difference compared to manufacturing industries (Rouse, 2007[19]).

46. Complexity and complex systems are described as those where "a dynamic and constantly emerging set of processes and object that not only interact with each other, but become defined by those interactions" (Cohn et al., 2012[20]; Greenhalgh and Papoutsi, 2018[21]). The high number of stakeholders, complex organisational structures, and adaptive capacity of the health care system have led it to be conceptualised as a complex adaptive system (Figure 2.1) (Plsek and Greenhalgh, 2001[22]; Begun, Zimmerman and Dooley, 2003[23]; Rouse, 2007[19]; Sturmberg, O'Halloran and Martin, 2012[24]; Braithwaite et al., 2016[25]). In practice it means that the health system's performance and behaviour change over time and cannot be understood by simply knowing about individual components (Braithwaite, 2018[26]). There are numerous *interdependent parts* e.g. patients, clinicians, patient associations, payers, and service providers that are connected through *feedback* loops, despite having *competing interests* (Begun, Zimmerman and Dooley, 2003[23]) (Braithwaite and Travaglia, 2008[13]) (Braithwaite et al., 2018[27]). For instance, patients' interest in involvement and high quality of care can be challenged by the drive for effectiveness and cost efficiency of payers and service providers.

Box 2.1. Complex adaptive system theory

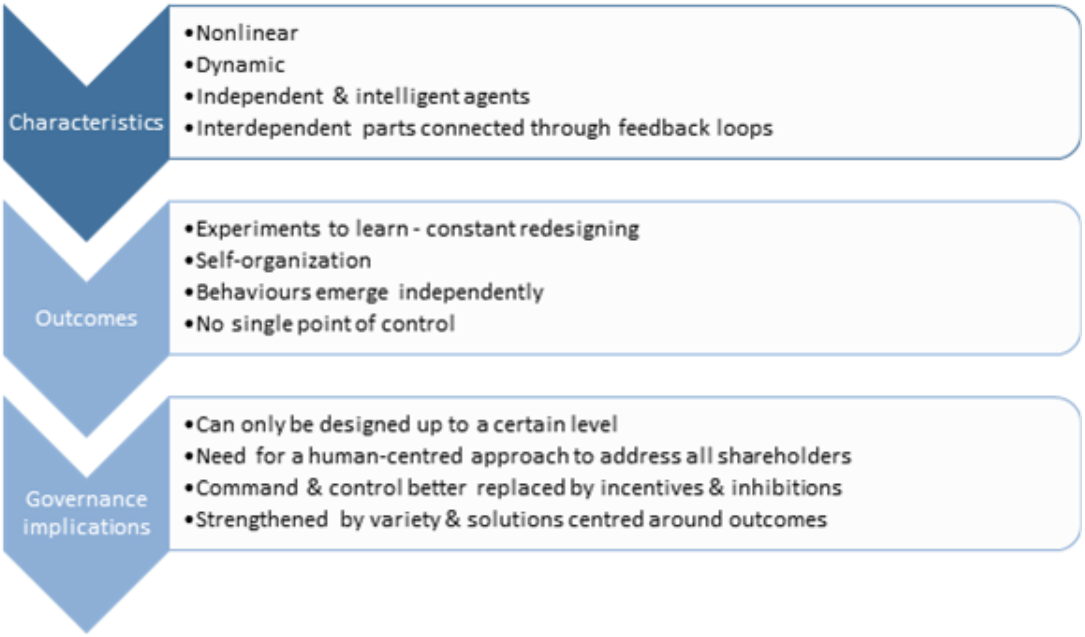
Complex adaptive theory is based on the notion that some systems are not deterministic and easily predictable but process-dependent (Holland, 1995[28]). Complex adaptive systems (CAS) e.g. the immune system, financial markets, or family, are composed of numerous parties. While free to act and do so in an unpredictable manner, often with competing interest, the agents are mutually dependent on each other (Plsek and Greenhalgh, 2001[22]).

Whereas traditional systems can be decomposed and recomposed by authority and resources, CAS tend to rely on self-organisation and nonlinear structure. The agents are intelligent and base their behaviours on physical, psychological, or social rules, rather than the demands arising from system dynamics or formal rules (Rouse, 2007[19]). Complex adaptive systems keep changing to adjust to their surroundings based on feedback loops and learning. There is no optimal equilibrium, resilience is built by constant evolving (Holland, 1992[29]) (Hollnagel, Braithwaite and Wears, 2013[30]; Wears, Hollnagel and Braithwaite, 2015[31]; Braithwaite, Wears and Hollnagel, 2016[32]).

47. The complexity of interactions in health care has rapidly increased over the last decades. Treatment is not a linear model of diagnosis and medication and health care delivery often involves multidisciplinary teams (Plsek and Greenhalgh, 2001[22]). The relations between the actors are structured based on *vertical divides* e.g. between nurses and physicians as well as *horizontal divides* e.g. between clinical wards. Active communication across boundaries is a requirement for high-quality care (Braithwaite et al., 2016[25]).

48. In complex adaptive systems like health care, leadership often does not stem from formal structures and the system can only be designed up to a certain level. Agents involved in health care are *intelligent*. They experiment, gain experience and learn to change their behaviours. There is *no single point of control,* behaviours emerge independently e.g. due to incidents (Rouse, 2007[19]) and can rather be influenced than controlled (Schneider and Somers, 2006[33]). Complex adaptive systems are therefore often grounded in self-organisation as much as by managerial control.

Figure 2.1. Characteristics of complex adaptive systems



Source: Adapted from (Begun, Zimmerman and Dooley, 2003[23]; Rouse, 2007[19]; Schneider and Somers, 2006[33])

Safety as a trigger to redesign self-regulation

49. There is a longstanding tradition of self-regulation in health care, which has to be considered when designing governance models. Self-regulation is strongly enforced through the role of professionals in health care. Modern medicine relies heavily on specialised professionals and technologies combined with self-regulation through mechanisms such as professional standards, peer-review and evidence based guidelines. It is the general norm (Freidson, 1988[34]). However this is changing.

50. Up until the end of the 20th century, healthcare was mostly self-regulatory (Yeung and Dixon-Woods, 2010[35]). Medicine was considered too complex to be organised by non-practitioners and a "social contract'' between the medical profession and the public was established. The public granted physicians the privilege of self-regulation in exchange for their commitment to altruistic service based on professional competence and ethicality (Cruess and Cruess, 2005[36]). Healthcare professionals were required to put the patient first and base their work on moral values and high standards of practice. In exchange, professional associations set standards for education, training, and the entry into practice (Irvine, 2011[37]).

51. Since the end of the 20th century, concerns about the inconsistencies and weaknesses of enforcing professional standards have come to the fore (Aldridge, 2008[38]). Patients are increasingly sceptical of medical expertise and there are more possibilities for conflicts of interest to arise within the health sector. The public expects more transparency (Collier, 2012[39]) and governments are getting more involved in health care (Oikonomou et al., 2019[9]).

52. Although the medical community has to be more transparent to win the trust of the public, self-regulation is still often considered as the most appropriate form of organisation in health care (Cruess and Cruess, 2005[36]). Professional self-regulation provides recognition and legitimisation that offers doctors the freedom and motivation to perform well. It decreases the financial burden on the government and the administrative burden on health care providers (Aldridge, 2008[38]).

53. The literature on professionalism has also emphasised the need for a balance between regulation and autonomy to ensure accountability (Bunker, 1994[40]). Freidson (1990[41]) has argued that the flexibility

needed to offer patient centred care is threatened by government regulation on the one side and market competition on the other. Guidelines, medical audits, and standards limit the autonomy of each medical professional, but are better influenced by colleagues under self-regulation than managers or regulators (Freidson, 1988[34]).

54. Research implies that health care professionals trust their own judgment and that of other professionals. Regulation designed by ''experts elsewhere'' faces a challenge of not being recognised (Piper, Slawomirski and Iedema, 2015[42]). It follows that safety governance in health care should consider the health care system as a complex adaptive system with high levels of professional self-regulation and base the governance interventions on this notion. Complex adaptive systems can only be designed up to a certain level in healthcare, the system learns, adapts, and self-organises, constantly redesigning itself.

55. In many situations standardisation and control is not the right response in health care. Rather, ways to enhance learning, transparency, and accountability based on self-regulation should be seen as a central tenet, likewise, command and control can be replaced by incentives and influences (Rouse, 2007[19]). As complex systems are strengthened by variety (The Health Foundation, 2010[43]), solutions should focus on outcomes for enabling the health care staff to adjust their work to the changing conditions (Johnson, Clay-Williams and Lane, 2018[44]).

From voluntarism towards meta-regulation on patient safety

56. Depending on the historical and political context, several approaches of governance can be applied to maximise effectiveness. Healy and Braithwaite (2006[45]) introduced the concept of responsive regulation. While emphasising the importance of scaling the regulation up or down according to compliance, the authors differentiate five approaches to governance based on the extent of centralisation.

57. Healy and Braithwaite (2006[45]) distinguish voluntarism, market mechanisms, self-regulation, meta-regulation, and command and control. Voluntarism is the least invasive mechanism, trusting on the individual or organisation to "do the right thing'' for upholding patient safety. Market mechanisms refer to incentives offered to providers and health care staff, self-regulation relies on professional enforcement. Meta-regulation is external control over internal safety practices, while command and control implies traditional top-down approaches e.g. licence revocation.

58. There is a body of literature (Braithwaite, Healy and Dwan, 2005[46]; Healy, 2013[17]) that advocates for the use of meta-regulation in patient safety i.e. national oversight on self-monitoring. For instance, having a system-level requirement for an infection control plan, but leaving the implementation at the discretion of the providers (Braithwaite, Healy and Dwan, 2005[46]). Meta-regulation aims to maximise creativity and professional autonomy while guaranteeing minimum safety standards and accountability, therefore, profiting from high-level professional knowledge.

59. Drawing on the meta-regulation idea, nursing homes in the United States were required to determine the gravest quality concerns in their organisation. After the assessment, the providers were obliged to address one issue each year with minor intervention in the process of implementation (Braithwaite, Healy and Dwan, 2005[46]).

Moving towards a system approach and proactive safety governance

60. Although there are specific characteristics to the health care sector, managing risks and safety is not a challenge unique to health care, therefore, practices from other industries have been applied to patient safety. In other industries, the focus of safety management has gone through multiple iterations – from an emphasis on technological problems, to human factors, to study of organisational and safety culture. Health care has been slower to follow those paradigmatic changes. Effective patient safety governance embeds the principles of safety management with the context of health care as described above.

61. A person approach and a system approach to human error have been differentiated in the literature on safety management (Reason, 1995[47]; Reason, 2000[48]). The person approach tends to be error-focused and relies on the assumption that errors happen due to individual actions, thoughts and belifs. The system approach, in contrast, depicts errors as expected since humans are fallible. It follows that systems have to be designed in a way to involve safeguards for preventing errors on all levels of health care.

62. As has been emphasised by the previous work of the OECD, it is widely acknowledged that a system approach has to be taken to enhance patient safety (Reason, 1995[47]; Reason, Carthey and De Leval, 2001[49]; Taylor et al., 2018[50]; Hollnagel, 2015[51]). Deficiencies built into systems (e.g. under staffing, time pressure, inexperience) can either provoke conditions for error or create long-lasting weaknesses in the defence mechanisms, such as untrustworthy alarms or unworkable procedures. Deficiencies may persist as long as there is no active failure as a catalyst (Reason, 2000[48]), they are, nevertheless, existent.

63. As a new strand of literature, resilience engineering has come to the foreground and research on resilience in health care has gained in relevance in the last decade (Ellis et al., 2019[52]; Hollnagel, Braithwaite and Wears, 2013[30]; Wears, Hollnagel and Braithwaite, 2015[31]; Braithwaite, Wears and Hollnagel, 2016[32]). Resilience as a term has also become central in the EU agenda on the performance of health care systems. In this context the term is used quite broadly to refer to the capacity of health care systems to respond to changing environments and challenges with limited resources (European Commission, 2014[53]). In resilience engineering, similarly, resilience is the ability of the health care system to succeed despite changing conditions (Øyri and Wiig, 2019[54]). Resilience engineering posits that variability is not merely inescapable, but also valuable and should therefore not be rooted out but proactively managed (Righi, Saurin and Wachs, 2015[55]).

64. Costella et al. (2009[56]) have defined four principles of resilience engineering: top management commitment, flexibility, learning from incidents and normal work, and awareness on system status. Literature on resilience engineering mostly concentrates on everyday clinical work and frontline staff. So far, studies on the meso and macro level are limited and primary care remains understudied (Berg et al., 2018[57]).

65. Drawing from resilience engineering, the Safety-II approach has been developed. According to the traditional, Safety-I approach, errors occur because of concrete failures or malfunctions, e.g. technology, procedures, or human workers. Safety management, in this context, is reactive and aims to eliminate sources of incidents and enhance protection against risks. This approach is limited to specific areas, especially the clinical setting (Braithwaite, Wears and Hollnagel, 2015[58]).

66. Safety-II, the alternative view, argues that variability of everyday performance provides the flexibility to excel under diverse conditions. Humans – the most flexible system components – are key to elasticity and resilience in systems. Humans deliver positive outcomes in spite of uncertainties and prevent safety lapses more often than they cause them. Therefore, it is more valuable to study how, despite inconsistencies and ambiguities, systems primarily produce the right care and good outcomes (Hollnagel, 2015[51]).

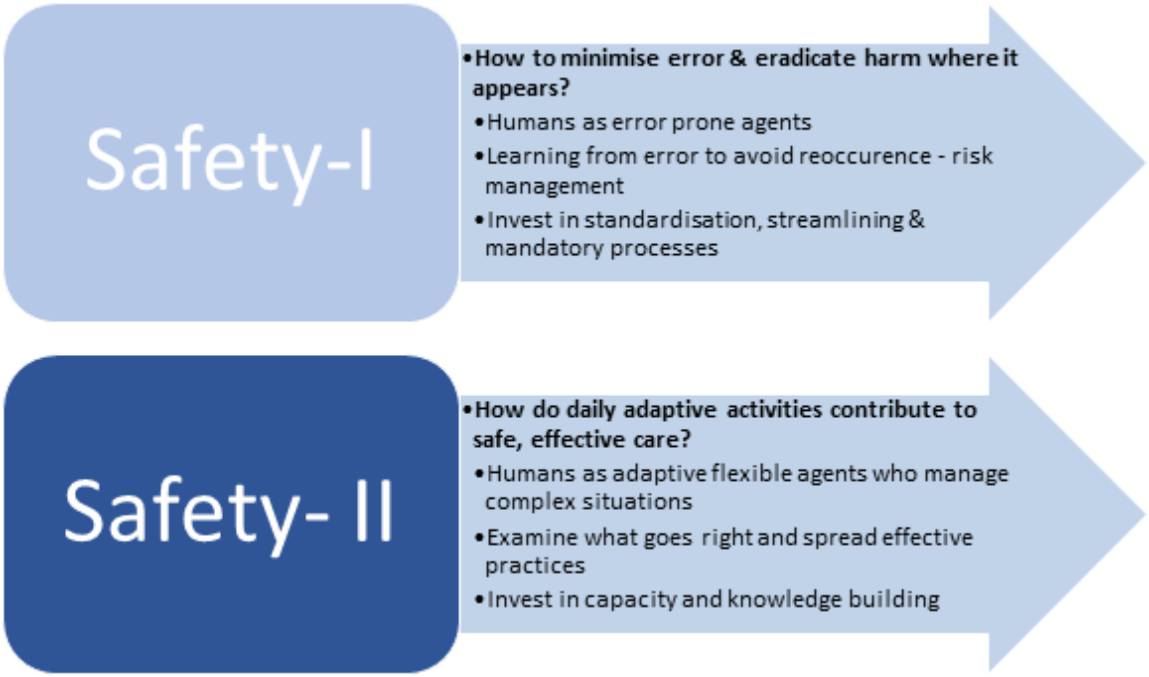
67. Safety-II is a shift away from the ‘’find and fix’’ model of *Safety-I* and embeds safety in the everyday functioning of organisations (Braithwaite, Wears and Hollnagel, 2015[58]). Applying Safety-II refers to continuously monitoring and evaluating systems, not only to find causes *ex-post,* but analysing the strengths and weaknesses of systems *ex-ante* (Figure 2.2).

68. In patient safety, proactive safety management under Safety-II provides more information than merely relying on Safety-I. For instance, 75% of the patient safety incidents reported to the National Reporting and Learning System (NRLS) in England did not cause harm to the patient (NHS Improvement,

2019[59]). Yet, near-misses are not usually widely reported and learning opportunities are not used to the fullest. (Braithwaite, Healy and Dwan, 2005[46]).

69. Reactive and proactive safety management are complimentary and should be both embedded into patient safety governance models. Safety-I strives to avoid the reoccurrence of errors while Safety-II facilitates spreading effective practices and investing in capacity building amongst all involved stakeholders, including patients. The idea of safety governance based on the complementary use of the two approaches is thus gaining traction (Hollnagel, 2015[51]; Braithwaite, Wears and Hollnagel, 2015[58]).

Figure 2.2. Complementary use of Safety-I and Safety-II



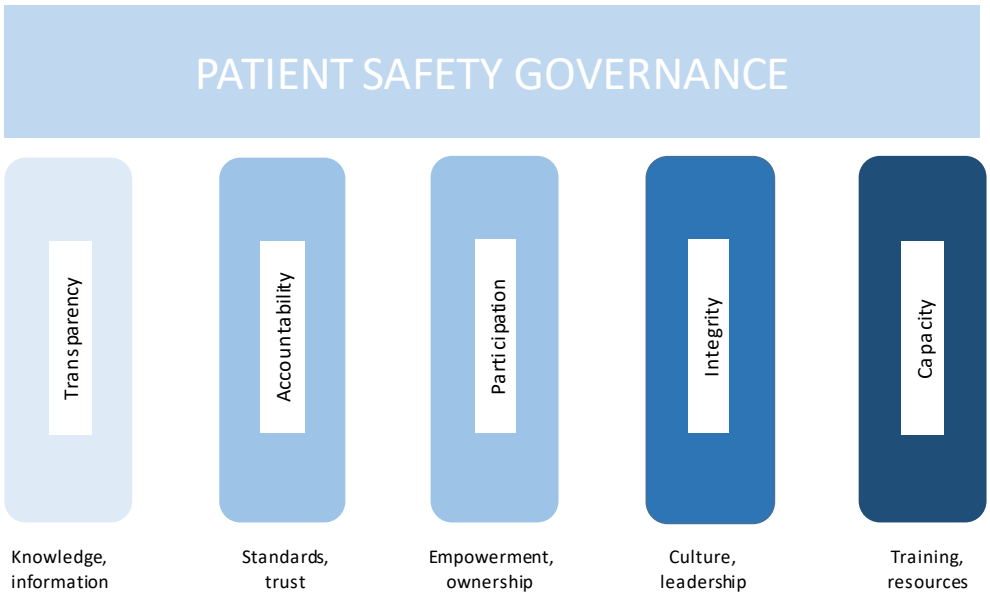
Source: (Slawomirski, Auraaen and Klazinga, 2017[5])

Establishing patient safety through health systems based on learning, inclusion, and accountability

70. While it has been argued that health care is a deeply interconnected system that cannot be divided into independent particles, there have been several approaches to conceptualise health system governance. One of the latest has been the TAPIC framework developed by Greer et al. (2016[7]). Based on the literature on health policy and public administration, the TAPIC framework defines five mutually exclusive pillars of health care governance; *transparency*, *accountability*, *participation*, *integrity*, and *capacity*. There are numerous governance functions, which can be used to steer the health care system, associated with each of the pillars

71. Elaborating the TAPIC framework and applying it to patient safety produces five pillars of governance (1) encouraging transparency and information sharing, (2) ensuring accountability, (3) promoting participation, (4) upholding integrity through effective leadership facilitating a culture of safety, and (5) building capacity. There are abundant – and non-exclusive – ways to embed these objectives into health care systems (Figure 2.3).

Figure 2.3. Patient safety governance adapted to the TAPIC framework



Source: Adapted from (Greer et al., 2016[7])

Accumulating knowledge through increased transparency

72. In the TAPIC framework, *transparency* refers to patient safety measurement, access to data and decisions, enhanced by watchdog committees, inspectorates, regular reporting, legislation, or performance assessment. It seeks to understand institutions, identify malfeasance and incompetence, and adapt (Greer et al., 2016[7]). In patient safety, the main venues of transparency are public reporting of safety indicators, incident reporting to induce collective learning and information sharing to avoid safety lapses stemming from miscommunication.

73. Transparency is crucial to identify the strengths and weaknesses of health care systems. While culture of silence has historically prevailed in medicine (Freidson, 1983[60]), safe health care is based on a learning system where information from the front lines of care creates evidence for improvement (Bates and Singh, 2018[4]). Transparency can be enhanced by governance functions like incidence reporting, external reviews, performance reports based on national indicators, or clinical expert groups and openness towards patients.

74. Open disclosure increases trust in health care. Reports from England and the United States discovered that out of patients experiencing adverse effects, 24% to 40% were informed about it (Quick, 2011[61]). Yet, doctors who disclose medical mishaps are less likely to be sued (Braithwaite, Healy and Dwan, 2005[46]; Boothman et al., 2010[62]) and patients suffering from adverse effects are prone to evaluate the quality of care higher if the incidents are disclosed (Quick, 2011[61]).

75. Effective reporting systems are user-friendly and embed feedback mechanisms (Runciman et al., 2006[63]). Staff have to be aware of the importance and purpose of reporting and reporting options ought to be multiple, short, and continuously available. Structural feedback can be provided by presenting descriptive statistics, findings of incident root-cause analyses and improvement actions (Hesselink et al., 2016[64]). Collective learning does not take place without analysing the data (Braithwaite, Healy and Dwan, 2005[46]). Including feedback mechanisms into reporting systems has the added potential to increase reporting since physicians are more likely to report on adverse effects if they are believe it would have positive implications elsewhere (Mello et al., 2006[65])

Box 2.2. Embedding learning into monitoring systems

Administrative compensation systems

Positive examples of feedback mechanisms can be found in the administrative compensation systems, sometimes referred to as 'no fault' compensation schemes. Administrative compensation systems encourage open disclosure of harm and strive to ensure justice and provide financial support in case of medical injuries. Such systems benefit patients and communities and can contribute towards cultural transformation, removal of barriers to reporting harm and can facilitate open discussions with patients. They also encompass the function of pooling information to generate new knowledge for preventing adverse events. The result is better and more complete data collection, encouraging good clinical practice and reducing defensive medicine. The databases are widely used to identify safety problems and publicly share knowledge and experiences on safe care practices.

Administrative compensation systems are implemented in many countries, including Japan (for cerebral palsy for children born since 2009), Finland and France. In New Zealand, the administrative compensation system was established in 1972. The database of incident claims is used for conducting a systematic analysis, which involves priority-based labelling to provide the government with solutions to reoccurring problems. The Danish Patient Insurance Association also has a comprehensive database, mainly used by collaborating researchers. In Sweden, descriptive analyses of the claims to administrative health courts are conducted and shared with health care providers, while the Norwegian System of Patient Injury Compensation is obliged by law to provide data on patient safety incidents to inform quality and safety improvement strategies.

Multidisciplinary expert groups

Another way of improving performance through transparency and learning is setting up expert groups. A study in Australia showed positive outcomes arising from the establishment of a multidisciplinary reference group conducting routine reviews of the management of all cases of invasive meningococcal disease. The group composed of representatives from primary care, acute care, public health, laboratory medicine and clinical governance produced significant results. Median antibiotic delay decreased from 72 minutes to 42 minutes and cases triaged appropriately increased from 38% to 75%. Participants reported high level of enthusiasm and found the audit meetings highly valuable. Meetings were thought to have increased collaboration, networking, and learning opportunities.

Source: (Mello et al., 2006[65]), (Kachalia et al., 2016[66]), (Taylor et al., 2018[67]) (OECD, 2018[68])

76. Transparency is not only about accumulating knowledge on incidents and near incidents, it also refers to sharing data and patient information to prevent safety lapses happening due to poor communication. For instance, by encouraging the use of information technology and Electronic Health Records (EHR). According to recent data, 20% of older adults in the United Kingdom, 23% in Sweden, and 43% in Norway reported that a specialist lacked their medical history or that their regular doctor was not informed about the care delivered to the patient by specialists (OECD, 2017[69]).

77. Improving interoperability of data systems between service providers is especially important for patients with a long or complex medical history. Although integrated electronic health systems allowing for interoperability across data platforms was considered the most cost-efficient intervention by survey respondents in a previous OECD report on patient safety (Auraaen, Slawomirski and Klazinga, 2018[6]), in most OECD countries, data is still provider-centric and not portable across organisations (OECD, 2017[69]).

78. Despite its promises, transparency can be difficult to implement. The evidence that public performance reports improve patient safety is limited (Braithwaite et al., 2017[70]). It is challenging to find

relevant indicators to measure patient safety in a way that is valid and at the same time, easily comprehensible to the public. However, one way could be to limit the number reported and thus, "retire" the ones where most providers achieve near perfect results (Kachalia et al., 2016[66]).

79. Transparency is key to building a learning system based on trust and accumulation of knowledge. In addition to reporting and oversight, data-sharing is a potential way to enhance patient safety. Data aggregation is particularly useful to notice system errors that might be impossible to detect on a lower level due to the small number of incidents, yet, it brings with it the issue of sensitivity related to data security and proportionality (Huckvale et al., 2010[71]). Excessive bureaucratic requirements to increase transparency can have a perverse effect on healthcare professionals' capacity to provide safe care because they are caught up in administrative obligations (Bismark and Studdert, 2014[72]). Data-sharing has to follow the principle of proportionality to respect the right to privacy. On the macro level, decision-makers have to weigh the advantages and disadvantages and find the appropriate balance between the right to privacy and the right to safe health care delivery.

Establishing accountability is important to ensure public trust

80. *Accountability* in TAPIC refers to explanation and sanction. It is a relationship where actors have to inform and explain their actions to others and can be mandated and sanctioned (Greer et al., 2016[7]). In patient safety, accountability is a necessary compliment to governance functions emphasising learning and transparency. In the absence of accountability, adverse event reporting is not expected to yield considerable improvement. Accountability can help to uphold public trust in health care by establishing responsibilities, minimum standards, and compliance. Accountability can be clinical, professional, legal, financial, political or ethical, depending on how or by whom it is enforced (Saltman, 2009[18]).

81. Accountability can be promoted by safety governance functions, such as national safety standards, external accreditation, high-level progress reports as well as financial incentives, contracting arrangements, or choice mechanisms that enable users to ''vote with their feet'' when choosing health care providers. Patient safety can therefore be embedded into the general framework of quality management that uses similar methods (Busse et al., 2019[73]). The most stringent way to ensure accountability is through national regulations setting out responsibilities and sanctions. Legislation on quality and safety can also include wider topics, such as the market entry of pharmaceuticals or medical devices (OECD, 2017[69]).

82. A 'just culture' is an important concept in the discussion of accountability in safety. Firstly, 'just culture' considers wider systemic issues when investigating patient safety incidents, which enable healthcare professionals to learn from safety incidents without fear of retribution (NHS Improvement, 2018[74]). Secondly, emphasising accountability of healthcare-providing organisations is fundamental to ensure reporting of safety incidents. By further extending the reporting to also include 'near misses', facilitates continuous learning and improvement (OECD, 2018[68]).

83. Making patient safety reporting publicly available is expected to increase accountability. In the United States, 11 states mandated reporting of the National Quality Forum 27 'never events', with another 16 mandating reporting of sever adverse events. Healthcare-providing organisations are accountable for correcting systematic weaknesses and issues found to having contributed to the event. The reporting of adverse events is mandatory and patient safety data are published at the jurisdictional level, however, but without any sanctions. This practice sends a strong signal that reporting is an important part of learning and improvement, which is enabled by accountability and just culture (OECD, 2018[68]).

Box 2.3. Legislation of the European Union regarding patient safety

While patient safety is not subject to international law, the European Union has adopted several directives related to patient safety.

Directive 2002/98/EC sets out the quality and safety standards for the collection, testing, processing, storage and distribution of human blood and blood components. The directive establishes standards for blood and its components when used in transfusion e.g. Member States must ensure blood is collected by authorised establishments with quality systems in place.

Directive 2004/23/EC is setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells. The directive poses the obligation to have appropriate control measures for procurement of human cells, among others, the requirement to conduct inspections.

Directive 2010/53/EU concerns standards of quality and safety of human organs intended for transplantation. The directive covers organ donation, testing, characterisation, procurement, preservation, transport and transplantation setting out quality and safety standards.

Directive 2011/24/EU regarding the application of patients' rights in cross-border healthcare sets out that Member States have to ensure patients from other member countries receive -upon request- relevant information on safety and quality standards enforced in the country as well as which providers are subject to these standards.

The European Union also has a set of regulations on **pharmacovigilance and falsified medicinal products**, covering procedures for the authorisation and supervision of medicinal products (EUR-Lex, 2019[75]).

Evaluating the effect of legislation

A recent evaluation on EU legislation on blood, tissues and cells found that EU legislation has ''effectively helped increase safety and quality of blood, tissue and cell therapies''. There has been no secondary spread of disease through transfusion or transplantation since its adoption. Legally binding rules have been adopted in all Member States, whereas prior to the directive, the oversight functions were limited or absent. However, it has been challenging to keep the requirements up to date with the latest developments e.g. scientific and technological developments, availability of digital tools, or increased commercialisation and more frequent epidemiological outbreaks. Also, in some cases, national oversight is not robust or specific enough, especially concerning the independence of oversight and verification of effective implementation of oversight functions.

Source: (European Commission, 2019[76])

84. Depending on the health care system, safety requirements could be part of contracting and commissioning arrangements. For instance, in the United States, Medicare funding is conditional upon the board having an adequate oversight role in guaranteeing quality control, e.g. having indicators to measure outcomes (Brown, Dickinson and Kelaher, 2018[77]). Also pay-for-performance programmes are increasingly prevalent. There are ''no-pay"' rules for preventable complications during admission and payments linked to clinical outcomes. However, the financial implications on providers are rather small and the effect on patient safety has remained modest (Kachalia et al., 2016[66]).

85. Governance functions aiming to enhance accountability face the risk of emphasising deterrence, reactive *ex-post* safety management, or blame culture based on punishment. Heavy reliance on economic instruments can contribute to inequality of care. Patients are not entirely free to choose a provider, either due to the restrictions arising from insurance plans or because of the specificities of clinical circumstances

e.g. in case of emergency care (Kachalia et al., 2016[66]). Financial instruments can increase inequality of care as there are patient groups who are more flexible in moving between providers than others. Furthermore, financial penalties decrease the resources of poorly funded or already underperforming systems (Beaussier et al., 2016[78]).

Participation of key stakeholders paves the way for quality and safety improvement

86. *Participation* is a crucial element of governance referring to the inclusion of all affected actors in decision-making to maximise efficacy. It enables the gathering of information from different stakeholders, thereby facilitating the design of more effective policies and ensuring legitimacy and ownership needed for successful implementation (Greer et al., 2016[7]). This is especially important in the context of health care and its tradition of self-regulation. Participation can involve functions such as patient representation in official roles and decision-making processes, reviewing safety by boards of health care-providing organisations, system reports by an agency responsible for patient safety to government, or patient reported incident monitoring.

87. There are numerous stakeholders that should be part and parcel of the patient safety agenda to build trust and legitimacy i.e. health care professionals, patients, management and boards of healthcare-providing organisations, payers, health care industry. Collaboration occurs between organisations with different roles (i.e. regulatory, care delivery, insurance) and between different sectors of health care (i.e. primary care, hospital care, rehabilitation) (Chan et al., 2019[79]).

88. Participation of key stakeholders is essential to ensure successful implementation. Case studies have demonstrated the importance of including healthcare professionals in the introduction of surgical safety lists to avoid opposition, for example. By starting on a small scale, goodness of fit can be tested while simultaneously convincing the staff, thus, establishing sufficient support for scaling up (Hayes, 2012[80])

89. Patients' participation is fundamental for safe care. The World Health Organization (2013[81]) has recommended involving patients in safety through technical tools, patients' rights legislation and other empowerment policies, such as educational campaigns. There is increasing evidence that organisations that encourage the inclusion of patients are less prone to risks (Braithwaite et al., 2016[25]). For instance, studies have shown an increase in hand sanitation of staff after campaigns encouraging patients to ask their doctors and nurses whether they had cleaned their hands before direct contact (McGuckin et al., 2004[82]). While reporting different information than health care workers, patients provide useful information (Berg et al., 2018[57]). Moreover, they tend to report suspected adverse effects earlier than professionals, therefore, decreasing the delays in seeking treatment (Allen et al., 2016[83]).

90. Although OECD countries increasingly collect Patient-Reported Experience Measures (PREMs), Patient-Reported Outcome Measures (PROMs) and Patient-Reported Incident Measures (PRIMs) are less prominent. PROMs and PRIMs can be included as a part of patient satisfaction surveys. In England, for instance, a question whether doctors and nurses cleaned their hands between touching patients has been added to the inpatient survey (OECD, 2017[69]). The previous work of the OECD on patient safety has suggested that empowering patients to be an active participant in treatment situations could reduce safety lapses by up to 15% (Auraaen, Slawomirski and Klazinga, 2018[6]).

Building integrity through patient safety culture and committed leadership

91. Strong patient safety governance implies that roles and responsibilities are clearly defined in a culture based on trust and team work. The pillar of *integrity* is important at all levels of governance. Integrity is the concomitant of strong leadership and crucial in health care governance to ensure coherence of action (Greer et al., 2016[7]). Clarification of authority between the stakeholders is the prerequisite for efficient regulatory activity and further associated with better commitment of individuals in group settings (Øyri and

Wiig, 2019[54]) (Chan et al., 2019[79]). Governance functions associated with integrity include defining the roles and responsibilities of patient safety in national legislation, setting up national quality and safety agencies, and encouraging leadership, which promotes patient safety culture.

92. Leadership is the underlining component of all patient safety governance functions (Frankel et al., 2017[11]). The role of leadership in patient safety goes beyond defining role as responsibilities through legislation. Leadership has a crucial stake in promoting an organisational culture characterised by a spirit of collegiality, collaboration, openness, and respect that are inherent to patient safety culture (Sammer et al., 2010[84]). Poor communication and ineffective teamwork are the suspected root cause of most sentinel events (Hayes, 2012[80]) while teamwork is associated with better patient outcomes (Rafferty, Ball and Aiken, 2010[85]).

93. Leadership further has the power to facilitate a blame-free culture. A blame culture can be reinforced by extensive regulatory control or focus on deterrence through litigation or the revocation of licences. Consequently, information sharing and collective learning are undermined (Braithwaite, Healy and Dwan, 2005[46]). A blame-free culture, on the other hand, can be supported by emphasising collective learning and trust. Less blame is thought to increase incident reporting (Yang et al., 2009[86]) and facilitate lesson drawing (Sammer et al., 2010[84]; Braithwaite, Wears and Hollnagel, 2015[58]).

Supporting capacity building through training and professional development

94. *Capacity* building and resource allocation are key to supporting patient safety. Capacity building in health care governance refers to developing intelligence about existing capacities, while investing in developing new capacities (Greer et al., 2016[7]). In patient safety it can include embedding safety into curricula of students, integrating safety training as part of professional development for health care professionals, or allocating enough resources to ensure patient safety in daily clinical practice. Capacity building can also take a broader approach and include aspects such as the establish positive safety culture within the organisation and shifting the focus on safety training from technical skill-building towards emphasising teamwork, quality improvement and organisational change (Vincent and Staines, 2019[87]).Health care is a field characterised by rapid scientific advancements, where education and training is indispensable to the quality of care. Here, the macro level can be the most effective way to pool and emanate knowledge. Embedding safety curricula into educational programmes is a governance function that produces results in the long term, hence, continuous staff training is fundamental to keep medical staff up with the latest developments. This does not only concern front-line professionals, also capacity for leadership is important. Training board members on quality and including clinicians in boards has shown to have a positive effect on the governance and quality of health care (Baker, Denis and Pomey, 2010[88]; Brown, Dickinson and Kelaher, 2018[77]).

95. While developing skills is essential, they cannot be put into practice without resources. Practice analyses suggest that professionals often attempt to meet regulatory standards but fail to overcome systemic constraints e.g. lack of staff, or competing interests like delivering care to several patients at the same time (Piper, Slawomirski and Iedema, 2015[42]). Supply shortages and manual dispensing of drugs can likewise lead to adverse events (Reason, 2000[48]; Hollnagel, 2015[51]). A high work load and a stressful working environment contributes to staff burnout, which has been associated with higher likelihood of adverse events (Hall et al., 2016[89]) and decrease in the reporting of near misses (Halbesleben et al., 2008[90]).

96. Information technology can help to build capacities for maintaining and improving safety. There is an increasing number of opportunities to leverage health information technology to capture and prevent errors, patient identification errors, and poor data accessibility (Bates and Singh, 2018[4]). Computerised Decision Support Systems (CDSS) can assist doctors in decision-making. For instance, ePrescribing systems can flag potential medical errors by aggregating data, therefore, preventing adverse events (Huckvale et al., 2010[71]).

97. Capacity building activities are challenged by resource constraints but contributing to patient safety is to be seen as an investment to decrease expenses stemming from adverse events. While there is an inherent tension between capacity building and accountability, they should be seen as complimentary. Offering support to enhance patient safety should be prioritised over holding the health care system accountable by the use of punishments.

The TAPIC pillars form the basis of safety governance

98. To conclude, the TAPIC pillars *transparency, accountability, participation, integrity,* and *capacity*, which form the foundation of health care governance, also apply to patient safety. Transparency enables information and knowledge sharing to evoke learning, accountability builds trust and enhances compliance, participation contributes to legitimacy that is key for trust and efficacy, integrity supports good management and safety culture, and capacity building strengthens the resilience of health care systems.

99. The main pillars and functions of governance are deeply intertwined and each pose certain challenges in implementation. It is a governance decision to choose the most appropriate steering and rule-making functions. The optimal equilibrium greatly depends on how actors are expected to behave and what are the possibilities to motivate and incentivise them for engaging in safety enhancing behaviours. The choices are largely determined by the model of health care, the allocation of roles and authority between the actors, and other context-sensitive factors contributing to path-dependency.

100. Although the health care sector has particular characteristics, it is not the only high-reliability industry that considers safety and risk management in its day-to-day functioning. Safety improvement programmes in health has sometimes found inspiration in practices from other industries, such as aviation. Further important lessons could therefore be learned from designing a resilient health care systems and strengthening governance functions with safety at its core with recourse to other industries.

3 Can looking to other high reliability organisations help improve patient safety governance?

101. Health care is a complex adaptive system prone to high safety risks but it is not the only one. There has been an increasing trend to compare health to other industries, which have a longer tradition of safety management and have thus been able to significantly decrease the number of incidents, such as aviation or energy. This section of the report will offer an overview of safety management in aviation and the energy sector to identify the key similarities and differences with health care and look for potential paths to improved patient safety governance based on lessons learned from other high reliability organisations.

Is making healthcare "highly reliable" an achievable goal?

102. Targeted safety improvement strategies inspired by the high reliability industries have effectively reduced the frequency of adverse events in some OECD countries. For example, in Michigan, United States, central line associated bloodstream infections have fallen by 80% over the past two decades (Bion et al., 2013[2]) (Pronovost et al., 2016[3]). However, progress in addressing patient safety outside of hospitals have been variable and patient harm extoll high human and economic costs (Bates and Singh, 2018[91]).

103. Some recent movements in the medical community have suggested that health care be held to the same paradigm as other complex and high risk industries, such as energy and aviation, which have been able to achieve high levels of safety and reliability (Liberati, Peerally and Dixon-Woods, 2018[92]). Recent safety improvement initiatives have pushed hospitals in the direction of 'high reliability organisations,' adapting lessons and practices from industry for use in the healthcare environment (Sutcliffe, Paine and Pronovost, 2016[93]). Findings note that healthcare has lagged behind these other industries in terms of important factors such as safety culture and systematic risk management (Hudson, 2003[94]).

104. The Agency for Healthcare Research and Quality of the United States defines high reliability organisations (HRO) as those which, "operate in complex, high-hazard domains for extended periods without serious accidents or catastrophic failures"[1]. The current hospital environment is still quite far from being a HRO. While the most serious events happen rarely—such as fires during surgery or operations on the incorrect body part or patient—health systems still have far to go in order to prevent them entirely (Chassin and Loeb, 2013[95]). Many health care leaders may be unwilling to commit to the goal of high reliability because they may see it as unrealistic or at odds with fiscal and regulatory pressures.

[1] https://psnet.ahrq.gov/primer/high-reliability

Box 3.1. Characteristics of High Reliability Organisations

- A highly centralised, formalised and hierarchical structure, mainly for strategic decisions;
- A decentralised, network based, team based, adaptable structure, for tactical/operational issues, and quickly reconfigurable for emergency management. Allows for quick and flexible field-level responses to surprises;
- A high level of agreement by the whole staff on the core values of the organisation; Safety is the primary objective;
- A formal structure of roles and responsibilities with redundancies and overlaps, and a high level of empowerment of front line operators to report abnormal events, adapt their behaviour and even stop operations when imminent danger is perceived;
- A clear map of relevant threats, risks and undesirable events, a wariness or permanent concern for risk (a 'chronic unease' to take Jim Reason's words), and a "requisite imagination" of what could go wrong;
- A capacity to "reorder" reorganise and self-organise, and to deal with new safety threats, through a combination of decentralization and improvisation;
- A high level of expertise throughout the organisation, and a permanent learning and training process, with reference to an elaborated, well documented and evolving set of procedures and practices;
- A "culture of reliability" that instils the values of wariness, care and caution, adherence to procedures, and individual responsibility for safety throughout the organization;
- The provision and maintenance of slack (excess capacity), buffers, stocks, in other words a form of waste, of sub-optimal state, to provide robustness against unpredicted events.

Source: (Pariès et al., 2019[96])

105. The published literature comparing risk management in health to other high-risk industries has increased markedly in the last decades. For instance, the concepts of *Safety-I* and *Safety-II* are used in other industries beyond healthcare, such as aviation that has adopted definitions similar to those used in health. The movement towards *Safety-II* allows for the focus on human adaptability and resiliency to ensure appropriate outcomes. Findings from air traffic management suggest that in order to move towards more Safety-II oriented systems, systems must focus on adaptability to changing conditions and everyday performance adjustments as much as system failures (Hollnagel, Wears and Braithwaite, 2015[97])

106. The health sector has been particularly inspired by aviation. Safety management in aviation has been extensively studied for potential applications on healthcare. Research has reviewed the use of aviation principles in many aspects and settings in healthcare--including team structure and communication (Flin, 2004[98]) (Hamman, 2004[99]) (Zeltser and Nash, 2010[100]), ambulatory care (Wilf-Miron et al., 2003[101]), surgical safety (Kao and Thomas, 2008[102]), identifying diagnostic errors (Singh, Petersen and Thomas, 2006[103]), primary care (Fernald et al., 2004[104]), and dentistry (Pinsky, Taichman and Sarment, 2010[105]). The potential for aviation to influence clinical care has become so established, that several major hospitals in the U.S. have been reported to have hired professional pilots to train their staff on how to apply aviation safety principals in the clinical environment (Murphy, 2006[106]).

107. Enthusiasm about potential applications of safety principles used in aviation has also driven a counter narrative that has built a significant literature base (Kar, 2019[107]). A comparative analysis between the industries notes that while professionalism is a common characteristic between aviation and health care, there are significant differences in terms of blame related to safety incidents, financial pressures,

media coverage of mistakes, and concerns of safety for all levels of leadership and management (Kapur et al., 2016[108]). In healthcare, adverse events happen to individual patients and the media coverage and pressure to adapt is not as high as in aviation, therefore, the investigation procedures are not always as rigorous. Optimal safety management is also different as a result of the higher predictability of airplanes compared to patients (Helmreich, 2000[109]).

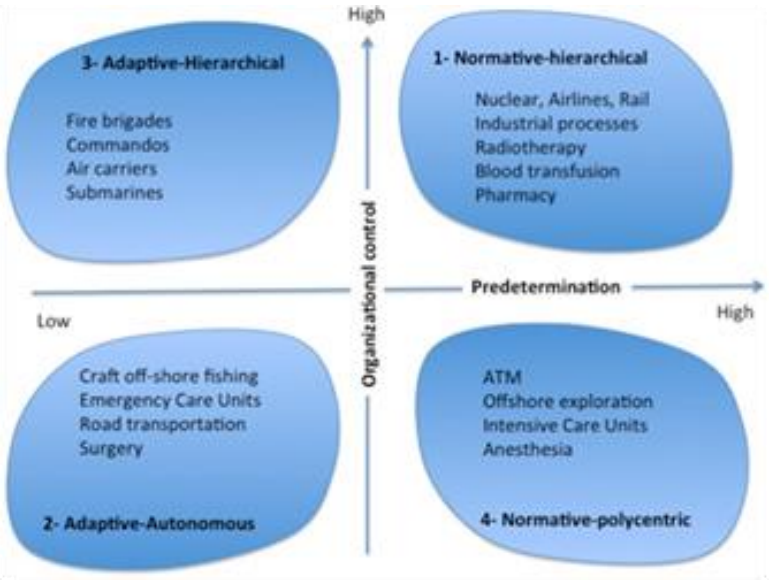
108. Other literature suggests that healthcare will never achieve the ultra-safe status due to systemic barriers, notably: "the need to limit the discretion of workers, the need to reduce worker autonomy, the need to make the transition from a craftsmanship mind-set to that of equivalent actors, the need for system-level (senior leadership) arbitration to optimize safety strategies, and the need for simplification" in ultra-sage systems (Amalberti et al., 2005[110]). Such arguments note that healthcare cannot be compared to HROs due to variation in risk among medical specialties, insufficient definitions of medical error, and other structural constraints.

Safety governance in high-risk industries

High Reliability Organisations and Resilience Engineering

109. Recent research on safety management has suggested that activities fall on a two dimensional continuum of *organisational control* i.e. level of autonomy of front line operators and *predetermination* i.e. management of uncertainty. Areas that exhibit low predetermination can be considered as more adaptive, allowing for more flexibility and innovation. Organisations in the top right corner are most adaptable to HRO principles, which focus on organisational capacity to operate high-risk processes by way of maintaining a highly efficient control of existing risk, managed, in part, by the organisational design (see Figure 3.1) (Pariès et al., 2019[111]). On the other hand, organisations in the bottom left corner may be most adaptable to the principles of another common concept of safety, resilience engineering, a model that allows efficient variability and uncertainty in safety management systems as a key component of managing safety (Pariès et al., 2019[111]).

Figure 3.1. Interaction of Organisational Control and Predetermination



Source: (Pariès et al., 2019[111])

110. An example of the difference between HROs and RE is illustrated in that of aviation (upper right) as compared to deep sea fishing (bottom left). Both activities entail significant exposure to risk, but the approach for managing risk varies significantly due to the particular characteristics inherent in these industries.

111. Aviation primarily handles risk by reducing risk exposure, by highly regulating training, staffing, and operations. For example, transatlantic and European flights were grounded for 6 days following the 2010 Eyjafjallajökull volcanic eruption in Iceland. These decisions were made by regulators, at times with backlash from individual aviation organisations (Millward, 2010[112]). Similar regulatory authority to minimise risk is demonstrated in the recent world-wide grounding of Boeing 737 MAX 8 and 9 aircraft since March 2019, a decision that also received criticism from industry at the time (Isidore, 2019[113]).

112. On the other hand, organisations dealing with a constantly changing work environment, such as deep sea fishing or intensive care units, are less able to manage risk by using rules and procedures and may be more amenable to resilience engineering (Vincent and Amalberti, 2016[114]). Operations using resilience engineering rely on the intelligence and resilience of frontline operators, so, organisations focus on providing operators the support they need to address and confront the risks to which they are exposed.

Catastrophic events have resulted in continuous regulatory changes to improve safety in the energy industry

113. The role of regulation, specifically, is a less studied aspect of health care in comparisons to other industries. In addition to safe practices at the micro and meso levels of governance, macro-level regulation is a lever that has been utilised in other high-risk industries with the intent of improving safety outcomes, often, in the aftermath of catastrophic events.

114. Catastrophic events not only cause significant human, environment and infrastructure losses--they are also often a catalyst for major structural, regulatory and organisational reforms and change. A crisis or catastrophic event has the capacity to mobilise significant system-level reorganisation of accountability mechanisms—including the creation or reform of regulatory standards, as well as programs for risk prevention, response, and resilience (Dahle et al., 2012[115]).

115. Safety standards for hazardous installations (including drilling instillations and refineries), such as requirements to implement process safety management protocols, were introduced in the EU in 1984, the US in 1992, and Korea in 1996 (Kwon, 2006[116]). The implementation of this wave of legislation was in part motivated by the catastrophic 1984 gas leakage in a pesticide plant in Bhopal, India resulting in over 2,000 deaths. The following year, in 1985, the ILO published a declaration stating that there should be a systematic procedure for preventing major industrial accidents (Kwon, 2006[116]).

116. Despite the attempts to reduce catastrophic events, they remain an ongoing occurrence in the public eye in industries deemed highly reliable. A famous example is the Deepwater Horizon blowout and spill in 2010, which caused the worst oil pollution disaster to date in U.S. history. The effects of the spill were numerous: 11 fatalities and 17 injured, 3.19 million barrels of oil spilled effecting over 1000 miles of coast line across Louisiana, Florida, Mississippi, and Alabama. The economic costs were significant as well, and included $13.9 billion for individual liability; $14 billion for operational response; $4.5 billion to $17.6 billion in civil penalties; $5 billion for environmental damage, and an estimated: $8.7 billion loss of about 22,000 jobs in fisheries-related sectors. (National Academies of Sciences, 2016[117]).

117. Catastrophic events have had a significant role in creating societal pressure to enhance safety practices, with attention to environmental and occupational safety beyond the accident in Bhopal (Hudson, 2003[94]). A study of four catastrophic events in the petroleum industry [including Piper Alpha (1988), Texas City refinery (2005), Montara (2009), and Deepwater Horizon (2010)] found that each incident resulted in the review and update of rules, regulation, and standards to improve safety (Dahle et al., 2012[115]). After

three of the incidents, stronger and more independent regulatory regimes were implemented at the institutional or regulatory level. In the last case, a new regulatory regime was established.

118. The type of regulation enacted varied depending on the incident. Following Piper Alpha, the UK shifted regime focus from a prescriptive approach, which outlines the exact activities regulated agents need to take, to a performance-regulatory approach that establishes performance goals and standards, while leaving implementation up to those regulated. However, following the Deepwater Horizon accident, favour was given to prescriptive regulation, in combination with performance-based regulation (Table 3.1).

Table 3.1. Regulatory and industrial consequences to improve safety following catastrophic events in the petroleum industry

	Nature and consequences of the accident	Recommended and Implemented regulatory changes (Regulatory Level)	Industrial Initiatives and Consequences (Procedural Systems and Compliance—Organizational Level)
PIPER ALPHA (UK)	• Condensate leak leading to a fire and an explosion • Mainly caused by lack of communication between shifts • 167 deaths • £1.7 billion insurance loss	• Independent safety regulator • Introduction of Safety Case • From a prescriptive to a performance based regime	• Stronger implementation of permit to work system and incident reporting systems • Enhanced emergency response systems • Introduction of "Step Change in safety" • Enhanced safety training • Changes to platform design
TEXAS CITY (US)	• Hydrocarbon liquid leak causing an explosion and a fire. • 15 deaths • 180 injured • $1.5 billion financial loss	• Management of change • Strengthened industrial supervision • Revise API standards	• Improved process knowledge among senior/corporate management and board members • Increased liability for senior/corporate management and board members • Adequate physical devices and technology (barriers) • Personal versus process safety indicators
MONTARA (AU)	• 74-day long oil and condensate spill • Total emissions estimated between 4,000 and 30,000 tons	• Separate resources and safety responsibilities • Independent safety regulator (NOPSEMA) • Legislation in marine environment • Stop activity criteria • Increased liability • Prohibition powers to NOPSA	• New requirements for barrier, well, risk assessments • More provisions, reviewing, verification, reporting and testing, documentation • Lower threshold for conducting risk assessments and independent reviewing • Operators emergency assistance • Communication and information sharing between stakeholders • Broader context when conducting decisions and risk assessments
MACONDO (US) [Deep Water Horizon]	See above	• Independent safety regulator • Balance prescriptive & performance/risk based regime • Safety case regime • Increased liability • Multilateral collaboration	• Proposed introduction of a Safety excellence institute • Proposed funding of regulators activities by the industry • Increased funding of oil spill control by the operators • Proposed stricter operating permit conditions (well integrity and oil spill response) • Proposed strengthening of Safety culture • Proposed increased system, operation and risk understanding • Proposed various technology enhancements like Capping, BOP, oil-spill recovery

Source: (Dahle et al., 2012[115])

119. All four cases resulted in more liability and responsibility on implementing companies. Another common result rested in the delineation of the roles of regular authorities. Prior to the accidents, one regulator was responsible for issues of resource management, safety, and national economic interests. Following these events in the UK and US, a clearer distinction was made between regulatory roles related to guidance and control.

Box 3.2. Findings of the National Commission on the BP Deepwater Horizon Oil Spill and Offshore Drilling

- The explosive loss of the Macondo well could have been prevented.
- The immediate causes of the Macondo well blowout can be traced to a series of identifiable mistakes made by BP, Halliburton, and Transocean that reveal such systematic failures in risk management that they place in doubt the safety culture of the entire industry.
- Deepwater energy exploration and production, particularly at the frontiers of experience, involve risks for which neither industry nor government has been adequately prepared, but for which they can and must be prepared in the future.
- To assure human safety and environmental protection, regulatory oversight of leasing, energy exploration, and production requires reforms even beyond those significant reforms already initiated since the Macondo disaster. Fundamental reform will be needed in both the structure of those in charge of regulatory oversight and their internal decision making process to ensure their political autonomy, technical expertise, and full consideration of environmental protection concerns.
- Because regulatory oversight alone will not be sufficient to ensure adequate safety, the oil and gas industry will need to take its own, unilateral steps to increase dramatically safety throughout the industry, including self-policing mechanisms that supplement governmental enforcement.

Source: (National Academies of Sciences, 2016[117])

120. Catastrophic events have been leveraged as opportunities of learning and improving in many high risk industries. In the wake of catastrophic events, in depth analyses have followed, both on the causes as well as the crisis handling and follow up. Safety governance has been adapted and industry has significantly evolved as a result. In many cases, such events have spurred a renewed focus on safety culture.

Application of TAPIC Framework to the Energy Sector

121. The petroleum industry, in particular, navigates challenging and remote working environments, highly explosive hydrocarbons, complex machinery, and workers of variable experience and training. Due to these factors, serious and fatal accidents were regarded as unavoidable in the oil and gas industries for decades.

122. Prior to 1990, safety improvement efforts in the energy sector focused primarily on equipment design and operational processes, as well as government enacted prescriptive regulations (National Academies of Sciences, 2016[117]). However, in recent years, new forms of governance have been enacted to improve safety as a response to the catastrophic events and due to advancements in technology and leadership.

123. A review and comparison of five Petroleum Safety Regulatory Regimes examined the safety governance structure of the UK, Denmark, Norway, Australia (Western) and Canada (Nova Scotia) (Murtagh et al., 2010[118]). Findings from the review note that all examined regulators are risk-based, require safety cases or similar documents, and operate in “permissioning regimes” where operations are only permitted following the approval of the regulator. This review found significant differences in the regulators approaches to occupational hazards, the use of third parties to ensure compliance, and the level of guidance included in legislation. The proceeding section will follow the TAPIC framework, demonstrating

examples of regulation in the domains of transparency, accountability, participation, integrity, and capacity, and how they have been influenced by governance functions. In particular, this section will shed light on regulatory examples on petroleum regulators.

Increased transparency and reporting were important mechanisms to learn from what went wrong in the Deepwater Horizon incident

124. Incident and performance reporting is a mechanism used in industry to improve transparency on the frequency, scope, and effects of workplace accidents—including injury and death of workers, contractors, or bystanders. Following the Deepwater Horizon incident, the US Bureau of Safety and Environmental Enforcement (BSEE) made compliance with the previously voluntary Safety and Environmental Management Systems (SEMS) compulsory. The SEMS requirements were initiated in order to refocus the industry's safety efforts from meeting minimum standards to creating mechanisms for continuous improvement (National Academies of Sciences, 2016[117]). From the perspective of energy regulators, there has been a movement to ensure that incident reporting requirements had to be highly prescriptive, this is required in order to ensure reported data is consist and comparable. Standardised information is then used to assess the need for standards or regulatory changes, determine research needs, and identify unsafe procedures (National Academies of Sciences, 2016[117]).

125. The Deepwater Horizon oil spill was followed by the creation of an independent, nonpartisan group—the National Commission on the BP Deepwater Horizon Oil Spill and Offshore Drilling—to conduct a thorough and impartial analysis of the incident. The report included a review as to the causes of the oil spill as well as recommendations for improving the response and improving the safety of offshore energy production (National Academies of Sciences, 2016[117]). The findings of this commission are noted in Box 3.2.

Financial liability, permissioning regimes and inspections are measures regulators often used to ensure accountability in the energy industry

126. The energy industry regulators have used financial liability and insurance requirements as tools to encourage investment in safe practices, by making organisations financially responsible for any accidents that occur. Financial liability enforced through regulation is common in the oil and gas industries. Following the 1987 Exxon Valdez oil spill, the US passed the Oil Pollution Act of 1990, which implemented a "polluter pays" regime, where liability was shifted to the polluter—thereby creating incentives for organisations to manage risk and reduce the possibility or accidents and subsequent damages (King and Library of Congress. Congressional Research Service., 2010[119]). As of 2016, Mexico's National Agency for Industrial Safety and Environmental Protection in the Oil Industry (ASEA) established new regulations which establish a minimum insurance requirement for companies directly performing activities or construction works relating to oil exploration and production, petroleum processing and refining, and processing of natural gas. These regulations required that organisations have mandatory coverage for civil liability, environmental damage liability and when applicable, well control (SKULD, 2017[120]). A study of bond requirements for oil and gas rolled out to all producers in 2001 found the legislation was correlated with improved environmental outcomes (Boomhower et al., 2014[121]).

127. Most petroleum safety regulatory regimes use permitting as a safety lever through occupational safety and health regulation permit and licence requirements as well as risk regulation through permissioning regimes. For example, Western Australia's Petroleum Submerged Lands Act 1982 (PSLA) includes detailed requirements concerning permits, leases and licences for offshore exploration and production of petroleum and pipeline licences. Requiring compliance with established standards in general is one of the most commonly used tools in regulation. While some catastrophic events have led to increased emphasis on management systems, safety culture, and risk assessment, others have led to reinforcement of traditional compliance mechanisms. For example, the 2010 BOEMRE Drilling Safety Rule,

introduced following the Deepwater Horizon accident, included prescriptive operating requirements and enhanced requirements for regulatory reviews and approvals (National Academies of Sciences, 2016[117]).

128. Regulators can provide guidance and implement inspections to ensure that safe practices are being followed. A significant amount of the risk management approach of petroleum safety regulatory regime is implemented through guidance and inspections. In the UK, there is not specific regulation that dictates the frequency of inspections by the Health and Safety Executive. However, inspections to ensure compliance may be initiated following a reported incident, in accordance with an HSE initiative, follow on to the revision of a safety case, or my the request of an interested party (for example policy makers) (Murtagh et al., 2010[118]). Similarly, immediate inspections are carried out by the Danish Energy Authority following work-related accidents and major near-miss occurrences, and more routine supervision is provided by both regular and unannounced inspections to assess operations (Murtagh et al., 2010[118]). Inspections from West Australia's National Offshore Petroleum Safety Authority (NOPSA) are triggered by reports of non-compliance including accidents that causes death or serious injury, accidents, dangerous occurrences, or complaints suggesting immediate threats to health or safety.

The energy industry focuses on empowering employees and the public to actively participate in the reporting of unsafe practices

129. There are numerous approaches that can be used to increase employee participation in ensuring a safe environment. A recent rule from the US Bureau of Safety and Environmental Enforcement was established to promote employee participation and the empowerment of field-level personnel. Current requirements in the US, implemented in 2013, related to employee empowerment include the following:

- Developing and implementing a stop work authority that creates procedures and authorises any and all offshore industry personnel who witness an imminent risk or dangerous activity to stop work;
- Developing and implementing an ultimate work authority that requires offshore industry operators to clearly define who has the ultimate work authority on a facility for operational safety and decision making at any given time;
- Requiring an employee participation plan that provides an environment that promotes participation by offshore industry employees as well as their management to eliminate or mitigate safety hazards;
- Establishing guidelines for reporting unsafe working conditions that enable offshore industry personnel to report possible violations of safety, environmental regulations requirements, and threats of danger directly to BSEE (National Academies of Sciences, 2016[117]).

130. The public needs to have access to appropriate information regarding risks in order to ensure that policy makers are implementing appropriate safety policies. Recent regulation implemented in Australia by the National Offshore Petroleum Safety and Environmental Management Authority created mechanisms for public comment on environment plans for seismic surveys and exploratory drilling (NOPSEMA, 2019[122]). A similar approach of enhancing opportunities for public comment was put into place by the U.S.'s Bureau of Ocean Energy Management following the Deepwater Horizon accident. New policies included opportunities for public input on environmental review of oil and gas programs as well as renewable energy proposals (Bureau of Ocean Energy Management, 2019[123]). The extent to which the targets of regulation know and understand the rules is another key aspect of regulatory compliance (OECD, 2000[124]).

131. Participation is a difficult concept to mandate through a regulatory framework, but one mechanism that regulators have to influence staff empowerment is through Whistle-blower policies. Whistle-blower policies function by all providing protection to staff that report concerns about health, safety and management issues-- protecting them against retaliation. The U.S. Department of Energy, for example, has numerous policies that allow both Federal Staff and Contractors to report safety issues under the

protection of laws, regulations and contracts that explicitly prohibit retaliation against whistle blowers (Department of Energy, 2019[125])

Integrity is the concomitant of strong leadership and a sound safety culture

132. As in health care, there is a significant focus on safety culture in the energy industry. In particular, there are a number of examples from the petroleum industry demonstrating safety governance regimes based on feedback and learning. Following the Piper Alpha event, Lord Cullen (author of the report on the Piper Alpha disaster) is quoted as saying "No amount of detailed regulations for safety improvements could make up for deficiencies in the way that safety is managed by operators [oil companies]" (Flin and Yule, 2004[126]). Research from the mining industry has found that there is a significant associations between levels of safety culture and the likelihood an individual worker has experienced an occupational accident (Tengilimoglu, Celik and Guzel, 2016[127]).

133. A notable example of efforts to improve safety culture is Norway, where the Norwegian Petroleum Safety Authority added a requirement related to safety culture, as regulations were adopted in 2002 requiring a "sound health, safety and environment culture" (Antonsen, Nilsen and Almklov, 2017[128]). By design, the language of the regulation is ambiguous and difficult to demonstrate legal adherence. However, a study examining the effects of this requirement notes that it has contributed to expanded practices of safety management and improvement (Antonsen, Nilsen and Almklov, 2017[128]). Further efforts from the Norwegian Petroleum Safety Authority have established a kind of co-regulation, consisting of enforced self-regulation, allowing regulated companies to establish flexible safety management practices (Nilsen and Størkersen, 2018[129]). Other offshore regulatory regimes that focus on operator safety management systems as opposed to prescriptive regulations include Australia, the United Kingdom, New Zealand, and the Netherlands (National Academies of Sciences, 2016[117]).

134. However, the effectiveness of regulatory methods to achieve improved process management practices has been mixed. Following the introduction of a Process Safety Management regulation in the chemical industry in 1992, there was not found to be a decrease in reports of plant accidents. However, it has been established that most accidents are linked to failure to comply with this standard (Mohd Shariff, Abdul Aziz and Abdul Majid, 2016[130]). In Korea, the regulation was found to be highly effective, resulting in a 62 percent decrease in fatalities and 58 percent decrease in injuries. (Kwon, 2006[116])

135. Research from the OECD's Public Governance Division (2019[131]) studying safety in the energy sector notes that the source of safety messages is very important for ensuring the uptake of safety messages. The principle studied suggests that individuals are most likely to conform to safety messages and norms, when they come from individuals that are perceived as experts or individuals placed in positions of authority. The study, which examined managers, staff, and regulators in the energy sector in Canada, Mexico, Ireland and Oman, found that the perceived effectiveness of safety messages was highest from regulators and managers. When reviewing comparative effectiveness between different levels of staff, the study found that messages were found to be better received from managers than senior managers. This follows the idea that individuals respond most to direct lines of accountability, and that all levels of management, not only senior management, should be involved in efforts to promote safety (OECD, 2019[131]).

Building capacities to ensure safe practices through staff training and safety case regulation

136. Safety case regulation is a significant aspect of petroleum safety governance. A safety case is a document that identifies hazards and risks and how they are controlled. Additionally, the safety case describes the instillation's safety management system and how it functions. Most regulators in the field require that all operating institutions have a safety case that is updated at regular intervals, or in the case

of any significant changes to the instillation. As they are tailored unique organisations and sites, the aim of safety case regulation is shift the onus of safety planning and management to the organisation, reducing burdensome regulation and detailed and prescriptive safety policies (Hale, Borys and Adams, 2015[132]).

137. Staff working on hazardous instillations should not only know applicable regulations, but they should also be able to appropriately comply with them. Majority of national and state regulations concerning staff training relates to the competency and training of inspectors. However, regulators have been able to influence staff training and resources through other mechanisms. For example, Denmark's offshore safety act includes requirements for Health and Safety Management Systems that comply with recognised standards (Murtagh et al., 2010[118]). The North Sea Offshore Authorities Forum (NSOAF), a partnership including representatives Denmark, the Faroe Islands, Germany, Ireland, the Netherlands, Norway, Sweden and the UK, works to harmonise safety training standards across regulatory regimes operating in the North Sea (Murtagh et al., 2010[118]). The Canadian Onshore Pipeline Regulations require the establishment of a training program (to include safety regulations, procedures and working practices).

Does health still have something to learn?

138. The health care industry has already adopted numerous safety approaches from other industries at the organisational level. Yet, there may be something more for health to learn as other industries continue to develop new systems of safety governance and health care seems to lag behind in preventing incidents.

Regulators in health and high-risk industries face similar challenges

139. Regulators across sectors face similar problems. In addition to high workloads and limited resources, they are put in an impossible position facing criticism of lax oversight on the one hand and being criticised for being too burdensome and intrusive, on the other (Reason, 1997[133]). Movements towards self-regulation in many industries have increased some of these challenges. While self-regulation has had the benefit of putting the onus of maintaining safe work practices on organisations—it still maintains the dilemma of how regulators can ensure that organisationally led safety practices are sufficient, without reverting back to a prescriptive regulatory mode.

140. There are some other striking similarities between health care and other high risk industries. In the offshore oil and gas industry, as in health care, employees work long shifts operating complex equipment to extract dangerous materials under high pressure (National Academies of Sciences, 2016[117]) — communication, teamwork and hand-offs between shifts are pivotal for maintaining the safety of operations. At the same time, employees operate with varying amounts of supervision and autonomy and tend to trust instructions that come from their peers and experts in the field instead of regulators.

141. Another similarity relates to perceived levels of safety within the organisation. Similar to findings in the healthcare field, research in the energy sector has demonstrated that levels of perceived safety are highest among senior managers and lowest among frontline staff. Moreover, regulators were found to have lower perceptions of safety than individuals (OECD, 2019[131]). This has implications for healthcare where similar findings have shown that frontline health staff, such as nurses, have the lowest perceptions of safety of care, with levels of perceived safety increasing to the highest levels among senior management. Culture and the devotion to safety by leadership remains crucial in health as well as other industries.

142. Safety governance in health care – where it exists – is already similar to that of other high risk industries. As in the energy sector, health care has adopted reporting systems, inspections and review boards for self-regulation or peer-to-peer learning. The main difference is the prevalence of these tools. The permitting systems in the energy sector are highly comparable to accreditation, regulation of pharmaceuticals and medical devices or minimum standards for certain types of surgery. Work processes

and licence renewals are less rigorously monitored in health and can often be subject to voluntary compliance. Similarly, the notion of safety culture is gaining ground in all high risk industries. While some countries are turning back towards self-regulation in the energy sector, few countries have deviated from that track in health care in the first place.

143. In contrast to the industrial sector, financial liability in health care varies greatly depending on health care governance and the legal system. However, the long prevailing culture of silence has limited medical community's exposure to penalties, as a result, investments into preventing failures seem to be less predominant. This underreporting could be overcome by drawing from the example of whistle-blower policies implemented in the energy sector and also applied to health care in some countries. Safety case regulations could also be introduced in health care as a form of enforced self-regulation to encourage health care providers to continuously map and reassess risks in their organisation.

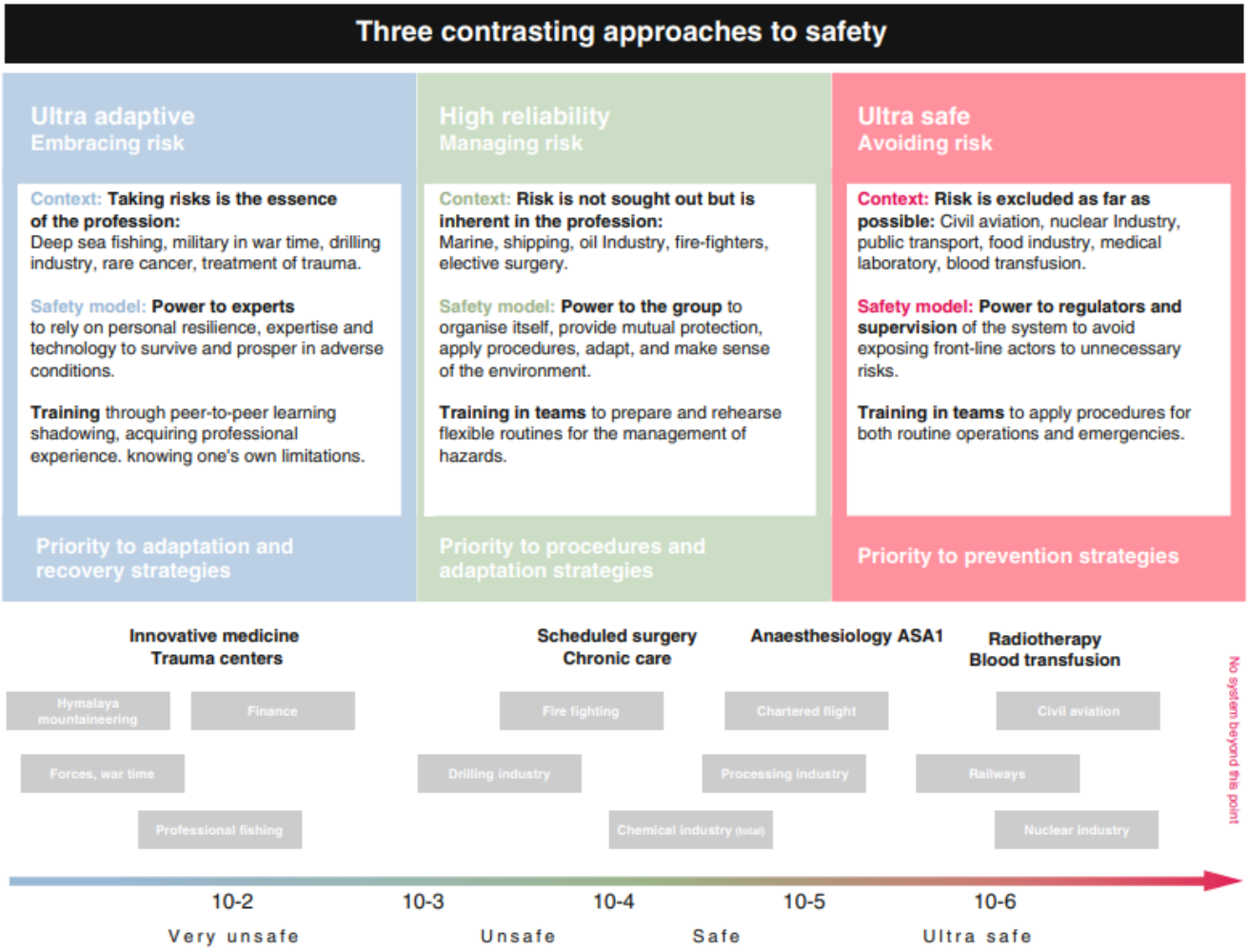
Challenges to lesson-drawing from other industries remain

144. Despite the similarities, significant differences between health and other high-risk industries remain that may necessitate differential approaches to safety governance. The first deals with the extreme variation in healthcare provision that spans the spectrum of approaches to safety (Figure 3.2). Some aspects of healthcare may be candidates for ultra-safe care (such as radiotherapy) but other aspects of healthcare may benefit from high reliability (chronic care) or ultra-adaptive (trauma) models, where the safety model gives more priority to flexibility and the ability to adapt to novel circumstances. Health is so broad of a field it can be seen as many different industries in one, therefore, different modes of governance may be needed for different kinds of care.

145. Additional differences relate to the influence of outside pressures for driving improvement. Safety accidents in other industries tend to include more victims at once and are therefore more forcefully covered in the media with potential effects on the perception of safety. Wide media coverage often results in strong mobilisation effects and introduction of new safety enhancing regulations on the macro level.

146. Concerns have been raised about the applicability of controls and safety mechanisms from other sectors regarding regulation and top-down approaches. A study in the NHS of 42 risk controls concluded that the adoption of hierarchical approaches borrowed from other industries may not be highly relevant in health care settings in their ability to increase the reliability of outcomes—and that a more dynamic and flexible approach may be needed (Liberati, Peerally and Dixon-Woods, 2018[92]).

Figure 3.2. Three contrasting approaches to safety



Source: (Vincent and Amalberti, 2016[114])

147. The long history of self-regulation has an important effect on safety governance in health care. In healthcare settings in particular, regulation often has a negative connotation, it is considered intrusive and distracting from conduct of clinical care (Oikonomou et al., 2019[134]). Moreover, the regulatory landscape in healthcare is complex and multi-faceted—including oversight from national laws, regulatory agencies, professional organisations and other stakeholders. Supporting capacity building by following the principles of resilience engineering could thus be more appropriate in the context of health care than the comparison with high reliability organisations, which are better suited for standardisation and top-down management.

148. James Reason writes, "Most technological operations, even very complex ones, are relatively simple in comparison to the task of maintaining safe working conditions" (Reason, 1997[133]). The same is true of health care. While managing health care, from chronic care in primary care, to surgery, are complex—it may be that neither is as complex as maintaining a safe health care environment. The recognition of this challenge, and the role of governance to address it, is key to establishing meaningful, adaptive policies to address it.

4 System-level safety governance in OECD countries

149. Safety in health is often considered as a dimension of quality of care and part of the overall performance of the health system. Similarities follow in the way safety and quality are governed. The OECD collects information on key health system characteristics every four years. The 2016 Health System Characteristics Survey provide the latest update of how OECD countries implement governance functions aiming to strengthen quality of health care services (Table A 3). OECD countries develop legislation and national and institutional regulations that define and ensure quality of care. Accreditation, inspections and audits are often used in monitoring compliance with national quality standards.

150. The Health System Characteristics Survey created the basis for the development of the 2019 Patient Safety Governance Survey. The OECD distributed the survey to a network of country experts on safety governance and policies in the summer of 2019. With a response rate of 25 OECD countries, a set of semi-structured interviews were undertaken in the late 2019[2], creating a broad and robust knowledgebase of countries' safety governance models.

151. This chapter describes how OECD countries report to have implemented safety governance functions, the extent to which functions are aligned into governance models and the strengths of these alignments. It further shares experiences and key lessons OECD countries have made when developing and implementing safety governance models, including perspectives from non-OECD countries. Safety governance is currently undergoing a shift of paradigms. The last piece of this chapter analyses the next steps bringing safety governance in to the future.

Patient safety is embedded in governance activities across all levels of the health system: system, organisational and clinical

152. Although the focus of this report is safety governance at the system-level, many safety governance activities are carried out at the organisational and clinical governance levels. For example, patient safety governance relies on the active involvement of health care leaders and boards in safety monitoring. Hospital boards are recommended to spend around 20% of meeting time on questions regarding quality and safety (Frankel et al., 2017[11]). Associations are established between hospitals' performance and board expertise on quality. Nearly half (46%) of the board chairs from high-performing hospitals in the England reported that their board members had substantial expertise in quality of care, compared to one in four board chairs of low-performing hospitals (Jha and Epstein, 2013[135])..

153. While quality and safety are important aspects of prioritisation, boards have traditionally devoted little time to quality and safety management as there were limited business incentives to do so (Botje, 2017[136]). Studies have shown that boards are more prone to put quality and safety in their agenda if the CEO of the hospital perceives there are external pressures and thus more likely to discuss quality issues at board meetings (Botje et al., 2014[137]). Hospitals with active board oversight on quality and safety are

[2] For more details on the responding countries and interviews, please see Table A 1 and Table A 2.

more likely to have improvement programmes and to perform better on a variety of indicators, including risk-adjusted mortality rates (Bismark and Studdert, 2014[72]). Moreover, the active engagement of managers has been shown to be crucial in implementing safety governance functions, such as surgical safety lists (Hayes, 2012[80]).

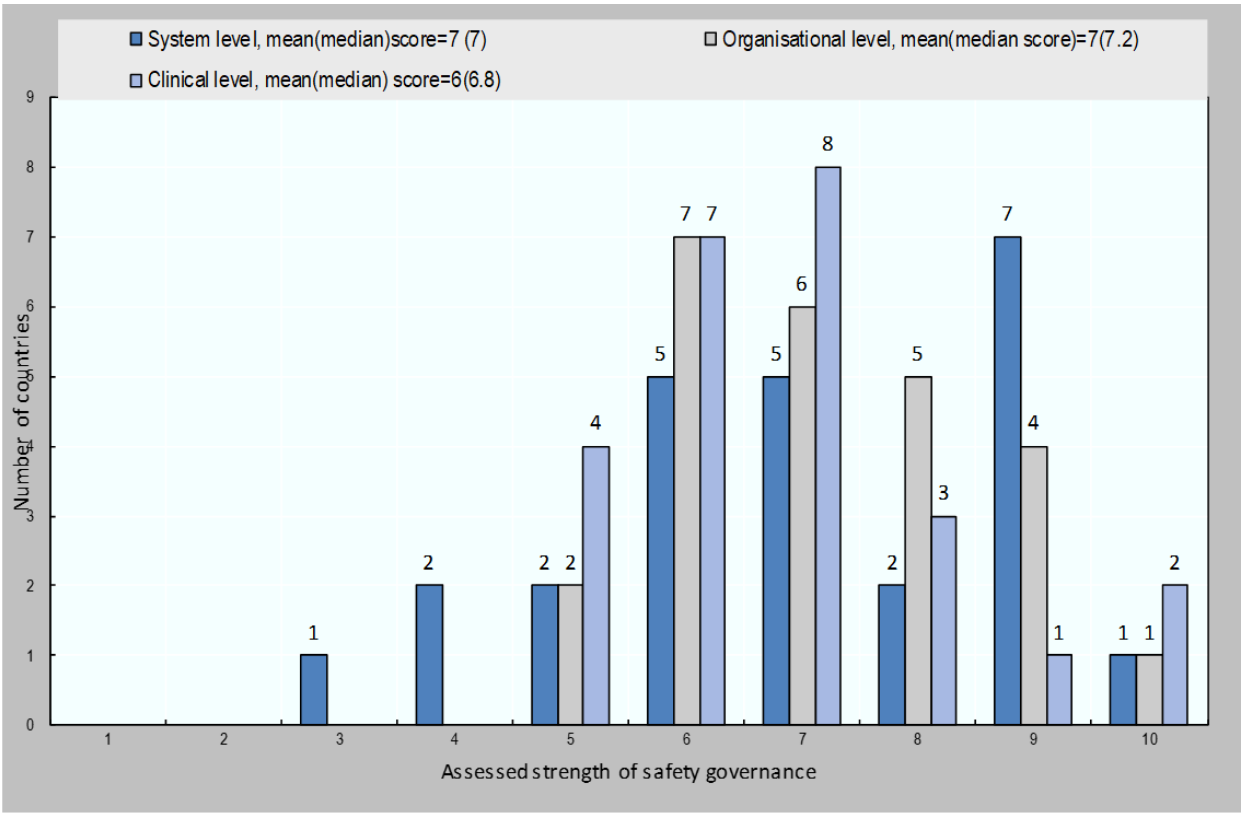
154. Clinical governance places quality and safety at the centre of healthcare activities in the clinical setting. Launched by the British NHS in 1998, clinical governance is defined as the "framework through which health service organisations are accountable for continually improving the quality of their services and safeguarding high standards of care by creating an environment in which excellence in clinical care will flourish" (Scally and Donaldson, 1998[138]). Clinical governance consists of seven core concepts, e.g. clinical effectiveness, risk management, patient involvement clinical audit and training, evidence-based care, and rely heavily on culture and leadership in day-to-day risk management to drive quality and safety improvement in clinical practice.

155. A wide range of clinical-level safety governance activities exist. For example, the Implementation of a Comprehensive Unit-Based Safety Programme in intensive care units developed with the aim to improve safety and reduce medication errors, length-of stay and nursing turnover. Multidisciplinary unit teams dedicated to oversee eight steps, including safety culture assessment, reporting practices and sharing of results. One year after the implementation of the programme, length-of-stay were halved in some of ICUs studied, while medication errors during transfer were nearly eliminated and nursing turnover decreased (Pronovost et al., 2005[139])

Safety governance in the OECD – how do countries assess the strength of safety governance in their system?

156. The 2019 Patient Safety Governance Survey casts the net wide in its search for information on OECD countries' patient safety governance practices. But before digging into the characteristics of governance functions and characteristics of governance models; the survey sought to identify respondents' assessment of patient safety governance within their respective health systems. Respondents were asked to assess the strength of system-, organisational- and clinical level safety governance by assigning a score from one, indicating 'major room for improvement' to ten, indicating 'no room for improvement' (Figure 4.1).

Figure 4.1. Assessed strength of safety governance across levels of care



Note: 25 responding countries
Source: 2019 OECD Patient Safety Governance Survey

157. Survey respondents consider safety governance reasonably strong across all levels. Organisational-level governance is assessed as the strongest, with a median score of 7.2, followed by system- and clinical level governance, with scores median scores of 7 and 6.84 respectively. The scores indicate strengths and weaknesses across levels of care, which are further elaborated in the rest of the survey responses and subsequent sections in the report. In brief, some health systems report challenges with establishing system-level oversight in safety governance, while clinical safety governance is dominated by a large degree of variation. The organisational level's comparatively strong position is primarily highlighted in health systems with strong clinical leadership and organisational support.

158. Health systems with large degree of decentralisation of decision-making processes and autonomous healthcare-providing organisations generally report room for improvement of system-level governance. However, the lowest tier of system-level governance scores report considerably stronger safety governance at the clinical level. Czech Republic and Switzerland, for example, report above-average clinical safety governance, but indicating considerable room for improvement in system-level safety governance. The highest tier of system-level safety governance scores report same-level or stronger clinical safety governance, as well as strong alignment of safety governance across levels of care. Denmark, England and Australia, for example, have long traditions in developing and implementing system-level safety governance functions, which is reflected in the reported high scores.

Safety governance functions are widely implemented by OECD health systems

159. The 2019 OECD Patient Safety Governance Survey presented sixteen functions grouped into give domains of safety governance. The five domains encompass; roles and responsibilities, systems for measuring and monitoring progress, key accountabilities, capacity-building to ensure right skills and competencies, involvement of key stakeholders. Each domain has a set of corresponding functions, considered as the building blocks of governance (Table 4.1).

Table 4.1. Patient safety governance functions

1. Clearly defined national/system-wide roles and responsibilities
1.1 National legislation on quality and safety
1.2 National quality and safety agency
1.3 National safety standards
1.4 National patient safety program
2. Systems for measuring and monitoring progress
2.1 National set of indicators supporting safety standards have been established
2.2 Internal monitoring of patient safety for continuous improvement
2.3 External accreditation, inspection or audit patient safety processes and outcomes
3. Key accountabilities
3.1 Provider financial incentives and/or penalties applied to promote and ensure safety
3.2. Routine public reporting of patient safety indicators and performance
3.3 Contracting and/or commissioning arrangements include safety requirements
4. Capacity-building to ensure right skills and competencies
4.1 Safety competencies built into curriculum of students in various health disciplines
4.2 Ongoing training as part of professional development of health care personnel
4.3 Leadership and management development to promote a patient safety culture
5. Involvement of key stakeholders
5.1 System report by agency responsible for patient safety to government (e.g. minister)
5.2 Healthcare-providing organisations integrating clinical governance with corporate governance
5.3 Patient representation in official roles and decision-making processes

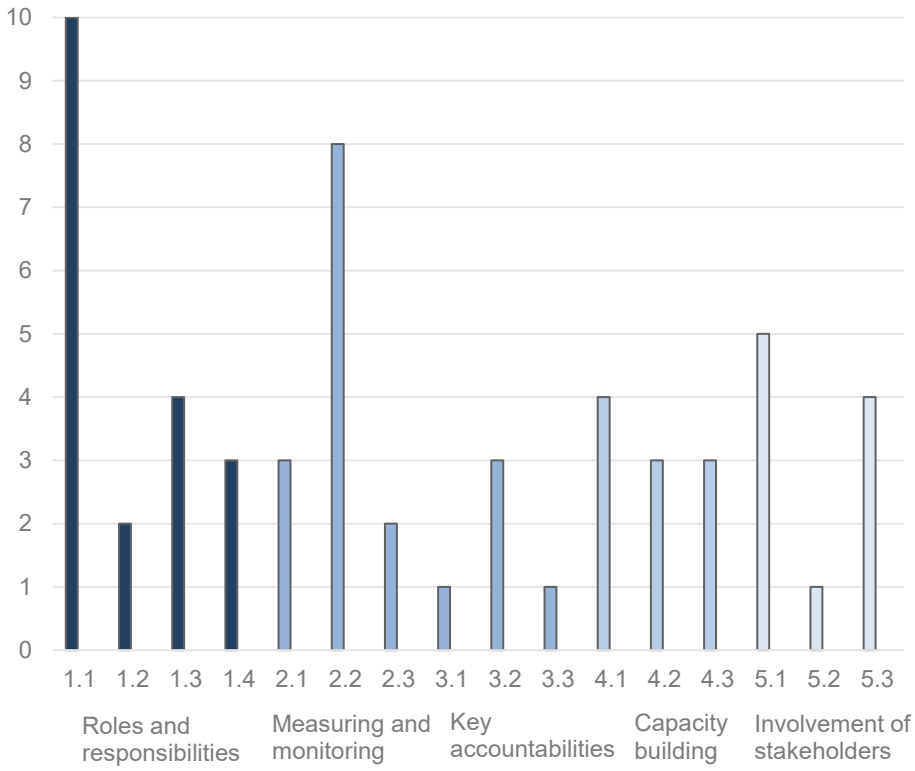
Source: 2019 OECD Patient Safety Governance Survey

160. Measured along those domains, the OECD Patient Safety Governance Survey listed in total sixteen functions (Summary table in the Annex Table A 3). Surveyed countries have to date focused implementation of safety governance on systems for measuring and monitoring progress, namely external accreditation (2.3), internal monitoring for continuous improvement (2.2). All responding countries have developed or are currently developing national legislation on patient safety and quality (1.1). About two-thirds of responding countries have established a national quality and safety institute (1.2) or developed a specific patient safety programme at the national level (1.4). Capacity-building is for the most part built into educational programmes or incorporated in ongoing training for health professionals (4.1, 4.2), while less often included in training of management and leadership (4.3). Governance functions under the domains of involvement of stakeholders and key accountabilities are less frequently implemented across OECD health systems. On average, 2/3 of responding countries produce and share a system-level report on patient safety to political leadership or governmental agency (5.1). Similarly, financial incentives tied to safety or routinely reporting of patient safety indicators occurs in 16/25 responding countries (3.1, 3.3).

The perceived importance and impact of governance functions vary

161. While governance functions are often interlinked and implemented in bundles, some functions are considered more important to implement than others. The Patient Safety Governance Survey asked respondents to identify the most important functions in a governance model (Figure 4.2). Three functions stand out as more important building blocks; notably national legislation on safety and quality (1.1), internal monitoring of patient safety indicators for continuous improvement (2.2) and system report by agency responsible for patient safety to government (5.1). Of the three functions given the least priority by respondents, two are in the key accountability domain; financial incentives/penalties applied to promote and ensure safety (3.1) and contracting/commissioning arrangements including safety requirements (3.3), in addition to integration of clinical and corporate governance (5.2).

Figure 4.2. Legislation and measurement/monitoring are considered the most important safety governance functions



Note: N=24 responding countries
Source: 2019 OECD Patient Safety Governance Survey

162. Although this exercise identifies the key priority functions, experts signalled that governance functions are considered as pieces of a bigger puzzle and some overarching elements must be in place in order to ensure continuous strengthening of patient safety. Broadly, respondents expressed the need to

establish a 'just culture'[3] of openness to improving safety through learning. Also, the availability and publishing of patient safety indicators are considered important elements to nurture commitment across all levels, ensure public trust and best practice.

OECD health systems frequently use governance functions to clearly define roles and responsibilities in patient safety

163. Functions under *clearly defined roles and responsibilities* refer to national-level legislation, dedicated quality and safety agency, development of national standards and national patient safety programmes (Table 4.2 and please see Table A 5 in the Annex for further details).

Table 4.2. Functions reported as implemented to clearly define roles and responsibilities at the system-level

	Clearly defined roles and responsibilities			
	1.1 National legislation on quality and safety	1.2 National quality and safety agency	1.3 National safety standards	1.4 National patient safety program
Australia	●	●	●	●
Austria	●	●	●	○
Belgium	●	○	●	●
Canada*	●	●	●	●
Czech Republic	●	○	●	●
Denmark	●	●	●	●
England	●	●	●	●
Estonia	●	○	●	○
Germany	●	●	●	○
Ireland	●	○	●	●
Israel[4]	●	○	●	●
Japan	●	●	●	●
Latvia	●	●	●	●
Lithuania	●	●	●	●
Luxembourg	●	○	●	○
Netherlands	●	●	●	●
Northern Ireland	●	●	●	○
Norway	●	●	●	● **
Portugal	●	●	●	●
Scotland	●	●	●	●
Slovenia	○	○	○	○

[3] 'Just culture' refers to a way of thinking that promotes a questioning attitude, is resistant to complacency, is committed to excellence, and fosters both personal accountability and corporate self-regulation in safety matters. A 'just' safety culture, is both attitudinal as well as structural, relating to individuals and organisations. Personal attitudes and corporate style can enable or facilitate the unsafe acts and conditions that are the precursors to accidents and incidents. It requires not only actively identifying safety issues, but responding with appropriate action. https://flightsafety.org/files/just_culture.pdf (accessed 24/01/2020).

[4] "The statistical data for Israel are supplied by and under the responsibility of the relevant Israeli authorities. The use of such data by the OECD is without prejudice to the status of the Golan Heights, East Jerusalem and Israeli settlements in the West Bank under the terms of international law."

	Clearly defined roles and responsibilities			
	1.1 National legislation on quality and safety	1.2 National quality and safety agency	1.3 National safety standards	1.4 National patient safety program
Spain	●	●	●	●
Sweden	●	●	●	●
Switzerland	●	○	○	○
Wales	●	●	●	●

Note: ●= yes, ○=no. * Canada has a federated, decentralised health system with safety policies and governance functions developed and implemented at the provincial/territorial level. ** In Norway, the national patient safety programme was discontinued from 2019 and integrated in the National Action Plan for Patient Safety and Quality Improvement.
Source: 2019 OECD Patient Safety Governance Survey

164. National-level legislation on quality and safety is one of the most frequently implemented safety governance functions. All responding countries report to have safety embedded in legislation, either at the national level or in federal states at the level of states/territories/provinces. Half of these have developed safety-specific legislation, while others ensure patients' right to safe care through other legislation. In Slovenia, patients have the legal right to adequate quality care and safe medical treatment through the Patients Right Act, as well as embedded in other legislation, e.g. The Contagious Diseases Act and the Health Services Act. Slovenia is currently amending the Patients Right Act to also include patient safety monitoring. Safety legislation is currently also being developed in Belgium, where the new law on quality in clinical practice legislation has been voted with effect from 2021, while HSE in Ireland has embedded quality and safety in the new governance structures and safety was further strengthened legislatively in the Patient Safety Bill introduced into the Irish Parliament, Oireachtas, by the Minister of Health in December 2019.

165. Twenty-two countries have adopted national quality standards to hold providers accountable for maintaining minimum levels of safety. In England, Fundamental Standards for quality and patient safety are contained in the Health and Social Care Act and the National Institute for Clinical Excellence (NICE) sets the standards and clinical guidelines for healthcare in England. Australia and Canada both hold long traditions in developing and establishing health service standards and both countries started revising national standards in 2019 and 2017, respectively.

166. The Canadian Patient Safety Institute developed the Safety Competencies Framework (SCF) in 2008 and revised in 2019. Several professional regulatory bodies have embedded patient safety standards into their core competencies and the SCF is currently integrated pre-professional education curricula by post-secondary education institutions, e.g. Canadian Association of School of Nursing, and post-professional training by healthcare organisations. The SCF has also been endorsed by various professional groups and some regulatory bodies are including the policies supporting safe patients care within their codes of conduct and standards of practice. For example, the Royal College of Physicians and Surgeons have integrated key concepts of patient safety in the core framework for physician training and credentialing by all specialties.

167. In other countries, national standards are not systematically established and implemented, but still exist. In Estonia, Germany and Luxembourg standards have been developed for specific domains of care, e.g. health technologies, blood transfusions and medicines in Estonia and hygiene and radiation in Germany. In Belgium, on the other hand, national standards are not developed, but follow the EU Directives on blood, tissues and organs (Box 2.3). Standards are less prevalent for primary care and might also not apply equally to public and private providers e.g. in Canada, Greece, Ireland, Mexico (OECD, 2016[140]).

168. National agencies responsible for safety and national safety programmes are less frequent. In total 17 countries have an agency responsible for safety, for example the Australian Commission on Safety and

Quality in Health Care, the Canadian Patient Safety Institute, NHS Improvement in England and the National Institute for Quality and Transparency in Healthcare in Germany, which collaborates with the Federal Joint Committee and the Federal Ministry of Health. The responsibility for safety at the national level is in some cases a specific unit within the Ministry of Health, as seen for Portugal and Slovenia, State Health Accreditation Agency within the Lithuanian Ministry of Health and the Patient Safety Unit in the Directorate of Health in Norway. Seven countries, including Belgium, Czech Republic and Luxembourg, report to not have an agency responsible for patient safety.

169. A similar pattern is observed for the implementation of a national-level patient safety programmes. In total 16 countries have developed national-level safety programmes, either targeting specific domains of care or system-wide. Safety plans on specific domains of care, e.g. Belgium's safety plans targeting acute care and psychiatric care and Czech Republic recently re-launched plan on healthcare associated infections.

170. System-wide plans are developed in Australia and England, and are currently being planned in Ireland to be launched late 2019. In Lithuania, the national programme on quality improvement runs from 2018-2020 and includes the following main tasks: strengthen the quality assurance architecture; improve patient safety in health care, strengthen monitoring, inspection and evaluation of health care services; patient-centred care as an approach to improving health care quality. In total 25 measures are developed to support and monitor the implementation of the program. In 2015, the Portuguese Ministry of Health published a legal framework - the National Plan for Patient Safety 2015-2020 – seeks to involve providers, managers and decision-makers in safety governance. The Plan developed nine strategic goals ranging from clinical to cultural aspects of care, to be achieved through specific actions to be developed at national, regional and institutional level. For more information on national plans, please see Box 4.1.

Box 4.1. National plans of patient safety

Portugal: National Plan for Patients' Safety 2015-2020

National Plan aims to support the managers and clinics of National Health Service in setting objectives to improve risk management, having in mind the collective effort of mobilising individual competences for the pursuit of safety. The strategy promotes a continuous cycle of quality improvement composed of identifying risks, evaluating and ranking them, followed by identifying the improvement actions. Further emphasis is put on safety culture, sharing of knowledge and information. National Plan for Patients Safety sets nine strategic goals with target indicators, defining key dimensions, responsible entities and timeline of actions. In order to achieve the golds, Commissions of Quality and Safety of hospitals and health centres are required to include the implementing activities in their annual action plans (Direção-Geral da Saúde, 2015[141]).

Strategic goals

1. Increase the safety culture of the internal environment.
2. Increase the safety of communication.
3. Increase the safety of surgery.
4. Increase the safety in using drugs.
5. Ensure the unequivocal identification of patients.
6. Prevent the occurrence of falls.
7. Prevent the occurrence of pressure ulcers.
8. Ensure the systematic practice of notification, analysis and prevention of incidents.
9. Prevent and control infections and resistance to antimicrobials

Ireland: Patient Safety Strategy 2019-2024

The Health Service Executive launched on the 13th of December 2019 the HSE Patient Safety Strategy 2019-2024 (HSE, 2019[142]).The HSE Patient Safety Strategy underlines the important role of patient safety culture based on transparency and learning. Safety improvement is further supported by meaningful involvement of patients and staff, effective leadership, monitoring and continuous assessment of quality, safety and experience of care. Effective implementation is the real test of any strategy, and the HSE is committed through Patient Safety Strategy to implement new governance structures and ensure further development of existing patient safety initiatives. The strategy introduces six commitments with six to eleven actions to implement each, such as support tools, national reports, enhancement of patient safety indicators, and the development of an investment strategy.

Patient Safety Commitments

1. Empowering and engaging patients to improve patient safety
2. Empowering and engaging staff to improve patient safety
3. Anticipating and responding to risks to patient safety
4. Reducing common causes of harm
5. Using information to improve safety
6. Leadership and governance to improve safety.

Systems for measuring and monitoring carry out the core activities in safety governance

171. *Systems for measuring and monitoring patient safety* capture valuable information on the status of patient safety within the health system. The functions falling under this domain are; the establishment of a national set of indicators supporting the safety standards, internal monitoring of patient safety for continuous improvement and external accreditation, inspection, audits of patient safety processes and

outcomes. The three functions in this domain are the most frequently reported as implemented by respondents (please see Table 4.3 below and Table A 6 in the Annex for further details).

Table 4.3. Functions reported as implemented for measuring and monitoring progress

	Systems for measuring and monitoring		
	2.1 National set of indicators supporting safety standards have been established	2.2 Internal monitoring of patient safety for continuous improvement	2.3 External accreditation, inspection or audit patient safety processes and outcomes
Australia	●	●	●
Austria	●	●	●
Belgium	○	●	●
Canada	○	●	●
Czech Republic	○	●	●
Denmark	●	●	●
England	●	●	●
Estonia	○	○	●
Germany	○	●	●
Ireland	●	●	●
Israel	●	●	●
Japan	●	●	●
Latvia	○	●	●
Lithuania	●	●	●
Luxembourg	●	●	●
Netherlands	●	●	●
Northern Ireland	●	●	●
Norway	●	●	●
Portugal	●	●	●
Scotland	●	●	●
Slovenia	●	●	●
Spain	●	●	●
Sweden	●	●	●
Switzerland	●	○	○
Wales	●	●	●

Note: ●= yes, ○=no
Source: 2019 OECD Patient Safety Governance Survey

172. Patient safety indicators are developed for different purposes. In 22 responding countries, indicators are developed and collected at sub-national levels for the purpose of internal monitoring for continuous improvement, while some countries in combination develop and routinely report safety indicators at the national level. One of these countries is England, where internal monitoring alongside external accreditation are tools used to improve safety. The NHS in England collects and publishes an extensive national set of indicators relating to patient safety, including information capturing never events[5],

[5] Never events refer to medical errors that are wholly preventable where guidance or safety recommendations that provide strong systemic protective barriers are available at a national level and have been implemented by healthcare providers (NHS Improvement, 2018[172]). Examples of "never events" include surgery on the wrong body part; foreign body left in a patient after surgery; mismatched blood transfusion; major medication error; severe "pressure ulcer" acquired in the hospital; and preventable post-operative deaths

incident reporting data, staff surveys, patient experience surveys, administrative data related to patient safety concerns, clinical audits and outcome reviews. Indicators also cover more condition-specific aspects of safety, including healthcare-associated infections, VTE risk assessments. Ireland reports on a limited range of patient safety indicators at a quarterly basis in a general Performance Report, while acute care hospitals and maternity units publishes patient safety indicators on their respective websites. National Patient Safety Experience surveys are conducted of inpatients on a regular basis and findings are included in the services quality improvement plan. A similar survey for maternity patients due to commence in 2020 and two further surveys in development; one for nursing home residents and one for bereaved relatives.

173. Germany has developed indicators on specific indications and procedures, for example hip fractures and implantation/exchange of cardiac pacemakers, and recently passed a law regarding the establishment of a patient registry for implants to be used in quality and safety monitoring and improvement. Currently, data are collected at the clinical/hospital level. All hospitals are obliged to have an information system recording adverse events and medical errors (CIRS) to be used in internal monitoring and safety improvement initiatives. When it comes to external monitoring, hospitals are obliged to report on a set of indicators as prescribed by the Federal Joint Committee, however, these indicators are mainly focusing on quality and not necessarily safety-specific. The hospital quality reports are available to the public. The long-term goal is to encourage a more systematic approach in collaborating and use information recorded in the internal quality and risk management systems in educational programmes in order to exploit the full potential of the CIRS.

174. External accreditation, inspection and audits are carried out in all responding countries except Switzerland making it the most commonly implemented governance function in the survey. In four countries, including Czech Republic, Germany and Slovenia, accreditation and inspections are voluntary. In Canada, accreditation is mandatory in two provinces; Alberta and Quebec (public and private health care organisations) (Government of Alberta, 2008[143]; Government of Quebec, 2011[144]). In other Canadian provinces, most but not all health and service providers undergo voluntary accreditation by Accreditation Canada or other accrediting body, being assessed against established standards and required safety practices. More than 1,000 health and social service organisations and 7,000 sites in Canada are accredited through their assessment programmes. In the remainder 20 responding countries, external accreditation and/or inspections are mandatory. In England, for example, external accreditation is the responsibility of the Care Quality Commission, which applies a rating system for health and social care, based on findings from inspections and analysis of available data. External accreditation, audits and inspection are considered as a way to ensure accountability in England.

Routine reporting of safety indicators is the most common function used to identify key accountabilities

175. Functions under *key accountabilities* include; financial incentives and/or penalties applied to promote and ensure safety; routine public reporting of patient safety indicators; contract and/or commission arrangements include safety requirements. The implementation of functions under this domains is partly influenced by the overall health system structure. For example, some health systems do not use contract with providers or develop commissioning arrangements, which in part may explain why the functions under this domain are the least frequently implemented.

176. Financial incentives and penalties to promote safety are used by 16 responding countries (Table 4.4 and Table A 7 in the Annex for further details for further details). In some countries, (Australia, Belgium, Germany and Ireland) incentives are incorporated into national price models or pay-for-performance models. In England, a range of financial incentives have been used to date to improve patient safety. The Care Quality Commission and NHS Improvement have enforcement authority and can apply penalties to providers who are in breach of their registration or licensing requirements. However, experience demonstrates that the application of financial penalties for associated safety incidents or similar

can be counter-productive and inhibits openness and reporting. Penalties are under some circumstances used in Lithuania. Following a warning, the Lithuanian Accreditation Agency has the authority to impose penalties on providers where poor quality care or negligence is reported. In Sweden, financial incentives and penalties exist, but are rarely used. In Canada, pilot projects on financial incentives and penalties were rolled out in two provinces, but not sustained.

177. Public routine reporting of safety indicators are more common among survey respondents and practiced in 19 countries. Some countries systematically report safety indicators to the public, e.g. Sweden, where an extensive set of safety indicators, comparisons and analyses are published on annual basis. Similar practices are seen in Norway, while Estonia publishes a system report on safety made annually by the Health Insurance Fund and National Institute for Health Development on different quality measures including safety. On the other hand, some countries report on safety at different levels of care or at subnational levels. In Canada, the federal system and health system governance characteristic result in a certain inconsistency in what information is reported to the public. Six out of 13 provinces and territories report some information out to the public, for example Ontario reports on system performance including hospital patient safety, as does Nova Scotia. Similarly, in Belgium the collected patient safety data are only collected and published on a routinely basis in Flanders, while Germany reports safety and quality indicators at the hospital level through the internal quality and risk management system.

178. Contracts and commissioning of care include safety requirements in 21 countries. In Estonia, the Health Board takes into account safety and quality when certifying all health care providers. Similarly in England, Israel and Ireland, contracting and licensing arrangements incorporate safety requirements. In Belgium and Japan safety is only part of contract and commissioning of hospital services. In Spain and Sweden, contracts may include safety requirements, but it is not mandatory.

Table 4.4. Functions reported as implemented to ensure key accountabilities

	Key accountabilities		
	3.1 Provider financial incentives and/or penalties applied to promote and ensure safety	3.2. Routine public reporting of patient safety indicators and performance	3.3 Contracting and/or commissioning arrangements include safety requirements)
Australia	●	○	●
Austria	●	●	○
Belgium	●	●	●
Canada*	○	●	●
Czech Republic	○	○	○
Denmark	○	●	○
England	●	●	●
Estonia	○	○	●
Germany	●	●	●
Ireland	●	●	●
Israel	●	○	●
Japan	●	●	●
Latvia	●	●	●
Lithuania	●	○	○
Luxembourg	●	○	●
Netherlands	●	●	●
Northern Ireland	○	●	●
Norway	●	●	●
Portugal	○	●	●
Scotland	○	●	●
Slovenia	●	●	●
Spain	●	●	●
Sweden	●	●	●
Switzerland	○	●	●
Wales	○	●	●

Note: ●= yes, ○=no. * Canada has a federated, decentralised health system with safety policies and governance functions developed and implemented at the provincial/territorial level. Public reporting exists in some provinces/territories, but not all.
Source: 2019 OECD Patient Safety Governance Survey

Capacity-building to ensure right skills and competencies is focused on medical and nursing students

179. Survey responses indicate that building capacity is considered as the second most important domain in system safety governance. Are healthcare personnel trained in how to provide safe care? Is safety a required part of ongoing training and licensing of healthcare personnel? Are staff being trained to create and maintain safe environments, and to speak up when they see unsafe practices or behaviours? Is patient safety culture measured at the leadership level? The functions under *capacity-building* to ensure right skills and competencies aim to answer those questions.

180. All responding countries, with the exception of one, report training either students or professionals or both in safety Table 4.5 and Table A 8 in the Annex for further details. One in five countries incorporate safety in curriculum of students in various health disciplines. In Canada, for example, the Safety Competencies Framework developed by the Canadian Patient Safety Institute is directly linked to the national safety standards and included in training programmes for both students and health professionals. Most frequently, safety is integrated in the curriculum for medical and nursing students, but in England and

Ireland students in dentistry, midwifery as well as allied health personnel are trained in safety. While many countries have standardised curricula at the national level, Sweden and Spain report that the focus and integration of safety in curricula depends on the individual educational institution. In countries where safety is not incorporated in curricula, safety is integrated in ongoing training of professionals, e.g. in Portugal the ongoing training of healthcare personnel also includes patient safety culture assessment.

181. Organisational culture is conducive to patient safety and positively associated with good patient outcomes, including reduced mortality, healthcare-acquired infections and patient satisfaction (Braithwaite et al., 2016[145]). The extent to which safety culture is regularly measured and training of leaders and managers is more varied. In total, 18 countries promote patient safety culture at the level of leadership and management. The recent NHS England Patient Safety Strategy has patient safety culture as the core focus and training as a central element (Box 4.4). Within the NHS, training is available to all, however, not all staff may choose to access it. Leadership and management training is available to staff throughout the NHS, for example; specific leadership development programmes, management modules in post-graduate education programmes, human factors training, fellowships into specific leadership roles. These programmes incorporate leadership and management for culture change which can positively impacts patient safety.

Table 4.5. Functions reported as implemented to ensure capacity-building and the right level of skills and competences

	Capacity-building to ensure right skills and competencies		
	4.1 Safety competencies built into curriculum of students in various health disciplines	4.2 Ongoing training as part of professional development of health care personnel	4.3 Leadership and management development to promote a patient safety culture
Australia	●	●	○
Austria	●	●	○
Belgium	●	●	●
Canada	●	●	●
Czech Republic	●	○	○
Denmark	●	●	●
England	●	●	●
Estonia	○	●	○
Germany	●	●*	○
Ireland	●	●	●
Israel	●	●	●
Japan	●	●	●
Latvia	●	●	●
Lithuania	●	●	○
Luxembourg	○	●	○
Netherlands	●	●	●
Northern Ireland	●	●	●
Norway	●	●	●
Portugal	○	●	●
Scotland	●	●	●
Slovenia	●	●	●
Spain	●	●	●
Sweden	●	●	●
Switzerland	○	○	○
Wales	●	●	●

Note: ●= yes, ○=no. * Germany: Varies between states and hospitals, but continuous educational programmes in patient safety and risk management exists.
Source: 2019 OECD Patient Safety Governance Survey

Involving key stakeholders in safety governance remains a challenge in many OECD countries

182. The fifth and last domain under which governance functions were mapped was *involvement of key stakeholders.* It is considered of paramount importance to involve key stakeholder across all levels to ensure that safety is at the heart of system-level governance and decision-making processes. Does political leadership know about the state of safety in their health system? Is clinical governance integrated with overall governance of the healthcare system? Are patients' heard discussions and decision-making processes?

183. More than half of survey respondents produce and deliver a system-level report on safety to government and political leadership (Table 4.6 and see Table A 9 in the Annex for further details). In Japan, several safety failures in late 1990s and early 2000s brought safety to the attention of the Japanese government. One of the measures implemented by the government following these events was a patient safety report describing the state of safety in Japanese medical facilities. The first system-level report on safety was produced in 2002, and from 2004 safety indicators were integrated in the annual report produced by the Japanese Council for Quality in Health Care (Taneda, 2019[146]). Similarly in Norway, the Parliament every year receives a White Paper reporting on the health system's performance on aspects of quality and safety. In Canada, the Canadian Patient Safety Institute (CPSI) reports annually on its activities to Health Canada and to the public in its annual reports. CPSI also partners with organisations like the Canadian Institute for Health Information to develop and publicly report on national aggregate system-level safety measures like the Hospital Harm Indicator, which can be used at a regional or local level for improvement purpose. Reporting practices vary at the level of territories/provinces, e.g. Health Quality Council of Alberta directly reports to the Alberta legislature on its activities and the performance of the provincial health system; Ontario hospitals report to Ontario Health.

Table 4.6. Functions reported as implemented to ensure involvement of key stakeholders

	Involvement of key stakeholders		
	5.1 System report by agency responsible for patient safety to government	5.2 Healthcare-providing organisations integrating clinical governance with corporate governance	5.3 Patient representation in official roles and decision-making processes
Australia	●	●	●
Austria	●	●	●
Belgium	○	●	○
Canada*	○	○	○
Czech Republic	○	○	○
Denmark	●	○	○
England	●	●	●
Estonia	○	●	○
Germany	○	○	●
Ireland	○	●	●
Israel	●	●	○
Japan	●	●	●
Latvia	●	○	●
Lithuania	○	●	●
Luxembourg	●	●	●
Netherlands	●	○	●
Northern Ireland	●	●	●
Norway	●	●	●
Portugal	●	●	○
Scotland	●	●	●
Slovenia	○	●	●
Spain	●	●	●
Sweden	●	●	●
Switzerland	○	○	○
Wales	●	●	●

Note: ●= yes, ○=no, * Canada has a federated, decentralised health system with safety policies and governance functions developed and implemented at the provincial/territorial level. Some provinces/territories have implemented functions aiming to ensure key stakeholder involvement, while others are lagging behind.
Source: 2019 OECD Patient Safety Governance Survey

184. Another aspect of stakeholder involvement is to integrate clinical and corporate governance, ensuring that all stakeholders are held accountable to patients and the community for providing safe and care of high quality. Most responding countries report to have implemented this at various extents. The Australian Commission on Safety and Quality in Health Care developed the Model Clinical Framework, which is mandatory to all healthcare-providing organisations that need to meet the National Safety and Quality Standards in Healthcare (Commission on Safety and in Health Care, 2017[147]). In addition to defining clinical and corporate governance, roles and responsibilities for personnel within the healthcare-providing organisation, the National Model Clinical Framework includes five components:

- Governance, leadership and culture
- Patient safety and quality improvement systems
- Clinical performance and effectiveness
- Safe environment for care delivery
- Partnering with consumers

185. In the NHS in England, the Care and Quality Commission carries out inspections of hospitals where governance and leadership are one of the topics investigated. All providers of regulated activities are required by law to register with the Care Quality Commission (CQC) and undergo regular, intelligence-guided inspections. Providers are further required to display their overall CQC rating, based upon the five domains of 'safe', 'effective', 'caring', 'responsive' and 'well-led'. In 2018, 68% of hospitals inspected by Care and Quality Commission were rated as *Good* or *Outstanding* and considered 'well-led'. In Belgium and Ireland, respondents identify clinical governance as a point of future priority and improvement. At the federal level in Belgium, future focus is on more coordination and alignment of patient safety initiatives with regional authorities, while the strengthening of the integration of clinical and corporate governance is embedded in the new governance structures in Ireland.

186. Putting people at the centre is a key policy priority also when it comes to safety governance. Involving patients in decision-making processes on quality and safety matters, either directly through official roles or indirectly in consultation processes, is practiced in many OECD countries. In Austria, patients are represented in official roles in the Advisory Board for Patient Safety, and requirements embedded in the Australian National Standards on Quality and Safety and Latvian legislation ensure patient representation in decision-making processes. In Germany, patient organisations are represented in the Federal Joint Committee.

187. In Ireland and Northern Ireland, patient involvement is currently varied, but improving. In Ireland, patient representation is satisfactory at the policy level, but more needs to be done at the national level for the public health system. Similarly, in Northern Ireland there is growing input by patients and their representatives in patient safety and quality initiatives. In Canada, practices vary at the level of territories and provinces, but nationally the Canadian Patient Safety Institute supports the inclusion of patients' perspectives in decision-making processes, particularly with its support of Patients for Patient Safety Canada, a pan-Canadian volunteer network of patients and families affected by harm (Box 4.2). For example, in 2018 patient volunteers met with elected officials to provide input, raise awareness and demonstrate support for Health Canada guidelines for plain language labelling of non-prescription medications (Patients for Patient Safety, 2018[148]). An e-petition led by this same group was successful in requiring the Minister of Health to address the regulations in Canada's House of Commons.

Box 4.2. Patients partner with governments and leaders to improve safety in Canada

Since 2006, Patients for Patient Safety Canada (PFPSC), the patient-led program of the Canadian Patient Safety Institute, a WHO Collaborating Centre on Patient Safety and Patient Engagement and the Canadian arm of the WHO Patients for Patient Safety Global Network have shaped safety policies, practices and programs at all system levels. From inception, PFPSC and the Global PFPS Network, have endorsed the 2005 London Declaration, that are founded on patients' involvement and empowerment in developing, building and establishing safe practices (World Health Organization, 2005[149])

As patients and family members impacted by unsafe care, they volunteer to engage as partners in initiatives focused on preventing and responding to harm. Here are a few examples:

- Contributed to national regulations regarding the labelling of non-prescription medication (by contributing the patient/ family/ public perspective on the committee leading this work)
- Supported the implementation of national legislation related to mandatory reporting of adverse drug reactions and medical device incidents (created learning modules by patients for patients)
- Leading meetings with Members of Parliament and Senators to increase awareness about the issue of patient safety and the key role patients can play
- Hosted meetings between provincial/territorial patient partners and Ministers/ Ministries of Health to discuss how to improve safety together
- Establishing the Patient Alliance for Patient Safety where patient partners and organisations from across Canada to identify and implement actions that matter to patients
- Contributing and collaborating with the WHO and Patients for Patient Safety Global Network
- Developing key patient safety strategies and resources that informed practices, standards and policies including:
    - Canadian Disclosure Guidelines
    - Canadian Incident Analysis Framework
    - Safety Competencies Framework
    - National Patient Safety Consortium
    - Canadian Quality and Patient Safety Framework [CPSI-HSO]
    - Patient Safety Culture Bundle for CEOs and Senior Leaders
    - #ConquerSilence public engagement campaign

The parallels between the TAPIC framework and what patients, families and citizens around the world are evident. Participation, or meaningful engagement, is what matters to patients. Transparency and accountability are the most important features so they can be safe and heal after a patient safety incident. Patients can help lead and build the culture and capacity for learning and knowledge-sharing to improve safety.

Source: Expert consultation, https://www.patientsafetyinstitute.ca/en/About/Programs/ppsc/Pages/default.aspx (accessed 20/01/2020)

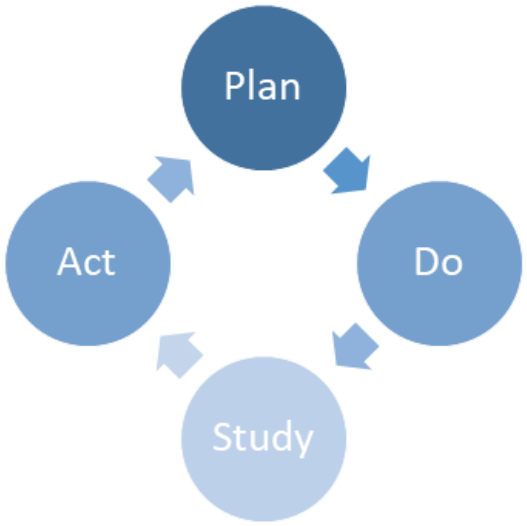
Building safety governance models that enable continuous learning and improvement

188. Effective governance entails the existence of a coherent strategy to ensure specific measures are not stand-alone elements but interlinked and following the same logic in a wider strategic approach implemented on all levels of health care. For an effective plan, SMART goals have to be set, meaning they are specific, measurable, assignable, realistic and time-bound (Chan et al., 2019[79]).

189. The effect transparency has on improving outcomes depends on the extent to which it is linked to accountability. In OECD Health Care Quality reviews (2017[69]), three approaches to external evaluation have been detected: formative, mixed and summative. Formative process refers to a strong alignment of transparency and accountability through mandatory accreditation and strong internal quality improvement i.e. external evaluation, monitoring, feedback, and incentives are used. This approach is prevalent in Denmark, Australia and England. Mixed approaches combine mandatory inspection with voluntary accreditation, thus limiting accountability. Such systems can be found in Israel, Japan, Portugal, Korea, and Turkey. Summative approach consists of one-time assessments with little repercussion e.g. in Czech Republic, Norway, Italy, Sweden, Northern Ireland, Scotland, and Wales (OECD, 2017[69]). Similarly, integrity and the ability to promote a blame-free culture depends on how accountability is implemented. In cases where accountability largely stems from litigation and judicial tools, it is difficult to encourage culture of transparency and learning. This means there also has to be an alignment between the different levels of governance i.e. managers and leaders on the clinical, organisational as well as the system level; all promote a culture of learning

190. The OECD emphasised in previous work the need for quality governance to focus on using transparency to steer performance through using plan-do-study-act cycles, a dynamic approach centred continuous feedback, learning and improvement (2017[69]) (Figure 4.3). The four steps entail; identifying what needs to be improved (plan): execute the plan while documenting observations (do); conduct analysis and interpret results (study); adopt the change, re-run the cycle or build changes into a new cycle (act) (Taylor et al., 2014[150]). In Norway, the 2017 Regulation for Leadership and Quality Improvement in Health and Care Services is based on the principles of the plan-do-study-act cycle (Lovdata, 2017[151]).

Figure 4.3. Plan-do-study-act cycle adapted to safety governance for continuous learning and improvement



Source: (Tague, 2005[152])

191. Adapted to the safety setting, the approach can be used to monitor existing functions or planned small-scale interventions e.g. a reporting followed by studying the outcomes and impact achieved. Based on the input, the next cycle of testing or full implementation follows (ACT Academy, 2018[153]). The plan-do-study-act cycle in patient safety should study the combined effect of functions to assess the alignment and compatibility of actions and adjust if necessary. In order to learn from the process, safety indicators must be developed, collected, made available, analysed and corrective measures taken to achieve continuous learning and improvement.

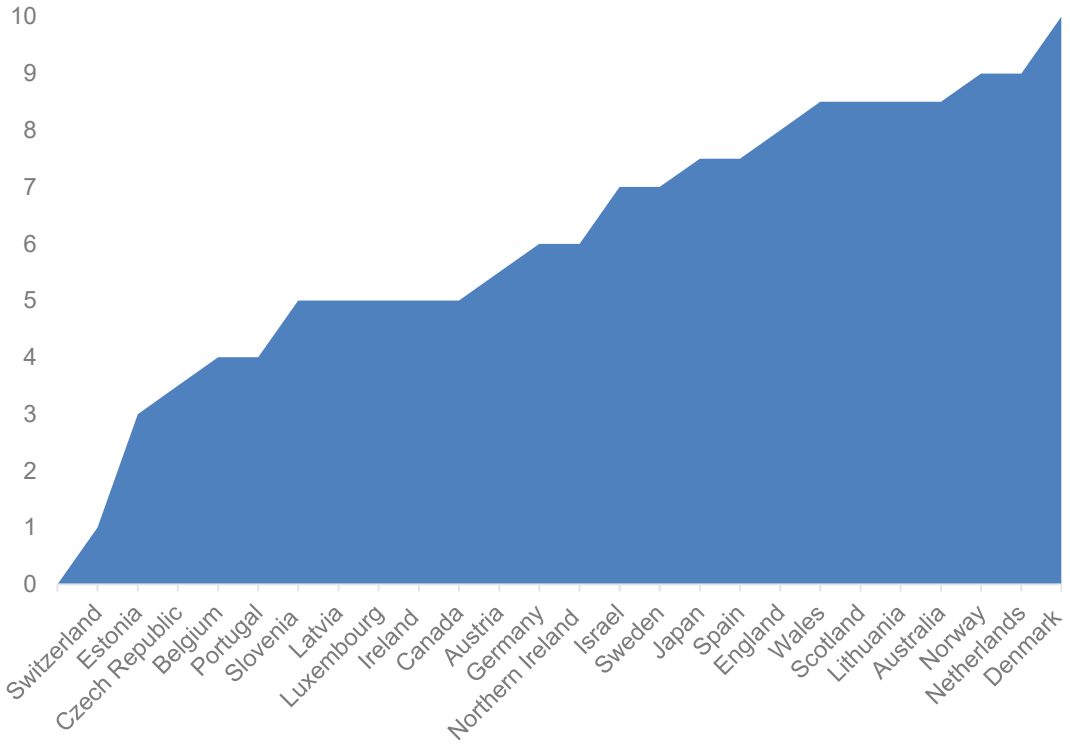
192. To maximise effectiveness, patient safety governance functions have to be aligned in three ways. First, functions are aligned across domains in order to contribute to feedback and learning. Second, functions are aligned across the different levels of care i.e. the clinical, organisational/institutional and system, in order to coordinate activities. Third, alignment of safety governance functions also extends beyond the healthcare setting and into other policy areas. For example, data governance and privacy considerations, workforce planning and education and training.

Alignment of governance functions across domains - do the pieces of the puzzle fit together?

193. Out of the three levels of alignment, the first explores whether the functions are interlinked across domains. For example, are national standards linked to the development of a set of safety indicators that are frequently collected and used for either internal improvement or external accreditation, inspection or audits of patient safety processes or outcomes?

194. Whether alignment exists, and across which domains, was measured by the following modalities and corresponding scores: yes (score=1), to a certain extent (score=0,5) and no (score=0). With a maximum attainable score of 10, Denmark is the only country among the survey responders with a maximum score. Norway and the Netherlands both reported alignment of functions corresponding to a score of 9. While the Netherlands report no alignment between functions in systems for measurement and monitoring and capacity building (2&4), Norway has fully aligned functions across all domains, but functions are aligned only to a certain extent between key accountabilities and systems for measurement and monitoring as well as capacity-building (2&3 and 3&4) (Figure 4.4).The majority of responding countries, however, report to have functions aligned across domains to a certain extent, for example Canada, Ireland, Slovenia and Luxembourg. Poor alignment is indicated by Switzerland, Estonia and Czech Republic, and the respondents highlight fragmentation of system governance and service delivery as the main reasons for limited or lacking alignment of different governance functions.

Figure 4.4. Alignment of patient safety governance functions in OECD countries

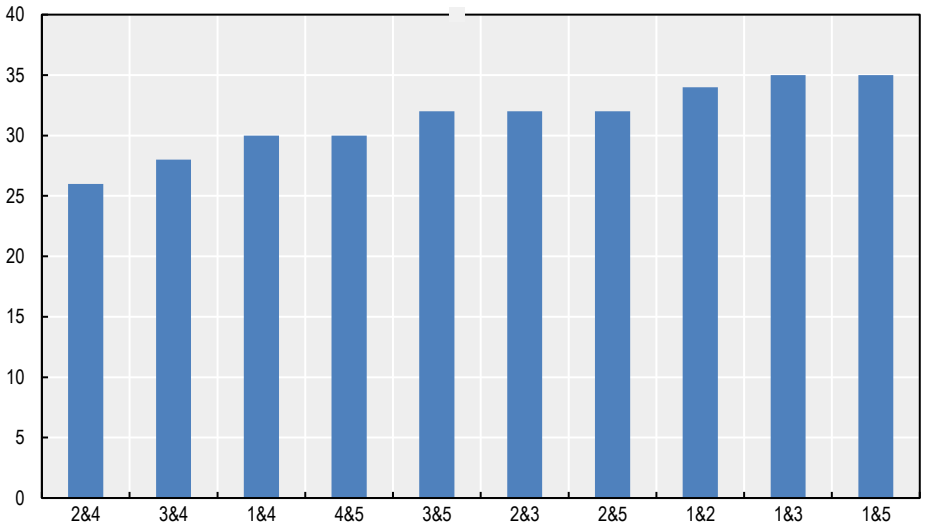


Note: 25 respondents
Source: 2019 OECD Patient Safety Governance Survey

Functions that clearly define roles and responsibilities are the corner stone of governance models in OECD countries

195. Functions ensuring clearly defined roles and responsibilities are most frequently aligned with other functions. Half of the responding countries have fully aligned functions ensuring clearly defined roles and responsibilities with involvement of key stakeholders, followed by key accountabilities and systems for measuring and monitoring (Figure 4.5). Alignments most frequently exist to a certain extent between systems for measuring and monitoring progress, capacity building and key accountabilities as well as involvement of key stakeholders.

Figure 4.5. Frequency of alignment of functions



Note: Scores calculated by assigning 2 points to functions that are fully aligned, 1 points to functions that are partly aligned, 0 points to no alignment. Max possible score indicating for alignment for all responding countries is 48.
1: Clearly defined roles and responsibilities; 2. Systems for measuring and monitoring patient safety; 3. Key accountabilities; 4. Capacity-building; 5. Involvement of key stakeholders.
25 country responses.
Source: 2019 OECD Patient Safety Governance Survey

196. Particularly strong alignments are found between the domains *clearly defined roles and responsibilities* and *systems for monitoring and measuring patient safety*. In Austria, for example, one of the leading principles of Health Care Reform (Zielsteuerung-Gesundheit) is to ensure alignment of the national legislation, through the Federal Health Care Quality Act and Quality Strategy and functions under measurement and monitoring. Similar strong links are reported from Australia, Canada and Sweden where national safety standards are closely linked systems for measurement and monitoring of safety and performance indicators.

197. Governance functions in the domain of *clearly defined roles and responsibilities* at the system level are also often strongly aligned with internal monitoring of patient safety indicators for continuous improvement and external accreditation or inspection of patient safety processes and outcomes. In Japan, for example, the risk management structure for patient safety is clearly defined in the Medical Care Act and the implementation of the risk management is monitored through on-site inspection. In Norway, the alignment of these functions extends across different levels of care. Every year the Ministry of Health and Care Services defines the goals for reduction of adverse events in letter of intent sent to the regional health authorities. The national system for measurement and training of reviewer teams are set up in all hospitals throughout the country. National-level quality and safety indicators are published in a White Paper and presented to the parliament as well as made available to the general public. In England, the National Quality Board provides a forum where the key NHS oversight organisations come together regionally and nationally to share intelligence, agree action and monitor overall assurance on quality and safety. It publishes national guidance where appropriate, for example on safe staffing and learning from deaths. At the regional level, the NHS England and NHS Improvement integrated regional teams play a key role in monitoring the quality, including safety, of services in the region.

Capacity-building functions implemented to ensure right skills and competencies are less frequently aligned with other domains

198. This report previously established that capacity-building to ensure right skills and competences are among the most frequently implemented functions across surveyed countries. Nevertheless, incorporating safety in curricula of students, ongoing training of professionals and promoting patient safety culture at the management level are the functions least likely to be aligned with other functions. The survey results further indicate that where there is alignment between capacity-building and other functions, the links are relatively weak. Poor alignment is exacerbated by unclear roles and responsibilities or lack of accountability structures ensuring compliance with capacity building functions. Norway is one of the countries where bridging the gap between the health system and the educational institutions in charge of developing curricula is listed as one of the key challenges. To meet this challenge, four ministries including the Ministry of Health and Care Services and the Ministry of Education and Research joined forces in restructuring the National Curriculum Regulations for Health and Welfare Educational (RETHOS). The aim of RETHOS is to develop curricula that reflect the health care needs and feed into the continuous work on quality and safety improvement. Israel also reports that integrating safety in education programmes and overall governance model remain underdeveloped, while the German government is actively engaging with stakeholders at state and university level to incorporate international best practices in planning and training courses.

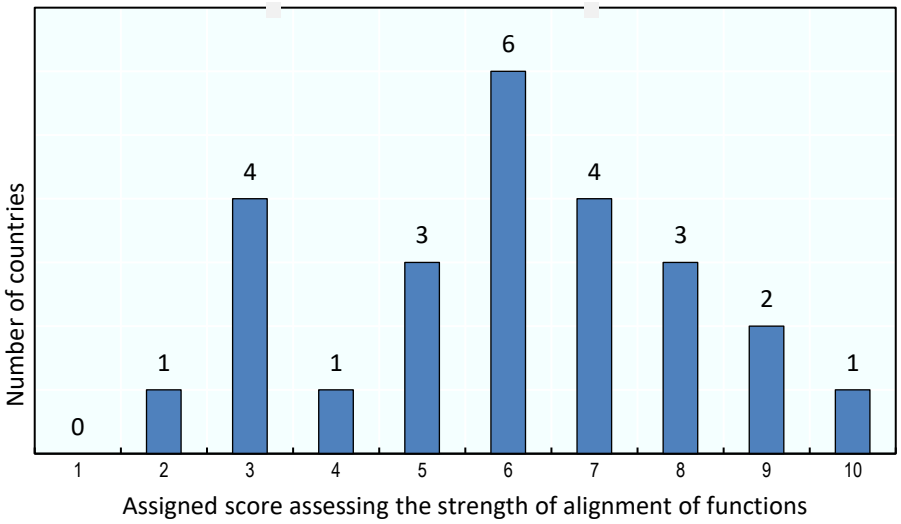
199. Links between functions involvement of stakeholders, both political leadership as well as patients, appears to be of weaker character. Even in the presence of strong legislation and policy support to include patients and the public in monitoring and developing safety and quality metrics, there is room for improvement in many countries. Involvement of political leadership remains a challenge in many health systems, particularly in those where functions for measuring and monitoring safety are not aligned to inform government and formal decision-makers about the status of safety within the health system.

Strength of alignment – how well do the pieces of the puzzle fit together?

200. While the extent to which alignments exist says something about whether the pieces of the puzzle fit together, it does not say anything about how well. To get a general idea of how survey respondents perceived the strength of alignments, or interlinkages, across domains, they were asked to assess the strength of how functions were aligned across the five domains of safety governance on a scale from one (major room for improvement) to ten (no room for improvement).

201. The responses revealed a very diverse picture (Figure 4.6). Reporting an overall mean score of 5,96 (median score = 6), the outliers share some common characteristics. Experts associating the alignment of functions across domains with a score above the median, for example Australia, Denmark England and Spain, have implemented governance functions that clearly define roles and responsibilities of all stakeholders, which in turn facilitates alignment of functions in other domains, e.g. linking quality and safety monitoring to legislation.

Figure 4.6. Experts' assessment of the strength of alignment of governance functions



Notes: 25 responding countries. Score of 0 corresponds to major room for improvement. Score of 10 corresponds to no room for improvement.
Source: 2019 OECD Patient Safety Governance Survey

202. The experts assessing the alignment to be below the median score point out that decentralisation of decision-making powers and fragmentation of care delivery act as barriers to aligning functions across different domains. In Germany, the strong divide between ambulatory and hospital care complicates alignment of functions across domains. More recently, Belgium passed in 2014 the 6th Reform of State that shifted responsibilities for some aspects of the healthcare system, e.g. organisation and delivery of care, from the federal to the regional authorities. While the responsibilities for core activities, e.g. financing and licensing of healthcare personnel, remained at the federal level, the decentralisation of care organisation blurred the strategic vision and the lines of responsibilities in activities related to quality safety in the health system as a whole. Reporting similar challenges with system fragmentation, Israel found that developing data infrastructure and investing in health digitalisation contributed to an improvement of alignment.

203. A recent report (Vincent and Staines, 2019[87]) acknowledged that little is known about the standards of quality and safety of health care in Switzerland. This is largely due to the complex structure of the Swiss health system, which causes inconsistencies and difficulties in identifying the roles and responsibilities of overseeing safety activities, or to launch system-wide safety improvement strategies. More can be done to strengthen patient safety in the Swiss health system and the report further sets out a set of recommendations for short, medium and long term. Recently, the Swiss Federal Government revised quality and safety legislation, defined national goals for quality improvement and established a Federal Quality Commission. These efforts resonate with some of the recommendations (Box 4.3).

Box 4.3.Patient safety governance in Switzerland

Revision of the Health Insurance Act: improving quality and cost effectiveness

On the 21 of June 2019, the Federal Parliament approved the partial revision of the Health Insurance Act to improve quality and efficiency. The revision addresses four-year national goals, the establishment of an extra-parliamentary Federal Quality Commission and the conclusion of quality agreements between federations of healthcare providers and insurers.

The goals of the Federal Council concerning quality improvement:

The Federal Council determines for a four-year period the national goals to promote the quality of care and quality development after having consulted the relevant organisations. The objectives can be adapted during the four-year period if any significant changes occur.

Extra-parliamentary Federal Quality Commission:

The Federal Council will elect the members of an extra-parliamentary Federal Quality Commission to support the Federal Council in improving the quality of healthcare. Cantons, healthcare providers, insurers, insured persons, patient organisations and specialists in quality improvement will have representatives in this Commission. This Commission will start its activities in 2021.

The Commission will be responsible to reach the four years quality goals of the Federal Council. It advises the Federal Council, the cantons, healthcare providers and the insurers on how to coordinate the activities to develop quality. Besides this advisory task, it will also mandate third parties to implement nationwide quality development programs or to perform systematic studies. The Commission will also decide on the allocation of financial support to national or regional quality improvement projects.

Quality Agreements

The revision of the Health Insurance Act shifts focus onto quality agreements. The federations of healthcare providers and insurers will conclude those quality agreements that will be mandatory country-wide. The purpose is to enforce the implementation of quality measures and ensure compliance. The agreements will describe how the stakeholders will work together to develop and improve quality, what minimal standards to apply, and how controls will be made. Annual reports will be submitted to the Commission and the Federal Council.

Patient Safety

Regarding Patient Safety, the new law states explicitly that the national programs must target the identification, analysis and reduction of risks associated with care. To achieve this goal, the Federal Quality Commission will fall back on organizations and experts with the necessary knowledge.

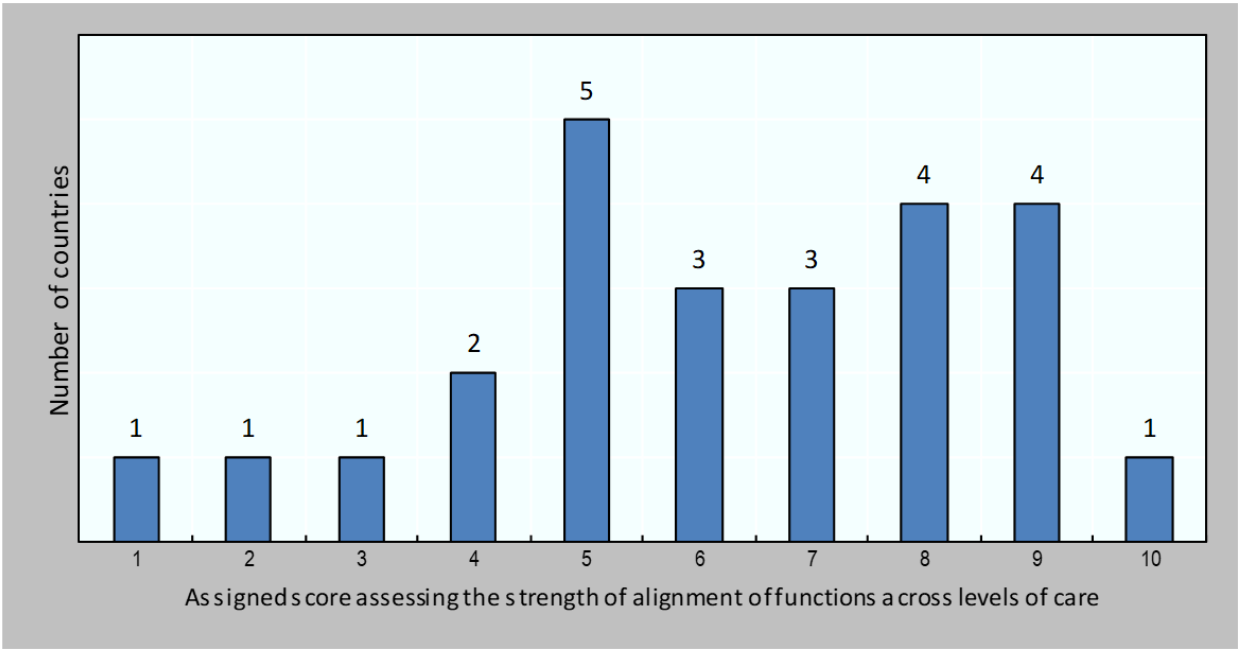
Source: Expert consultation with Switzerland

Alignment of governance functions across levels of care remains a challenge

204. The second level of alignment refers to the governance functions' alignment across levels of care. While functions aligned across domains contribute to building a governance model, dynamic governance models strive to align functions across different levels of care. Respondents were asked to assess the extent to which governance functions extended across system to organisational and clinical level within their health system. The responses point towards generally strong governance models, but some health systems identify a clear need for improvement (Figure 4.7). Similar to other assessment exercises in this

survey, the responses indicate a clear divide between health systems with a more national approach to system governance and those characterised by system fragmentation and care delivery.

Figure 4.7. Experts' assessment of alignment of governance functions across levels of care



Note: 25 responding countries. Score of 0 corresponds to major room for improvement. Score of 10 corresponds to no room for improvement.
Source:2019 OECD Patient Safety Governance Survey

205. Health systems reporting the highest ability to achieve cross-level governance are those having implemented most of the governance functions in Table 4.1, for example Denmark, Netherlands, Norway and Japan. Another characteristic of these health systems is the defined, system-level strategic vision for safety. The recently published NHS Patient Safety Strategy provides a single aligned vision for patient safety in the NHS across all levels of the system (Box 4.4). Similarly in Wales, safety legislation is supported by the national performance oversight and safety surveillance, supported by national independent inspectorate and patient voice body. In Scotland, the data collection develops an understanding and awareness at the clinical level which further identifies areas for improvement, capacity-building. At the organisational level, the cultural focus on openness and learning support continuous development of safety improvement strategies and maintains the momentum.

Box 4.4. NHS Patient Safety Strategy provides a single, aligned vision for patient safety in NHS England

Cross-level alignment promoted by linking inspection against national standards and stakeholder involvement

The Care Quality Commission (CQC) provides a common thread through its inspection of providers against national standards, supported by the operational activities of NHS England and NHS Improvement and supported by relevant stakeholder organisations. A single oversight framework is in place across NHS England and NHS Improvement, aligned with CQC standards and penetrating through regional teams into the operation of providers and their sub-organisational divisions and units. Greater coherence and alignment across the system has emanated from the reforms implemented as a result of the Mid Staffordshire Inquiry.

This promotes a focus on the systems approach to patient safety, supported by strong safety cultures, and supports work on further understanding where care is safe and not safe and why. Full involvement of clinicians, managers, patients and the public is key, supported by appropriate training, education and knowledge sharing, and using a consistent approach to tackling key safety concerns using the principles of safety science and quality improvement methodologies.

The NHS Patient Safety Strategy – Safer Culture, Safer Systems, Safer Patients

The new strategy of the NHS focuses on improving patient safety systems and patient safety culture, taking a macro approach to patient safety governance. The strategy outlines three aims – insight, involvement and improvement, respectively referring to improving the understanding of safety by drawing intelligence from sources of patient safety information, equipping patients, staff and partners wits skills an opportunities to improve patient safety throughout the whole system, and designing and supporting programmes that deliver effective and sustainable change in the most important areas. Among other insight activities, the NHS intends to promote culture measurement, use digital technologies for designing a learning system, and share insights from litigation for harm prevention. Involvement policies include creating the first system-wide and consistent patient safety syllabus, training and education framework for the NHS as well as ensuring learning from what goes well. Improvement dimension focuses on delivering programmes on neonatal safety, medication safety, mental health safety and supporting research and innovation for patient safety improvement.

Source: Expert consultations and (NHS England and NHS Improvement, 2019[154])

206. The feasibility of achieving across-level alignment and taking a system-wide approach to safety governance depends on the system governance structure. Health systems considering cross-level alignment as a weakness often have a high degree of decentralisation with insurance-based coverage, e.g. Austria, Belgium, the Czech Republic and Estonia. In Germany, the decentralised structure combined with high numbers of autonomous healthcare-providing organisations complicates alignment of safety governance functions across levels of care. A complex governance model also reduces cross-level alignment in Canada, with health system governance is the responsibility of the thirteen territories and provinces. Large variations are observed at the province level where the same legislation guiding practice both poor and strong performance can be seen when it comes to patient safety governance and patient safety outcomes.

207. Having already identified the room for improvement, Ireland and Luxembourg are actively implementing measures to improve cross-level alignment. Ireland has already implemented its national

monitoring system of hospital and community services, which has impacted the development of safety processes. In Luxembourg, increased transparency around safety activities and patient safety outcomes as well as accountability of healthcare providers is expected to strengthen safety governance.

Broadening governance functions to other policy areas will strengthen safety in the future

208. The third and last level of alignment broadens to include other policy areas and whether they are developed in a way that puts safety first. There is little attention devoted to the relationship of patient safety activities and governance with other policy fields and priorities e.g. data privacy, IT-system development, health workforce planning, personalised health care, introduction of technological innovations or financing reforms, despite the great influence that competing interests have on system level governance.

209. Datasets on safety and quality outcomes are to be considered a goldmine in patient safety improvement work. However, many countries are prevented from collecting and/or using patient-level data due to legislative or technical barriers. The Nordic countries are among the countries that have overcome these barriers and have long track records in using national databases and quality registries with patient-level data for research and quality improvement. In Denmark, for instance, there are more than 100 national registries in healthcare. National clinical registries record data in relation to patient pathways, diagnostics, treatment, care, and outcomes, thus, enabling a comprehensive overview to uncover adverse events (Mainz, Hess and Johnsen, 2019[155]). Mainz et al. (2019[155]) have noted that recording of data is generally accepted by Danish residents since it has been mandatory for nearly 100 years and people have grown accustomed to it.

210. Health innovations and new technologies are presented to the market at a rapid pace, while health budgets are under pressure and efforts to increase health system efficiency is high on policy agendas at the OECD. The extent to which patient safety concerns are taken into account in the development of governance functions of the system, e.g. safety of new technologies, is unclear and remain a challenge in many health systems.

211. All these developments have an impact on the implementation of safety, but they are usually considered in isolation. Privacy and data-security policies may hamper data linkage that might have been beneficial for patient safety. Workforce shortages of nurses may lead to substitution of task to nursing aids or, as is often the case with long-term care, to family, which imposes new safety risks. Technological innovations may hold the potential for enhancing effectiveness of care but may also pose new safety risks that need handling. Through its design and policies the system has influence on how safety risks are assessed and handled and therefore safety governance has a much broader scope than only facilitating the correct clinical handling of a series of risks associated with hospital care.

212. Consequently, it is key that patient safety governance considers the implications on other policy areas and evaluates risks and potential gains. The balance between competing objectives could be found by adopting special legislation or regulations that limit the potential damages. In the United Kingdom, legislation has been adjusted to allow health information to be collected, stored securely, and used to deliver safe and high-quality health care. In Turkey, patient records are maintained with a single identification number and patients can access their data to pick the institutions to share it with (OECD, 2017[69])

Adapting safety governance functions to the TAPIC framework – how does health compare to other high reliability industries?

213. Patient safety governance in the OECD largely draws from the TAPIC framework that emphasises the role of transparency, accountability, participation, integrity, and capacity building in good governance. As discussed above, applied to patient safety, TAPIC produced five pillars of governance (1) encouraging transparency and information sharing, (2) ensuring accountability, (3) encouraging participation, (4) upholding integrity through effective leadership facilitating a culture of safety, and (5) building capacity. While often having a complementary effect, it can roughly be said that the domains of governance explored in the OECD survey on patient safety governance each mainly contribute to one pillar of patient safety governance under the TAPIC framework. Hence, *transparency* is achieved by the functions related to *measurement and reporting, accountability* overlaps with the domain of *key accountabilities*, *participation* is encouraged through functions related to *stakeholder involvement*, *integrity* is upheld by functions related to *roles and responsibilities* and finally, *capacity* overlaps with the functions related to *capacity and skills development* (see Table 4.7)

Table 4.7. Patient safety governance functions within the TAPIC framework

TRANSPARENCY	ACCOUNTABILITY	PARTICIPATION	INTEGRITY	CAPACITY
2.1 National set of indicators supporting safety standards have been established	3.1 Provider financial incentives and/or penalties applied to promote and ensure safety	5.1 System-level report on patient safety by national agency responsible for quality and safety to government	1.1 National legislation on quality and safety	4.1 Safety competencies built into curriculum of students
2.2 Internal monitoring of patient safety for continuous improvement	3.2 Routine public reporting of patient safety indicators and performance	5.2 Healthcare-providing organisations integrating clinical governance with corporate governance	1.2 National quality and safety agency	4.2 Ongoing training as part of professional development of health care personnel
2.3 External accreditation, inspection or audit patient safety processes and outcomes	3.3 Contracting and/or commissioning arrangements include safety requirements	5.3 Patient representation in official roles and decision-making processes	1.3 National safety standards	4.3 Leadership and management development to promote a patient safety culture
			1.4 National patient safety programme	

Source: 2019 OECD Patient Safety Governance Survey

214. As in other high risk industries, safety governance in health care is simultaneously targeting several aspects of care provision that increase safety. Governance functions associated with all pillars of TAPIC are widely prevalent but their extent and alignment to other governance functions differs. Mirroring what happens in other sectors, health care has put great emphasis on transparency. Similar to the permissioning[6] systems in the energy sector, patient safety relies on external accreditation and inspection – it is the most widely implemented governance function in the OECD. The majority of countries have established national patient safety indicators for enhancing transparency regarding care quality. In patient safety, the main objective is not compliance with top-down regulation as is often the case in energy, but rather learning and improvement. Several countries mention building a culture of learning has been their

[6] Please find more information on permissioning systems in the energy sector on p 32

aim in designing their governance model or is the current goal for further developments in the domain of patient safety.

215. While accountability and financial incentives are among the key drivers of safety governance in high-risk sectors, they are relatively weak points in patient safety governance in the OECD. The link between transparency and accountability differs between countries e.g. whether safety indicators are reported internally or to the national level, whether they are public or not, or whether accreditation is voluntary or mandatory. Accountability corresponds to least implemented governance functions and can be a challenge in countries where the state is not directly engaged in the provision or commissioning of health care. Financial incentives have been implemented in some countries but have been discontinued or not produced expected benefits. The lack of accountability has a direct effect on the ability of transparency increasing activities to produce tangible changes.

216. The pillar of integrity is witnessing similar trends in health care and other high-risk industries. On the one hand, health care is increasingly regulated. On the other hand, there are trends of moving towards more self-governance and meta-regulation in some parts of the energy sector. In both, meta-regulation through standard-setting is gaining in prevalence. The softer dimension of integrity is likewise similar: culture of safety is the new prevailing paradigm in safety governance and even if not yet always the reality in the health sector, the awareness and direction towards it is widely spread. Similarly, participation is the governance pillar with less uptake but is gaining attention and seems to be more salient in health care compared to other industries as it is the medium-term objective of several surveyed countries. Capacity building is a crucial pillar of safety governance in health care as well as other industries, especially those more complex and less apt for standardisation.

An incremental road to safety governance – country experiences in developing and implementing safety in governance functions

217. Governance models come in different shapes and sizes and are often a result of implementation over time, building on previous efforts and experiences. Over the last ten years, patient safety governance in OECD has largely concentrated on establishing legislative frameworks for quality and safety and setting up incident reporting systems. In some countries, the focus has mainly been on capacity building and training of medical professionals or patient safety culture. Legislative activities have focused on quality and safety strategies, mandatory requirements subjected to inspection, or adoption of frameworks establishing the roles and responsibilities of different actors.

218. Reporting safety incidents has been a high priority across OECD. It has been incentivised by financial tools, promoted through professional standards or protection of reporting staff. Often, transparency in reporting is part of capacity building and awareness raising in education and training of professionals. While rarely implemented, a few countries, like Canada, have specially targeted the training and capacity building of healthcare boards and management. Recent trends indicate a greater attention to patient safety culture that is starting to get measured and stimulated by a focus on learning programmes. In Norway, for example, hospital staff is surveyed on work environment and patient safety culture every year.

219. The Patient Safety Governance Survey asked countries to report on experiences in implementing and establishing safety governance functions and key enablers and barriers encountered in building safety into their governance models. Studying safety governance through the lens of low- and middle income countries, key information is included from Ghana and Malaysia (Box 4.5 and Box 4.6). This section aims to point out key experiences in building governance models in the past as well as the next steps. What does the future hold for patient safety governance?

Box 4.5. Patient safety governance in low- to-middle income countries: Ghana

Inconsistencies in the level of safety governance across the country

In Ghana, patient safety continues to evolve as an emerging area in health care, which is tightly linked to quality governance. Ghana reports to having implemented nine of the sixteen governance functions covered in the survey and patient safety is embedded in the National Quality Strategy of Ghana. A National Quality Technical Committee composed of technical members nominated by the heads of Agencies, and representatives of Patient groups, Civil Society Organisations, Coalitions of NGOs in Health, Consumer Protection Agency is chaired by the Chief Director and operationally led by the Director, Policy, Planning, Monitoring and Evaluation. They meet every quarter to address technical issues in quality and safety and issues recommendations to the Inter-Agency leadership Committee, which is chaired by the Minister of Health for consideration. As proposed by Objective 3 of the National Healthcare Quality Strategy (NHQS), patients are encouraged to be active participants in their care, thus Patient safety awareness programmes are carried out and safety agenda is gaining increasing attention among the providers and professionals. Currently, inequalities in the level of safety governance exist across the country as there are some strong examples and devoted clinicians in the system as well as attention, which has only arisen recently. Bottom-up and top-down approaches are used simultaneously and they are tied into a feedback loop by using the community scorecard as an accountability tool.

Increasing the accountability and capacity of the health system

Ghana is working to close the gaps in its health system. There is no specific legislation or agency for patient safety, however, the right to health is stated in the constitution and the Ministry of Health has a specialised Unit for Quality Management. Safety is governed by the Accountability Framework for national Healthcare Quality Strategy, indicators, and district peer review tools. Yet, patient safety indicators are not yet implemented across the entire health sector. External accreditation and inspections have only been started in some facilities. Supportive supervision guidelines and checklists have been developed for internal monitoring of patient safety.

There is no strong accountability system in patient safety in Ghana and governance functions regarding stakeholder involvement are embedded in the quality governance structure. Financial incentives are being tested but are not fully operational. Similarly, public reporting of performance indicators and contracting agreements which include safety requirements are currently being explored. As part of capacity-building for health care professionals, including nurses, midwives, doctors, dentists, pharmacists, allied health care personnel, there are Continuous Professional Development (CPD) in quality and safety organised by various agencies and institutions in charge of quality and safety. These CPDs are accredited for renewal of professional licenses. One critical milestone is working with stakeholders to make quality and safety training mandatory for renewal of license. Currently, Ghana is working with stakeholders to incorporate comprehensive safety competencies into the curriculum of trainee health professionals, which, so far, is only covered in some aspects.

Source: 2019 OECD Patient Safety Governance Survey

Political leadership is the key enabler to developing and implementing safety governance functions

220. System level governance is essential for continuously improving patient safety. Political leadership and involvement of key stakeholders are key enabling factors to patient safety governance functions. Leadership and political will to put patient safety on the national agenda have driven patient safety improvements in OECD. While consistent system-level effort in monitoring and reporting have a direct effect on the quality of health care, national level focus also enables sustainable funding and resources needed for capacity building. At the same time, respondents outline that patient safety governance can be sustained if there is a cultural change towards patient safety, involvement of key stakeholders is therefore crucial to raise public awareness and gain the support from professional associations that are implementing governance on the ground.

Box 4.6. Patient safety governance in low- to-middle income countries: Malaysia

Macro-level approach to governance, with focus on internal monitoring and involvement of key stakeholders

Patient safety is relatively strong in Malaysia at all levels of governance. At the system level, Patient Safety Council of Malaysia, established in 2003, is composed of representatives from public and private health sector, associations, academic institutions, professional bodies and patient representatives. At the organisational level, healthcare facilities have Patient Safety Committees to evaluate risks and improve safety. There are also other committees, including Incident Reporting Committee, Safe Surgery Saves Lives Committee and Medication Safety Committee. At the clinical level, safety governance depends more on individual staff. However, Ministry of Health has been promoting institutionalising patient safety extensively to all health leaders, administrators, clinicians, paramedics and junior staff. Currently patient safety initiatives are more prevalent in hospitals than in primary care.

Malaysia implements 13 out of the 16 governance functions in the survey. The alignment between different governance domains in Malaysia is assessed as relatively strong. Currently, there is no designated agency for patient safety, but a specialised Patient Safety Unit under in the Ministry of Health was established in 2011. In 2013, Malaysian Patient Safety Goals were established to identify priority areas and serve as a benchmark for private and public healthcare providers. Incident Reporting and Learning System is set up as well as Risk Reduction Strategies. Following an adverse event, root-cause-analysis are conducted and risk reduction strategies are implemented. Patient safety is emphasised in accreditation schemes, carried out by Malaysian Society for Quality in Healthcare.

Accountability functions are still not implemented for safety governance purposes, but safety training is integrated in curricula and courses for managers

While capacity building is central to patient safety governance in Malaysia, accountability specified by law is still not in place. Nevertheless, the Ministry of Health has developed and implemented a wide range of patient safety policies and guidelines. Patient safety is integrated into curriculum of medical, allied health, and nursing curriculum. Post-graduate Masters of Surgery students have Safety Surgery as part of their programme. . In 2017, Malaysia launched a Mandatory patient Safety Course for House Officers, inspired by the WHO Patient Safety Multiprofessional Curriculum Guide.

Regular training in patient safety is provided to all healthcare professionals, with focus on strategies targeting infection control, AMR, safe surgery, fall prevention, and medication safety etc. Numerous training programmes have been established for hospital leaders as well as policy-makers in the Ministry of Health. For instance, quality and patient safety is part of Leadership Course for Hospital Directors.

In collaboration with an international medical college, the Ministry of Health is developing an online course on patient safety for junior doctors.

Working strategies in patient safety

1) Leadership on patient safety at various levels
2) Promote patient safety among healthcare staff and public
3) National monitoring and surveillance of patient safety performance
4) Patient safety governance structure at the clinical, organisational and system-level
5) Establishing specific policies, programmes, and guidelines based on national monitoring
6) Capacity building - Education on patient safety
7) Collaboration with various stakeholders
8) Engagement and empowerment of patient representatives.

Leadership and patient safety remain the key priorities

The need to focus on leadership, safety culture, and investing in patient safety have been the key lessons from patient safety governance in Malaysia. As in many OECD countries, macro-level governance and high level leadership coupled with the interest of state officials and hospitals have been the key drivers of progress in patient safety. Moreover, the support of the World Health Organization has been an enabler of improving patient safety governance in Malaysia. Challenges have emerged from the fact that there is no special funding for patient safety and allocations are incorporated into the quality programme. Future plans are focused on strengthening the current governance framework and assessing the suitability of establishing a governance structure on the department or unit level.

Source: 2019 OECD Patient Safety Governance Survey

221. The main barriers in progress with patient safety governance are highly linked to the enablers. Therefore, system fragmentation and lack of sustainable commitment and funding can act as obstacles to stronger safety governance. System fragmentation, lack of oversight and data interoperability hamper capturing safety issues beyond hospitals – limiting transparency and learning in the system. Progress is dependent on the quality of the health system in general and is an especially salient issue in federalised states, where the power of the federal government to intervene on the local level is limited. In Austria, system fragmentation is to a certain extent overcome by the establishment of a common understanding of safety and the development of a system-wide Patient Safety Strategy involving all stakeholders.

222. However, not all organisations adequately invest in local quality improvement and assurance. Legal barriers further impede the collection and reporting of patient safety indicators, for instance, in association with data privacy rules that have also hindered the adoption of electronic health records. Moreover, shifting political priorities and competing interest from other improvement programmes, such as general quality or performance can hinder the consistent improvement of health care systems. Building safety into educational programmes is not yet mainstream across the OECD, which is related to the lack of competencies and skills on the frontline as well as in management level. Even when the political will is there, establishing objective standards for patient safety and defining target levels for patient safety can be challenging, especially as different stakeholders can have a different idea of it.

Stakeholder involvement and patient safety culture are the elements for success safety governance

223. Reflecting on countries' experiences of developing and implementing patient safety governance structures, the two main lessons that stand out are *involvement of stakeholders* and building patient safety *culture* of openness that encourages learning.

224. Involving patients and health professionals in developing, implementing and participating in patient safety and quality improvement activities foster cooperation and accountability. In Germany, for example, the Patient Safety Coalition plays a positive role as a platform linking practice, science and governance. Safety remains somewhat also a political domain. In many countries, the public expects the providers and politicians to be held accountable for unsafe care. There is therefore an important role for measuring and monitoring safety and quality outcomes. However, organisations that unduly focus on finance and limited performance measures are at higher risk of failing to provide high quality and safe care.

225. The most effective drivers of patient safety and quality improvement are likely to be a culture of openness that encourages learning and having local capacity to drive safety improvements. These need to be aligned with the adoption of a system approach to patient safety that recognises the importance of designing work in such a way that maximises the ability of staff to operate safely.

Continuous improvement of alignment remains a key priority the next ten years

226. Patient safety governance is an ongoing learning journey where there is always room for improvement and adjustments. While further improvement of already existing governance functions is the main priority in all responding countries, some specific priorities are highlighted. In Spain, where safety governance is assessed strong at the system and organisational level, there is an identified need to further develop the alignment of governance functions across all levels. In a similar vein, Northern Ireland seeks to develop a regional body focused on supporting quality improvement and innovation throughout the health and social care system. As elsewhere in the health sector innovation and digitalisation present great opportunities as well as challenges. Creating a platform for sharing best practices and experiences will also create new grounds for collaboration and improvement.

Shift of paradigms in patient safety governance towards increased trust and openness

227. Policy-makers are faced with a range of different approaches to patient safety governance. For example, whether safety governance is planned and implemented at the national level or the responsibility rests on the shoulders of local health authorities. Another example is whether harm is predominantly met with punishment, command and control, or if there is a culture nurturing trust and learning. There is often neither one nor the other, no right or wrong, but rather a balancing of different approaches. The Patient Safety Governance Survey posed different approaches to respondents, asking them to indicate the approach taken within their respective health systems. The chosen direction provides interesting insights and grounds for identifying future trends in safety governance.

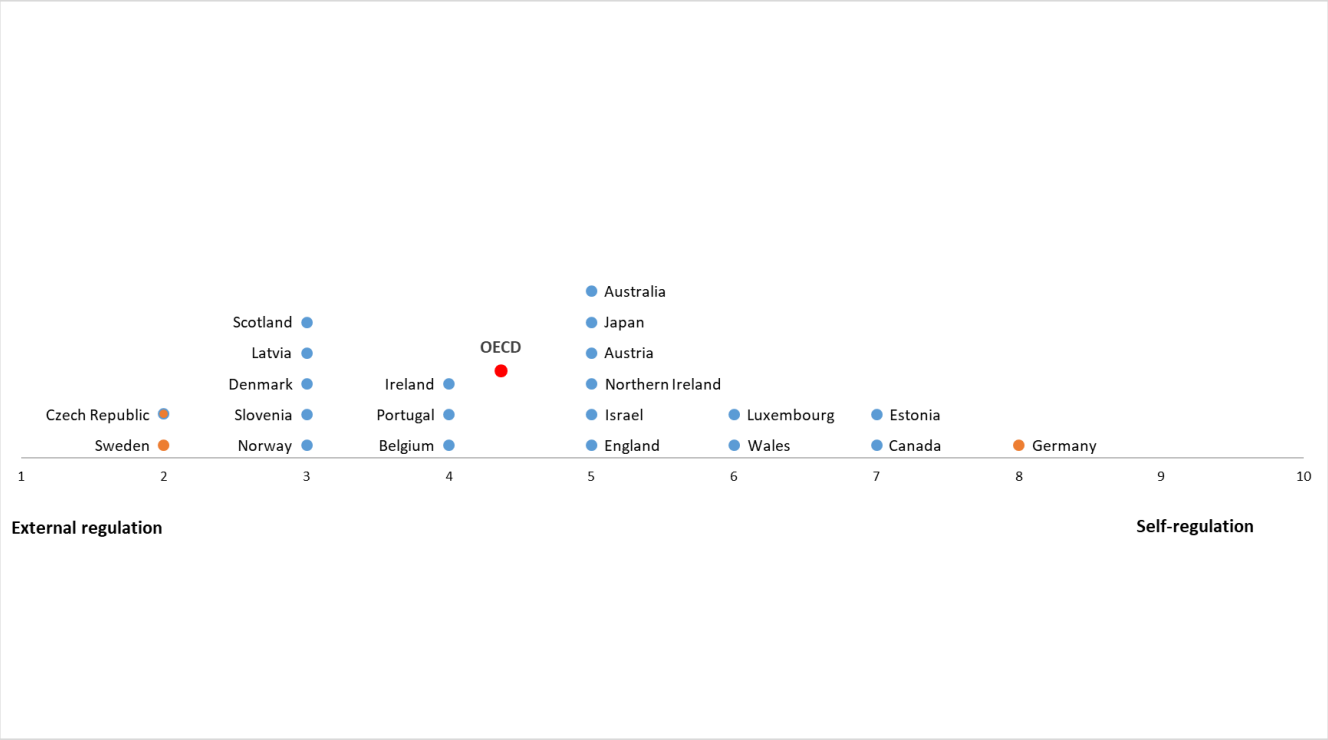
Increased local flexibility, self-regulation and bottom-up initiatives aims to strengthen patient safety governance

228. Finding the delicate balance between top-down and bottom-up, external regulation and self-regulation and national standardisation and local flexibility is a challenge facing all policy-makers. Countries have found different solutions to address the dilemmas between top-down and bottom up measures. Both approaches are necessary and the appropriate balance between them is difficult to assess

since it depends on governance priorities and the political context. For instance, the level where quality monitoring and improvement takes place differs across health systems in OECD countries, some systems mostly rely on central authorities e.g. Czech Republic, England, Turkey whereas others prioritise having the focus on the local level e.g. Italy, Norway, Scotland (OECD, 2017[69]).

229. The 2016 OECD review of health care quality in the UK described a predominantly top-down approach for England, which also applied to patient safety governance (OECD, 2016[156]). Since then, there has been a shift towards a greater recognition of the role of local improvement and a just / learning culture. The recent publication of the NHS Patient Safety Strategy confirms this change towards a more mature and bottom up approach (Box 4.4). More recently, Norway's Action Plan for Patient Safety and Quality Improvement takes decentralisation of safety governance a step further placing the responsibility for developing, implementing and monitoring safety improvement measures on the shoulders of the health services (Box 4.7)

Figure 4.8. Redesigning self-regulation



Note: 21 responding countries, missing score from 4 countries.
Source: 2019 OECD Patient Safety Governance survey

230. In most systems, voluntarism, market mechanisms, self-regulation, meta-regulation, and command and control are all used, in differing configurations and to different extents. For example, in Australia, most governance functions are based on voluntarism and self-regulation. In Finland, standards are set by central government but implemented through self-regulation. In the Netherlands, self-regulation and voluntarism are balanced by meta-regulation (Schweppenstedde et al., 2014[157]).

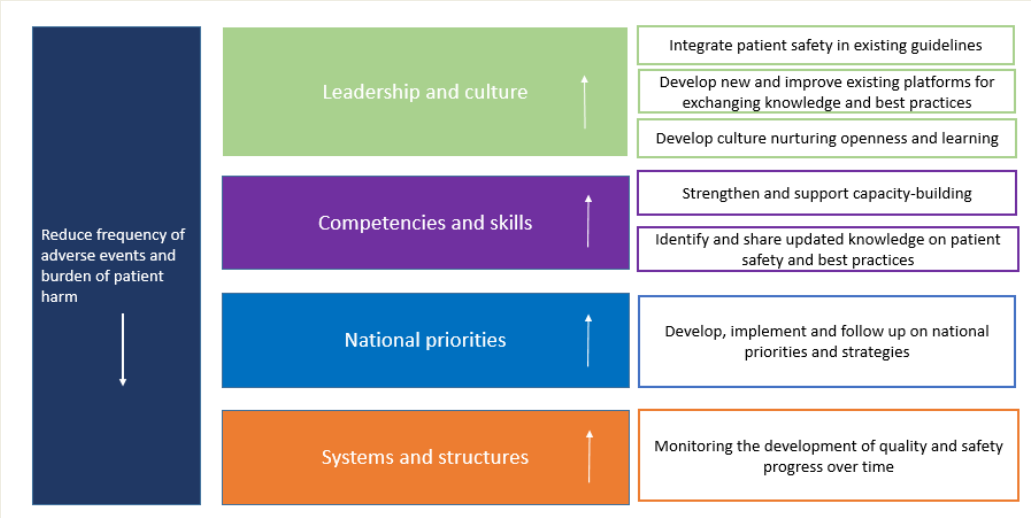
231. Overall, responding countries are leaning slightly towards external regulation, nevertheless, the majority indicate some shifts towards self-regulation (Figure 4.8). In Canada, for example, the health workforce are heavily self-governed and regulators are responsible for creating standards of practice to hold registered members accountable to an expected level of quality and safety. Licensure and re-licensure by regulators are decentralised and occur at a provincial/territorial level. In Germany, the development and

enforcement of indicator sets concerning quality of care lies in the hands of the Federal Joint Committee, which consists of health insurances and healthcare providers organisations. Patient organisations and regional governments have advisory rights and take an active part in the decision-making process of the Federal Joint Committee. The Federal Ministry of Health has the function of legal supervision, i.e. it is allowed to check for the abidance by the general law.

Box 4.7. Norway takes a huge leap towards local flexibility in new national action plan

Patient safety is a long-standing priority in the Norwegian health system, which is demonstrated by the number of governance functions and clearly defined roles at the national level. Patient safety regulations have changed markedly in recent years, notably in the shift in responsibilities from the national level to the regional health authorities. In 2017, the Law for Internal Control for Health Services was replaced by the Regulation for Leadership and Quality Improvements in Health. The new regulation defines the Regional Health Authorities', hospitals' and municipalities' legal duty to "work systematically with quality improvement and patient safety across all levels of care" and responsibility to document the planning, implementation, evaluation and corrections taken to improve quality of care and patient safety.

Patients' rights to safe care is embedded in national legislation, while the Directorate of Health is the national agency responsible for safety and quality within the Norwegian healthcare system. The National Patient Safety Programme was discontinued from 2018 and replaced by the new National Action Plan for Patient Safety and Quality Improvement (2019-2023). Based on experiences from the National Patient Safety Programme (2014-2018) and the patient safety campaign In Safe Hands (2011-2013), the Action Plan defines four broad principles; Leadership & Culture, Competences and Skills, National Priorities for Quality and Safety, System & Structures. Each of the principles are supported by national-level measurements of different patient safety indicators, including harm and patient safety culture. It is up to the Regional Health Authorities, hospitals and municipalities to further define and adapt the safety indicators to the local context.



Source: Adapted from (Norwegian Directorate of Health, 2019[158]), https://lovdata.no/dokument/NL/lov/1999-07-02-61/KAPITTEL_3#%C2%A73-3a (accessed 15/10/2019)

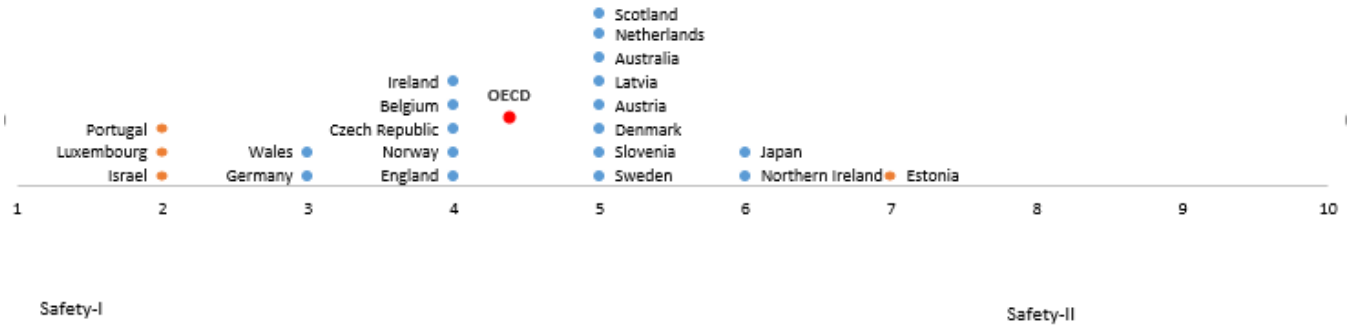
Do governance models allow health systems to learn from the near misses?

232. Governance can take a reactive or a proactive approach to patient safety. It involves the trade-off between investment in prevention versus costs of compensating adverse events, and assessing risks versus assessing harm by balancing Safety-I and Safety-II.

233. Survey responses reveal a strong trend broadening the focus from Safety I to increasingly adopting principles from Safety II, although barriers are blocking or slowing down this shift in some countries (Figure 4.9). In Estonia, for example, the legislation acts as a barrier to learning from harm as it does not

take blame-free culture philosophy into account. In Ireland, the health service has traditionally adopted a more reactive approach to managing risk. However, risk managements procedures have been in place for several years and the current HSE Risk Management Review 2019 proposes a range of actions to anticipate and manage risk in a more proactive way.

Figure 4.9. Broadening slowly, but surely from Safety I to Safety II



Note: 21 responding countries, missing score from 4 countries.
Source: 2019 OECD Patient Safety Governance Survey

234. Risk assessment and harm assessment can also be implemented in parallel, i.e. by encouraging complimentary use of Safety-I and Safety –II. In the Netherlands, in addition to phased supervision, the Health Care Inspectorate (IGZ) also enforces theme-based supervision i.e. preventative supervision that focuses on a single aspect of care, thus, applying Safety-II. Incident supervision applying Safety-I, on the other hand, is more prescriptive and often results in an intervention (Schweppenstedde et al., 2014[157]).

235. While it is clear investments in prevention are more efficient than covering costs arising from adverse events, risk assessment and harm assessment have to be both embedded into governance systems to combine the strengths of Safety-I and Safety-II.

236. Up to 15% of public hospital spending goes to treating patient harm in OECD countries (Slawomirski, Auraaen and Klazinga, 2017[5]). The failure to provide safe care dwarfs the cost of prevention. Paradoxically, health systems have historically focussed public spending towards covering the costs caused by harm rather than investing in patient safety improvement measures in order to prevent harm from happening. While this is starting to change, it is slow-moving process. Governance functions should therefore be designed with the aim to further facilitate the prevention of adverse events.

237. Another way of taking a proactive approach is risk assessment. It enables the prioritisation of threats that are more likely to happen. In the United Kingdom, the Care Quality Commission (CQC) adopted a risk-based model for health care quality to target the providers with greatest statistical risk of failures (Beaussier et al., 2016[78]). Similarly, in the Netherlands, IGZ also exercises risk-based phased supervision. Risks are identified based on several quality indicators after which, IGZ can opt to conduct a random site inspection with the possibility of follow-up site visits. In the final stage, the IGZ can intervene through statutory enforcement measures, such as administrative sanctions or penalty measures (Schweppenstedde et al., 2014[157]).

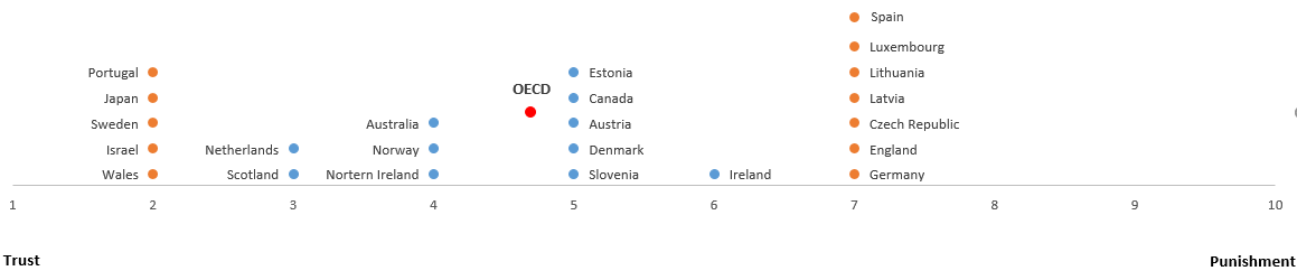
238. However, risk assessment requires clear aims and an understanding of adequate levels for care quality. A qualitative study (Beaussier et al., 2016[78]) including in-depth interviews with 15 high-level informants in the UK underlined several challenges that have undermined the efficiency of risk-based regulation. These included ambiguities in the meaning of health care quality, lack of consensus on what is considered "acceptable risk'', inability to assess risks due to complex organisations, as well as the impracticality of punitive interventions.

Patient safety culture and mutual learning are the key elements of future safety governance

239. Patient safety governance requires overcoming several dilemmas i.e. punishments and learning, prevention and reaction, as well as remaining centred on people in the pursuit of safety. Choosing the appropriate options for steering and rule-making remains the role and responsibility of macro-level governance and governments.

240. Governance can be oriented towards supports or towards sanctions, often facing the trade-off between trust and learning versus compliance and punishment. As has been outlined, cultures of trust, openness and learning are crucial for patient safety improvement. Yet, governance is ineffective if it fails to ensure enforcement and compliance. The survey responses indicate that governance models are at different stages of evolvement (Figure 4.10). Although still being under the influence of a punitive culture, Latvia's approach to inspection is currently changing, moving from conformity assessment to collaborative inspection methods. Similarly NHS England's recent Patient Safety Strategy is designed to nurture patient safety culture, trust and continuous improvement. Wales has developed governance principles grounded in collaboration and cooperation, which is a result of extensive work undertaken by healthcare organisations to improve responsiveness to feedback and learning from adverse events.

Figure 4.10. While trust is the goal, punishment is still prevalent in many health systems



Note: 23 responding countries, missing score from 2 countries.
Source: 2019 OECD Patient Safety Governance Survey

241. Once a command and control approach has been taken, it is difficult to win back the trust of interest groups. In Ireland, the Healthcare Information and Quality Authority (HIQA), which was created as a response to high-visibility incidents of patient safety, has faced an uphill battle to overcome its deterrence orientation focused on standards, inspections, and audits (Mcdermott et al., 2015[159]). A well-developed plan for patient safety governance focussed on culture is crucial not to lapse into reactionary action due to political or public pressures following highly publicised accidents.

5 Conclusion

Strong safety governance requires alignment of governance functions

242. Patient safety is considered as a dimension of quality and a central element of health system performance. Safety is governed through a set of steering and rule-making functions. Legislation ensuring delivery of safe care to patients is reported as the most frequently implemented governance function and creates the basis of governance models alongside external accreditation or inspection activities. Integrating safety in education programmes for medical students and other health professional students is often a measure to build competencies and skills, however, it is rarely aligned with other functions. **There is no ideal patient safety governance model. Health systems should focus on building inclusive, outcome-oriented leadership-driven models that fit the health care systems' underlying governance model**. **It is important that patient safety governance (a) complements overall health system governance and financing measures, and (b) aligns its individual components and functions.**

243. How health systems govern safety is highly dependent on the underlying system governance model. The most elaborate safety governance models with the strongest reported alignments of functions are found in health systems with a centralised approach to decision-making. On the other hand, health systems with decentralised decision-making processes tend to have a more fragmented approach to safety governance, with fewer implemented governance functions and weaker alignments. This does not necessarily affect the overall strength of governance. Centralised strategic oversight can be ensured through the development of national level patient safety strategy or an agency dedicated to safety and quality. Centralised guidance can further provide constructive interactions and involvement of all stakeholders towards improved patient safety.

The scope of patient safety governance should include all healthcare settings

244. The common characteristics of safety governance across all types of health system is the focus on hospitals. Safety standards, routine reporting for internal improvement and ongoing training of professionals are developed and implemented in hospitals, but similar standards and reporting do not exist in other parts of the healthcare system, for example primary care and long term care. If health systems are to continuously improve safety governance functions, **extending and strengthening safety governance outside hospitals must become a priority.**

People-centeredness in safety governance still needs enforcement

245. Building public trust in the health system requires close involvement of patients in formal safety governance processes. **The basis of safety governance must be what is best for the patient, whose perspectives should be included in the design, implementation and execution of governance models through consultations, surveys and participation in formal decision-making processes.** This involves empowering patients to ensure they are able to carry their roles and responsibilities. Survey responses reveal strong policy and legislative support for increased involvement of patients in safety governance, however, it is seldom implemented to its full potential.

Governance should foster a culture openness and trust among health professionals and regulators

246. OECD health systems are addressing concerns related to lack of oversight and limited capacity by monitoring compliance with standards of care. Cultures of silence and highly publicised patient safety incidents have undermined the public's trust in health systems and regulators have reacted. Health systems are increasingly moving towards meta-regulation that defines the standards of care while maintaining the flexibility and freedom of healthcare professionals in terms of implementation, capturing the strengths of the Safety-I and Safety-II approaches. Similar reactions should be reflected in governance activities and regulatory assessments at the meso- and micro level, by boards of healthcare-providing organisations monitoring and assuring safety and active involvement of health care professionals in day to day risk-management activities.

247. This movement further emphasises the trust in healthcare professionals' capacity to provide safe care, but also their ability to report on unsafe practices when appropriate. The **cultural shift towards increased transparency and openness enables continuous learning across all levels of the healthcare system.** While central regulation enables to share knowledge and decreases the cost of setting up independent safety measures, the tension between self-regulation and macro-level governance remains.

Safety governance should enable continuous learning from both harm and success

248. Traditionally, efforts aiming at improving safety have been reactive, focusing on identifying and assessing the cause of harm. Despite the extensive safety improvement efforts, adverse events rates have remained fairly stable demonstrating the complexity of the healthcare system.

249. Governance has to build resilience by strengthening the capacity of the system and its stakeholders for adapting to change and managing risks. **Patient safety improvement efforts should broaden the focus from reacting to harm to risk assessment and management.** The broadening towards proactive safety management is in process and several countries are working to move from ex-post ''find and fix'' models to continuous assessment of strengths and weaknesses supported by learning systems. Capacity-building and skill development of health professionals and managers is high on the agenda in most health systems in OECD.

Safety governance should incorporate other policy areas, notably data privacy/security policies and workforce preparedness

250. Strengthening patient safety through governance functions involve policy areas beyond the health sector. Current safety governance practices do not ensure alignment of functions across sectors, potentially compromising the safety of patients. Strict legislation on data protection and privacy sets limitations for systems' ability to measure and monitor safety outcomes and processes. The lack of system knowledge on the state of safety may lead to unsafe practices going undetected and patients being harmed. Workforce policies also influence patient safety. The OECD Report Economics of Patient Safety in Long Term Care identifies the potential safety risks that may arise from shortage of long-term care workers. **Efforts to incorporate safety governance into other policy areas should be a key priority in safety improvement activities in OECD health systems.**

Safety governance should encourage healthcare financing and investment that balances failure costs with prevention costs.

251. Patient harm exerts a considerable burden on health systems. The 2017 OECD report on the Economics of Patient Safety showed that up to 15% of public hospital budgets go to treating patients that

have experienced harm (Slawomirski, Auraaen and Klazinga, 2017[5]). Since up to 70% of harm is deemed preventable, safety failures represent a considerable waste of health resources. The cost of failing to provide care dwarfs the investment required to implement effective prevention. **Health systems should develop financial incentive structures that facilitate the shift from covering failure costs to investing in safety.**

252. In a similar vein, investments in patient safety should be made based on insight in the overall societal return on investments. **The "best-buys" safety strategies in OECD's report on the economics of patient safety should become realities through targeted investments**. This approach will be explored further in an OECD report that will be prepared for the G20 in 2020.

Political leadership should keep putting patient safety at the top of its health policy agenda.

253. Safety governance must be supported with commitment to implementation of safety improvement initiatives and clear political and policy leadership. The Global Ministerial Summits on Patient Safety have since 2016 established the policy importance and political commitment at the global level. The Global Ministerial Summits on Patient Safety in 2018 and 2019 resulted in the signing of the Tokyo Declaration and the Jeddah Declaration (Global Ministerial Summit on Patient Safety, 2018[160]; Global Ministerial Summit on Patient Safety, 2019[161]). Patient safety has further been a central element to the discussion at the World Health Assembly and the first World Patient Safety Day on September 17th 2019 with great success. In 2020, patient safety will be part of the G20 agenda under the Presidency of Saudi Arabia. At the national level, ministers, political leaders and decision-makers have the possibility to ensure patient safety improvement through their position, commitment to implementing patient safety strategies. **Safety first – also when setting the political agenda for health care.**

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Annex A.

Responding countries

Table A 1. Responding countries

Australia
Austria
Belgium
Canada
Czech Republic
Denmark
England
Estonia
Germany
Ireland
Israel
Japan
Latvia
Lithuania
Luxembourg
Netherlands
Northern Ireland
Norway
Portugal
Scotland
Slovenia
Spain
Sweden
Switzerland
Wales
Ghana
Malaysia

Countries participating to semi-structured interview

Table A 2. Country experts participating in semi-structured interviews

Canada	Sandi Kossey, Senior Director of the Canadian Patient Safety Institute Lindy van Amburg Assistant Director, Health Canada
Denmark	Jan Mainz Director of Psychiatry Nord Jylland, Danish Quality Programme
England	Matthew Fogarty, Head of Patient Safety, NHS England and NHS Improvement Paul Stonebrook Department of Health and Social Care Jennifer Benjamin Department of Health and Social Care
Japan	Ken Taneda Chief Senior Researcher National Institute of Public Health
Latvia	Jana Lepiksone Head of Research and Health Statistics Department Centre for Disease Prevention and Control
Norway	Torunn Granlund Omland Senior advisor Ministry of Health and Care Services
Slovenia	Vesna Zupančič Ministry of Health
Switzerland	Therese Grolimund, Martine Reymond Federal Office of Public Health

Annex B.

Summary tables on implemented quality and safety and governance functions

Table A 3.Quality governance in the OECD

Summary table

Country	National legislation on quality	Organisation with responsibility for national policy on quality	National standards for quality	Compliance assessment tools	National metrics available to monitor compliance with standards	Metrics publicly reported at the provider level at least annually
Australia (AUS)	Yes	Yes	Hospital care and technologies	Accreditation scheme	Yes	Yes
Austria (AUT)	Yes	Yes	Hospital care, primary care and technologies	Inspectorate and clinical audits	Yes	No
Belgium (BEL)	Yes	Yes	Hospital care and technologies	Accreditation scheme and inspectorate functions	No	No
Canada (CAN)	No	No	No	Accreditation scheme	No	No
Chile (CHL)	Yes	Yes	Hospital care, primary care and technologies	Accreditation scheme and clinical audits	Yes	Yes
Czech Republic (CZE)	Yes	Yes	Hospital care only	Accreditation scheme	No	Missing
Denmark (DNK)	Yes	Yes	Hospital care, primary care and technologies	Accreditation scheme, inspectorate functions and clinical audits	Yes	Yes
Estonia (EST)	Yes	No	Hospital care, primary care and technologies	Accreditation scheme, inspectorate functions and clinical audits	No	Yes
Finland (FIN)	Yes	Yes	Hospital care, primary care and technologies	Clinical audits	No	No
France (FRA)	Yes	Yes	Hospital care, primary care and technologies	Accreditation scheme, inspectorate functions and clinical audits	Yes	Yes

Country	National legislation on quality	Organisation with responsibility for national policy on quality	National standards for quality	Compliance assessment tools	National metrics available to monitor compliance with standards	Metrics publicly reported at the provider level at least annually
Germany (DEU)	Yes	Yes	Hospital care, primary care and technologies	Accreditation scheme, inspectorate functions and clinical audits	Yes	Yes
Greece (GRC)	Yes	No	Technologies only	Missing	No	No
Iceland (ISL)	Yes	Yes	No	Missing	No	Missing
Ireland (IRL)	No	Yes	Hospital care only	Inspectorate functions	No	No
Israel (ISR)	Yes	Yes	Hospital care and technologies	Accreditation scheme, inspectorate functions and clinical audits	Yes	Yes
Italy (ITA)	Yes	Yes	Hospital care and technologies	Accreditation scheme, inspectorate functions and clinical audits	Yes	Yes
Latvia (LVA)	Yes	Yes	Hospital care, primary care and technologies	Accreditation scheme and inspectorate functions	Yes	Yes
Luxembourg (LUX)	Yes	No	Hospital care and technologies	Inspectorate functions	No	Missing
Mexico (MEX)	Yes	Yes	Hospital care and primary care	Accreditation scheme and inspectorate functions	Yes	Yes
Netherlands (NLD)	Yes	Yes	Hospital care, primary care and technologies	Accreditation scheme and inspectorate functions	Yes	No
Norway (NOR)	Yes	Yes	Hospital care only	Clinical audits	Yes	Yes
Poland (POL)	Yes	Yes	Hospital care and primary care	Accreditation scheme, inspectorate functions and clinical audits	Yes	No
Portugal (PRT)	Yes	Yes	Hospital care and primary care	Accreditation scheme, inspectorate functions and clinical audits	Yes	Yes
Slovenia (SVN)	Yes	Yes	Hospital care, primary care and technologies	Accreditation scheme and clinical audits	Yes	No
Spain (ESP)	Yes	Yes	Hospital care and primary care	Accreditation scheme and inspectorate functions	Yes	Yes
Sweden (SWE)	No	Yes	No	Missing	Missing	Missing

Country	National legislation on quality	Organisation with responsibility for national policy on quality	National standards for quality	Compliance assessment tools	National metrics available to monitor compliance with standards	Metrics publicly reported at the provider level at least annually
Switzerland (CHE)	Yes	Yes	No	Missing	Yes	Yes
Turkey (TUR)	Yes	Yes	Hospital care only	Missing	Yes	Yes
United Kingdom (GBR)	Yes	Yes	Hospital care, primary care and technologies	Inspectorate functions and clinical audits	Yes	Yes
Costa Rica (CRI)	No	Yes	Hospital care, primary care and technologies	Inspectorate functions	No	No
Lithuania (LTU)	Yes	Yes	Hospital care, primary care and technologies	Accreditation scheme, inspectorate functions and clinical audits	Yes	Yes
South Africa (ZAF)	Yes	Yes	Hospital care, primary care and technologies	Accreditation scheme and inspectorate functions	Yes	No

Source: 2016 OECD Health System Characteristics Survey

Table A 4. Implemented governance functions in OECD countries

Summary table

	Clearly defined roles and responsibilities				Systems for measuring and monitoring			Key accountabilities			Capacity-building to ensure right skills and competencies			Involvement of key stakeholders		
	1.1	1.2	1.3	1.4	2.1	2.2	2.3	3.1	3.2	3.3	4.1	4.2	4.3	5.1	5.2	5.3
Australia	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes	No	Yes	Yes	Yes
Austria	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes	Yes	Yes
Belgium	Yes	No	Yes	Yes	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	Yes	No
Canada	No	Yes	Yes	No	No	Yes	Yes	No	No	No	Yes	Yes	Yes	No	No	No
Czech Republic	Yes	No	Yes	Yes	No	Yes	Yes	No	No	No	Yes	No	No	No	No	No
Denmark	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	Yes	No	Yes	Yes	Yes	Yes	No	No
England	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Estonia	Yes	No	Yes	No	No	No	Yes	No	No	Yes	No	Yes	No	Yes	Yes	No
Germany	Yes	Yes	Yes	No	No	Yes	Yes	Yes	Yes	Yes	Yes	No	No	No	No	Yes
Ireland	Yes	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	Yes	Yes
Israel	Yes	No	Yes	Yes	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes	Yes	Yes	No
Japan	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Latvia	Yes	Yes	Yes*	Yes	Yes*	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	Yes
Lithuania	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	No	Yes	Yes	No	No	Yes	Yes
Luxembourg	Yes	No	Yes	No	Yes	Yes	Yes	Yes	No	Yes	No	Yes	No	Yes	Yes	Yes
Netherlands	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	Yes

	Clearly defined roles and responsibilities				Systems for measuring and monitoring			Key accountabilities			Capacity-building to ensure right skills and competencies			Involvement of key stakeholders		
	1.1	1.2	1.3	1.4	2.1	2.2	2.3	3.1	3.2	3.3	4.1	4.2	4.3	5.1	5.2	5.3
Northern Ireland	Yes	Yes	Yes	No	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Norway	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Portugal	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	Yes	Yes	No	Yes	Yes	Yes	Yes	No
Scotland	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	Yes	No	Yes	Yes	Yes	Yes	Yes	Yes
Slovenia	No	No	No	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	Yes	Yes
Spain	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Sweden	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Switzerland	Yes	No	No	No	Yes	No	No	No	Yes	Yes	No	No	No	No	No	No
Wales	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes

*Currently being developed
Sources: 2019 OECD Patient Safety Governance Survey

Table A 5. Functions implemented to define roles and responsibilities in safety governance

Summary table

	Clearly defined roles and responsibilities			
	1.1 National level legislation on quality and safety	**1.2 National Quality and Safety Agency**	**1.3 National safety standards**	**1.4 National patient safety programme**
Australia	National legislation on quality and safety	The Australian Commission on Safety and Quality in Health Care	National safety standards exist. Assessment of the second edition of national safety standards commenced in 2019	National patient safety programmes are described and outlined in the strategic work documents and plans of the Commission on Safety and Quality in Health Care
Austria	Federal Quality Act	Austrian Public Health Agency	National safety standards	No national patient safety programme
Belgium	New law on quality in clinical practice voted and implemented from 07/2021 onwards	No national agency	No national safety standards, except for the EU Directive on blood, tissues and organs.	Federal multiannual programmes on safety and quality for acute care hospitals (2007-2017) and psychiatric hospitals (2007-2022) and Patient Safety Culture Measurement
Canada	Not applicable given Canada's federal system, provinces and territories are responsible for healthcare delivery. One exception is the law Protecting Canadians from Unsafe Drugs Act.	Established by Health Canada in 2003, the Canadian Patient Safety Institute	Health service standards are developed and established by the Health Standards Organisation. In 2008 the CPSI developed the Safety Competencies Framework, revised in 2019, that has been integrated into pre- and post-professional education curricula	Not applicable, given Canada's federal system. The CPSI has led many national safety improvement programmes, education and training, campaigns and policy initiatives.

	Clearly defined roles and responsibilities			
	1.1 National level legislation on quality and safety	**1.2 National Quality and Safety Agency**	**1.3 National safety standards**	**1.4 National patient safety programme**
Czech Republic	Internal and external system of quality and safety assessment f the health services	No national agency	National Safety Goals that are part of Decree No.102/2012 on the evaluation of the quality and safety of inpatient care. National radiological standards.	National Action Plan to ensure quality and safety in healthcare, based on a council recommendation from 2009 on patient safety, including prevention and control of healthcare associated infection was re-launched in 2018
Denmark	National legislation on quality and safety	National quality and safety agency, National Association for Patient Safety	National safety and quality standards	National safety and quality programme
England	Health and Social Care Act 2008 (Regulated Activities) Regulations 2014 and Health and Social Care Act 2012	NHS Improvement leads patient safety policy and has responsibilities for wider quality improvement work aligned with safety.	Fundamental standards for quality and safety embedded in the Health and Social Care Act. National Institute for Clinical Excellence (NICE) develops guidelines and national quality standards. The national patient safety team, the Medicines and Healthcare products Regulatory Team, NHS Estates and Facilities teams issue safety standards and requirements.	NHS Patient Safety Strategy
Estonia	Embedded in other legislation		In some specific areas, i.e. blood transfusion, health technologies, medicines	
Germany	National legislation in quality assurance, extensive regulations on safety and quality requirements of medicinal products and devices	National Institute for Quality and Transparency in Healthcare (IQTIG), cooperating with the Federal Joint Committee and the Federal Ministry of Health	In some specific areas, i.e. radiation and hygiene, but not yet systematically developed	Since 2008, an action plan to improve medication safety across different levels (in- and outpatient), stakeholders and has a particular focus on vulnerable groups
Ireland	Safety in embedded in HSE's new governance structures. The Patient Safety (Notification of Patient Safety Incidents) Bill 2019, was introduced into the Oireachtas (Irish parliament) by the Minister for Health in December 2019.	Department of Health has a dedicated Patient Safety Office	Included in the national standards for health	The Health Service Executive launched a national HSE Patient Safety Strategy on the 13th of December, 2019.
Israel	National legislation on quality and safety embedded in the Law of Patients' Rights		National safety standards exist	National patient safety programme

	Clearly defined roles and responsibilities			
	1.1 National level legislation on quality and safety	**1.2 National Quality and Safety Agency**	**1.3 National safety standards**	**1.4 National patient safety programme**
Japan	Medical Care Act	Patient safety planning office	Ordinance for Enforcement of the Medical Care Act	Collect Medical Near-miss/ Adverse Event Information, the Medical Accidents Investigation System, the Japan Obstetric Compensation System for Cerebral Palsy
Latvia	Latvia implemented International Patient Safety goals in the mandatory requirements for all health care institutions in October 2017. Specific legislation developed for ensuring safe maternal and neonatal care.	The Centre for Disease Prevention and Control is responsible for providing the methodological support to medical treatment institutions in the field of quality and patient safety.	National safety standards currently in development	The Ministry of Health has developed the Concept of Health Care Quality Improvement and Patient Safety" (January 2017)
Lithuania	Safety and quality is ensured through legally binding and mandatory licensing and accreditation of healthcare personnel and institutions.	State Health Care Accreditation Agency in the Ministry of Health	National safety standards exist	National Improvement Programme on personal health care quality 2018-2020
Luxembourg	National legislation is restricted to certain domains of care	No national quality and safety agency	National safety standards restricted to certain domains of care	No patient safety programme
Netherlands	National level legislation on quality and safety	National quality and safety agency	National safety standards exist	National patient safety programme
Northern Ireland	National level legislation on quality and safety	National quality and safety agency	National safety standards exist	No national level safety programme, but several regional initiatives and priorities, e.g. reducing never events in surgery, improvement in sepsis care, mental health
Norway	National level legislation on quality and safety	Dedicated unit to patient safety sitting within the Directorate of Health	Reflected in the Regulation for leadership and quality improvement in health care services	National safety programme discontinued in 2018, replaced by an action plan
Portugal	Legal frameworks implemented in 2015; National Plan for Patient Safety and National Plan for Quality in Health Care.	Department of Quality in Health	National safety standards exist	The 2015-2020 National Plan for Patient Safety
Scotland	National level legislation exist, e.g. Safe Staffing Legalisation	Healthcare Improvement Scotland	National quality and safety standards are developed	National patient safety programme
Slovenia	Currently no national level legislation on safety and quality, but safety is to a certain extent embedded in other legislation, e.g. the Patients' Rights Act, the Contagious Diseases	Patient safety unit within the Ministry of Health	National safety standards exist	The last national safety strategy was adopted for 2010-2015.

	Clearly defined roles and responsibilities			
	1.1 National level legislation on quality and safety	**1.2 National Quality and Safety Agency**	**1.3 National safety standards**	**1.4 National patient safety programme**
	Act, the Health Services Act.			

	Clearly defined roles and responsibilities			
	1.1 National level legislation on quality and safety	**1.2 National Quality and Safety Agency**	**1.3 National safety standards**	**1.4 National patient safety programme**
Spain	National level legislation on quality and safety		National safety standards exist	National Strategy on Patient Safety implemented in all 17 regions
Sweden	Patientsäkerhetslag (2010:659), regulations on reporting and investigating adverse events, pharmaceutical regulations, basic hygiene practices, patient injury law	The National Board of Health and Welfare, the Health and Social Care Inspectorate (IVO), The Swedish Medical Products Agency (MPA), the Swedish Work Environment Authority, the Swedish Radiation Safety Authority and t he Public Health Agency of Sweden	National standards and guidelines on patient safety	National level agreement from 2011-2014. The patient safety action plan is currently on referral.
Switzerland	National level legislation on quality and safety			
Wales	Duty of Quality	Improvement Cymru	Healthcare Standards; Putting Things Right	Improvement Cymru

Source: 2019 OECD Patient Safety Governance Survey

Table A 6. Functions implemented to enable measuring and monitoring progress and outcomes

Summary table

	Systems for measuring and monitoring progress		
	2.1 Establishment of national set of indicators supporting safety standards	**2.2 Internal monitoring of patient safety for continuous improvement**	**2.3 External accreditation, inspection, audits of patient safety processes and outcomes**
Australia	There are a number of safety standards agreed, including: Sentinel events , Hospital-acquired Complications, Avoidable Hospital Readmissions, Core Hospital-based Outcome Indicators, Clinical Care Standard Indicators, The Australian Hospital Patient Experience Question Set, Patient-Reported Outcome Measures, Healthcare variation indicators	Monitoring of adverse events local, at organisational level and state level for the most serious events. Local clinical audits, analysis of administrative and clinical data systems. Comparison on local data against peer, national and adjusted benchmarks. Peer and performance review processes	Mandatory for all acute services since 2013
Austria	National set of patient safety indicators exists	Internal monitoring of patient safety for continuous improvement takes place	External accreditation, inspection or audit of patient safety processes and outcomes take place
Belgium	No	Internal monitoring of patient safety for continuous improvement takes place at the hospital level	Accreditation is promoted by regional health authorities
Canada	National set of patient safety indicators exist. In 2016, new approach to measuring harm in hospitals	Well established at local levels	Majority of health care providers undergo voluntary accreditation
Czech Republic	No	Internal monitoring of patient safety for continuous improvement is mandatory and carried out as self-assessment.	External accreditation, inspections or audits of patient safety processes and outcomes are not mandatory
Denmark	National set of patient safety indicators exists	Internal monitoring of patient safety for continuous improvement takes place	External accreditation, inspection or audit of patient safety processes and outcomes take place
England	Standardised Hospital Mortality Index, publication of statistics on Never Events, incident reporting data, patient experience data, staff surveys.	National indicators are disaggregated by provider and support internal monitoring of patient safety improvemen.t	Care Quality Commission inspection and rating system for health and social care, NHS England and NHS Improvement Single Oversight Framework, CGC contract management
Estonia	No	No	Audits carried out by the Health Insurance Fund. Although this is not considered as a patient safety measure, the health Insurance Fund holds long traditions in auditing hospitals and healthcare providers.
Germany	No general set of indicators exclusively supporting patient safety at the national level, but some indicators measuring by indication and specific procedures.	Hospitals are obliged to have an internal quality and risk management system	Audits are carried out on a voluntary basis.

	Systems for measuring and monitoring progress		
	2.1 Establishment of national set of indicators supporting safety standards	**2.2 Internal monitoring of patient safety for continuous improvement**	**2.3 External accreditation, inspection, audits of patient safety processes and outcomes**
Ireland	Some standards are in place, e.g. National Standards Better, Safer Healthcare	Patient safety monitoring key performance indicators in place, quality improvement projects currently underway, but no overall patient safety surveillance system in place.	Various monitoring programmes implemented by regulators. Legislative changes to introduce licensing for hospitals and high risk activities.
Israel	National set of patient safety indicators exists	Internal monitoring of patient safety for continuous improvement takes place	External accreditation, inspection or audit of patient safety processes and outcomes take place
Japan	Inspection of hospitals in accordance with the Medical Care Act	Risk Management Committees	Community peer-reviewed system for patient safety
Latvia	Development of national algorithms, clinical pathways and clinical indicators has started	According to safety legislation, health providers are legally required to establish an internal reporting-learning system on patient safety	The Health Inspectorate developed a self-assessment questionnaire to verify compliance with requirements and the International Patient Safety Goals. Self-assessments are carried out on voluntary basis.
Lithuania	National set of patient safety indicators exist and are used in mandatory licensing and accreditation.	Adverse event monitoring at the national level. The national accreditation standards for primary care services are designed to support the development and continual quality improvement of family medicine service (released in 2016).	Inspection and audits carried out by the Accreditation Agency to ensure quality and safety of care. Unplanned audits are carried out if concerns are signalled from patients or reports about low-quality care.
Luxembourg	National set of patient safety indicators exist, but only applies to certain domains of care	Internal monitoring of patient safety for continuous improvement takes place, but only applies to certain domains of care	External accreditation, inspection or audit of patient safety processes and outcomes take place
Netherlands	National set of patient safety indicators exist	Not applicable	External accreditation, inspection or audit of patient safety processes and outcomes take place
Northern Ireland	National set of patient safety indicators exist, e.g. surgical standards	Internal monitoring of patient safety for continuous improvement takes place	External regulation with local regulator
Norway	National set of patient safety indicators exists	Internal monitoring of patient safety for continuous improvement takes place, by using global trigger tool, patient safety culture measurements and healthcare associated infections.	External inspection is carried out by the Norwegian Board of Health Supervision and the Office of the Auditor General. In 2019, the Investigation Commission was established, very similar to the Health and Safety Investigation Branch in NHS England.
Portugal	National set of patient safety indicators exist	Internal monitoring of patient safety for continuous improvement takes place	External accreditation, inspection or audit of patient safety processes and outcomes take place
Scotland	National set of quality indicators developed	Internal monitoring of patient safety for continuous improvement carried at out the local level	External accreditation, inspection or audit of patient safety processes and outcomes take place

	Systems for measuring and monitoring progress		
	2.1 Establishment of national set of indicators supporting safety standards	**2.2 Internal monitoring of patient safety for continuous improvement**	**2.3 External accreditation, inspection, audits of patient safety processes and outcomes**
Slovenia	National set of patient safety indicators exists and will be updated over the next two years	Health providers organise patient safety meetings and perform internal supervision	External accreditation, inspections or audits of patient safety processes and outcomes are not mandatory
Spain	National set of patient safety indicators exists	Internal monitoring of patient safety for continuous improvement takes place	External accreditation, inspection or audit of patient safety processes and outcomes take place
Sweden	Patient safety indicators are developed and used at the local, regional and national level.	Internal monitoring of patient safety for continuous improvement is at the responsibility of each health provider	Inspection and audit of patient safety processes and outcomes carried out by the Health and Social Care Inspectorate.
Switzerland	National set of patient safety indicators exists	No	No
Wales	National set of patient safety indicators exists and embedded in the Delivery Framework	Internal monitoring of patient safety for continuous improvement takes place at the health Board Level	External accreditation, inspection or audit of patient safety processes and outcomes carried out by the Healthcare Inspectorate Wales; mortality reviews, peer review framework, Nurse Staffing Act

Source: 2019 OECD Patient Safety Governance Survey

Table A 7. Functions implemented to ensure key accountabilities

Summary table

	Key accountabilities		
	3.1 Provider financial incentives and/or penalties applied to promote and ensure safety	**3.2 Routine public reporting of patient safety indicators and performance**	**3.3 Contract and/or commissioning arrangement include safety requirements**
Australia	Safety and quality indicators are incorporated into national price models	Not applicable	Contracts regularly include requirements for safety and quality
Austria	Financial incentives and/or penalties to promote and ensure safety exist	Collected patient safety data are published on a routinely basis.	No
Belgium	Safety ensured in new national pay-for-performance programme for acute and psychiatric hospitals through one indicator on reporting and learning	Collected patient safety data ion a limited set of indicators are published on a routinely basis in Flanders. Federal Report on hospital hygiene indicators with results publicly available at the hospital-level	Contracts and commissioning arrangements include quality and safety requirements for acute care hospitals
Canada	No	No, there is inconsistency in what information is publicly reported	No
Czech Republic	Not applicable	Not applicable	Not applicable
Denmark	No	Collected patient safety data are published on a routinely basis	No

	Key accountabilities		
	3.1 Provider financial incentives and/or penalties applied to promote and ensure safety	**3.2 Routine public reporting of patient safety indicators and performance**	**3.3 Contract and/or commissioning arrangement include safety requirements**
England	A range of financial incentives and penalties have been used to improve patient safety	Collected patient safety data are published on a routinely basis.	All health providers are required by law to register with the CQC and to carry out case record reviews of unexpected deaths and publish results in their Quality Accounts
Estonia	No	No	Health Board certifies both providers and health providers
Germany	National-level on pay-for-performance, but only applies to specific domains of care	Hospital quality reports are public and a summary is published in the Institute for Quality Assurance and Transparency's annual quality report	Statutory health insurance are allowed to include quality aspects in their contracting, but the priority given to patient safety varies.
Ireland	Initial pilot projects, e.g. quality payment for hip fracture patients	Some reporting takes place across a number of mechanisms, HSE reports on a limited number of patient safety indicators, National Healthcare Quality Reporting System Annual Report, Maternity Patient Safety Statements, National Clinical Audits	Limited to Service Arrangements between HSE and voluntary partners, but will be enhanced under the planned hospital licensing system:
Israel	Financial incentives and/or penalties applied to promote and ensure safety at the regional level	No	Contracts and commissioning arrangements include safety requirements
Japan	Financial incentives applied to primate and ensure safety exist	Routine reporting of patient safety indicators are used in the evaluation and accreditation by the Japanese Council for Quality in Health Care	Contracts and commissioning arrangements include safety requirements for hospitals seeking to be cleared as Special Functioning Hospitals
Latvia	Financial incentives and/or penalties applied to promote and ensure safety	Routine reporting of some patient safety and performance indicators take place	Contracts and commissioning arrangements with publicly funded healthcare include safety and quality criteria
Lithuania	Financial penalties applied to promote and ensure safety	No	No
Luxembourg	Financial incentives applied to promote and ensure safety	Routine reporting of patient safety indicators are expected to commence in the near future	Contracting and commissioning arrangements include safety requirements in certain domains of care
Netherlands	Financial incentives and/or penalties applied to promote and ensure safety	Routine reporting of patient safety indicators and performance	Contracts and commissioning arrangements include safety requirements
Northern Ireland	No	Routine reporting of patient safety indicators and performance are published in annual reports	Contracts and commissioning arrangements include safety requirements
Norway	The Norwegian System of Patient Injury Compensation provide financial compensation to patients that have experienced harm	Routine reporting of patient safety indicators and performance are published in annual reports	Contracts and commissioning arrangements include safety requirements
Portugal	No	Collected patient safety data are published on a routinely basis	Contracts and commissioning arrangements include safety requirements, certification of blood, tissues and cells

	Key accountabilities		
	3.1 Provider financial incentives and/or penalties applied to promote and ensure safety	**3.2 Routine public reporting of patient safety indicators and performance**	**3.3 Contract and/or commissioning arrangement include safety requirements**
Scotland	No	Collected patient safety data are published on a routinely basis	Yes
Slovenia	Health providers are incentivised to fund trainings and patient safety days	Reports are published only at the level of providers	Safety is included in contracts
Spain	Financial incentives and/or penalties applied to promote and ensure safety at the regional level	Routine reporting of patient safety indicators and performance	Contracts and commissioning arrangements may include safety requirements in most regions.
Sweden	Financial incentives and/or penalties to promote and ensure safety exist, but rarely used.	Routine reporting of patient safety indicators and performance are widely used, indicators are available to carry out comparisons of patient harm and reports are published across different levels of care.	Contracts and commissioning arrangements may include safety requirements, but not mandatory
Switzerland		Routine reporting of patient safety indicators and performance	Contracts and commissioning arrangements include safety requirements
Wales	Financial incentives are not used in a non-market based economy	Annual quality reports	Contracts and commissioning arrangements include safety requirements

Source: 2019 OECD Patient Safety Governance Survey

Table A 8. Functions implemented to ensure right skills and competencies

Summary table

	Capacity-building to ensure right skills and competencies		
	4.1 Safety competencies built into curriculum of students in various health disciplines	**4.2 Ongoing training as part of professional development of health care personnel**	**4.3 Leadership and management development to promote patient safety culture**
Australia	In place, but not standardised. The Commission is working to set standards for health professional's curriculum to include requirements of the National Safety and Quality Health Service Standards (NSQHS)	Required for all licensed and registered health personnel	Variable, provided by some states and territories, and professional organisations
Austria	Safety competencies built into curriculum of students in various health disciplines, including doctors, nurses and other health personnel	Ongoing training as part of professional development and health care personnel	Leadership and management development to promote patient safety culture
Belgium	Only to a limited extent	Federal support programmes, technical workshops, incidence reporting and adverse events analyses related to the multiannual federal programmes on safety in acute and psychiatric care	Support programme at a university course on patient safety and patient safety culture

	Capacity-building to ensure right skills and competencies		
	4.1 Safety competencies built into curriculum of students in various health disciplines	**4.2 Ongoing training as part of professional development of health care personnel**	**4.3 Leadership and management development to promote patient safety culture**
Canada	CPSI developed a Safety Competencies Framework (SCF) in 2008 with a later revision being published in 2019. These concepts are being integrated into pre-professional education curricula by post-secondary educational institutions	Post-graduate safety training is required organisational practice under the Accreditation Canada for all health professionals and staff of health institutions	Patient Safety Culture Bundle established for CEOs, Senior Leaders and is currently being implemented across the country
Czech Republic	Safety competencies to a certain extent built into curriculum of students in various health disciplines, including doctors, nurses	No	No
Denmark	Safety competencies built into curriculum for students in various health disciplines	Ongoing training as part of professional development and health care personnel	Leadership and management development to promote patient safety culture
England	Safety competencies to a certain extent built into curriculum of students in various health disciplines, including doctors, nurses, midwives and allied health personnel	Ongoing training as part of professional development is available to all health care personnel, but not all can access	Leadership and management development to promote patient safety culture is available to all health personnel, but not all can access
Estonia	No	Ongoing training as part of professional development is available to all health care personnel is required by law, 60 hours per year	Leadership and management development to promote patient safety culture is rarely offered
Germany	Safety competencies to a certain extent built into curriculum of students in various health disciplines, including doctors, nurses, midwives and allied health personnel	There is no national programme, so large geographical variations. Patient safety and risk management educational programmes exist	No
Ireland	Nursing, Pharmacy, Medicines, Dentistry and Dietetic professional regulatory bodies have patient safety included in code of conduct and/or standards for education or practice and/or competency frameworks	Mandatory hand hygiene training for all staff. Various quality improvement programmes offered by the Royal College of Physicians and Surgeons	Various trainings exist in quality improvement, incident management, risk management. Diploma in Leadership and Quality in Healthcare developed by HSE
Israel	Safety competencies built into the core curriculum of nursing students	Ongoing training as part of professional development and health care personnel	Leadership and management development to promote patient safety culture
Japan	Safety competencies built into the core curriculum of medical students	The Medical Care Act requires patient safety training to be provided to all health personnel	Patient Safety Administrators must undergo specific training to acquire additional reimbursement points for patient safety measures
Latvia	In 2018, the Centre for Disease Prevention and Control developed recommendations for educational institutions to integrate safety into their curricula. The recommendations was supported by the Ministry of Health	According to the activities outlined in the Concept of Health Care Quality Improvement and Patient Safety, healthcare staff received safety training	According to the activities outlined in the Concept of Health Care Quality Improvement and Patient Safety, healthcare staff received safety training
Lithuania	Safety competencies built into curriculum of students in various health disciplines, including doctors, nurses, midwives, physiotherapists, ergotheraptists	Ongoing training for doctors in residency programmes and PhDs students.	No

	Capacity-building to ensure right skills and competencies		
	4.1 Safety competencies built into curriculum of students in various health disciplines	**4.2 Ongoing training as part of professional development of health care personnel**	**4.3 Leadership and management development to promote patient safety culture**
Luxembourg	No	On a voluntary basis	No
Netherlands	Safety competencies built into curriculum for students in various health disciplines	Ongoing training as part of professional development and health care personnel	Leadership and management development to promote patient safety culture
Northern Ireland	Safety competencies built into curriculum for students, including doctors, nurses and allied health personnel	Ongoing training as part of professional development and health care personnel is offered by most secondary care organisations	Leadership and management development to promote patient safety culture
Norway	Safety competencies built into curriculum for students in various health disciplines, but currently building a new programme	Ongoing training as part of professional development and health care personnel	Leadership and management development to promote patient safety culture
Portugal		Ongoing training as part of professional development and health care personnel, including patient safety culture assessment	Leadership and management development to promote patient safety culture assessment
Scotland	Safety competencies built into curriculum for students in various health disciplines	Ongoing training as part of professional development and health care personnel	Leadership and management development to promote patient safety culture
Slovenia	Safety competencies built into curriculum for students in various health disciplines	Ongoing training as part of professional development and health care personnel	Leadership and management development to promote patient safety culture
Spain	Safety competencies built into curriculum for medical students in some universities	Ongoing training as part of professional development and health care personnel is an evaluation requirement for resident medical doctors	Leadership and management development to promote patient safety culture
Sweden	Only in to a limited extent, large variation since there is no national standardised curriculum	Ongoing training as part of professional development and health care personnel exist, but large variations	Leadership and management development to promote patient safety culture exist, but large variation
Switzerland			
Wales	Safety competencies built into curriculum for students in all health disciplines	Ongoing training as part of professional development and health care personnel	Leadership and management development to promote patient safety culture

Source: 2019 OECD Patient Safety Governance Survey

Table A 9. Functions implemented to ensure involvement of key stakeholders

Summary table

	Involvement of key stakeholders		
	5.1 System report by agency responsible for patient safety to government	**5.2 Healthcare-providing organisations integrating clinical governance with corporate governance**	**5.3 Patient representation in official roles and decision-making processes**
Australia	System report by the Commission to the Commonwealth, government and the general public	Healthcare-providing organisation integrating clinical and corporate governance, as described in the Model Clinical Framework and requirement of the NSQHS Standards	Yes, patients are represented in official roles and decision-making processes and a requirement of the NSQHS Standards
Austria	System report by agency responsible for patient safety to the government	Healthcare-providing organisation integrating clinical and corporate governance	Yes, patients are represented in official roles and decision-making processes, for example the Advisory Board for Patient Safety
Belgium	No	Healthcare-providing organisations integrate clinical and corporate governance	No
Canada	No single system report, but some provinces develop patient safety reports to their respective provincial Health Quality Councils, for example in Ontario and Alberta.	Not applicable	To some extent, practices vary at the provincial and territorial level. Nationally, CPSI has a national programme that supports the inclusion of the patient perspective in decision-making processes.
Czech Republic			
Denmark	System report by agency responsible for patient safety to the government		
England	No, there is no single system report, but the CQC published the State of Care Report	Healthcare-providing organisations integrate clinical and corporate governance	Yes, patients are represented in official roles and decision-making processes within NHS Improvement
Estonia	No	Healthcare-providing organisation integrating clinical and corporate governance	No, patients are under-represented in official roles and decision-making processes
Germany	No, but there are multiple reporting systems that are established and run by non-government bodies, Association of Statutory Health Insurance Physicians, Chamber of Surgeons, German Hospital Federation.		Yes, patient organisations are part of the decision-making processes at the Federal Joint Committee
Ireland	No	Some integration of clinical and corporate governance, but need for more focus and development, which is underway with the new with the implementation of new governance structures	Varied, but improving at service level. While patient representation is satisfactory at the policy level, more needs to be done at the national level for the public health system.
Israel	System report by agency responsible for patient safety to the government	Healthcare-providing organisation integrating clinical and corporate governance	

	Involvement of key stakeholders		
	5.1 System report by agency responsible for patient safety to government	**5.2 Healthcare-providing organisations integrating clinical governance with corporate governance**	**5.3 Patient representation in official roles and decision-making processes**
Japan	System report on safety and quality provided by the Japanese Council for Quality Health Care	Peer review process to ensure patient safety is a requirement for additional reimbursement points for the implementation of community-based peer-review system for patient safety	Yes, patients are represented in the Steering committee for the Medical Accident Investigation System
Latvia	Information on the implementation of the activities included in the Concept of Health Care Quality Improvement and Patient Safety is regularly collected.	Not applicable, established Patient Safety and Healthcare Quality Improvement Unit at the Centre for Disease Prevention and Control provides methodological support to health care institutions on quality improvement and patient safety issues.	Patient representation is ensure through the Regulation of the Cabinet of Ministers of the Republic of Latvia No.970 "Procedures for the Public Participation in the Development Planning Process" adopted on 25 August 2009.
Lithuania		Healthcare-providing organisation integrating clinical and corporate governance	Yes, patients are directly or indirectly involved in formal decision-making processes through participation in working groups or submitting comments in legislative processes
Luxembourg	Yes, annual white paper on patient safety and quality presented to the Parliament	There is a low level of integration of clinical and corporate governance	Yes, patients are represented in official roles and decision-making processes, but limited to only certain domains
Netherlands	System report by agency responsible for patient safety, NIVEL, to the government		Yes, patients are represented in official roles and decision-making processes
Northern Ireland	No, there is no single system report.	Clinical and corporate governance matters are addressed at organisation senior management team meetings	Limited, but growing input by patients and their representatives in patient safety and quality initiatives
Norway	Yes, annual white paper on patient safety and quality presented to the Parliament	Healthcare-providing organisation integrating clinical and corporate governance	Yes, patients are represented in official roles and decision-making processes
Portugal	System report by agency responsible for patient safety to the government	Healthcare-providing organisation integrating clinical and corporate governance	
Scotland	System report by agency responsible for patient safety to the government, namely improvement and inspection reports	Healthcare-providing organisation integrating clinical and corporate governance	Yes, patients are represented in official roles and decision-making processes
Slovenia	No, there is no single system report.	Healthcare-providing organisation integrating clinical and corporate governance	Yes, patients are represented in official roles and decision-making processes
Spain	System report by agency responsible for patient safety to the government	Healthcare-providing organisation integrating clinical and corporate governance	Yes, patients are represented in official roles and decision-making processes
Sweden	System report by agency responsible for patient safety to the government	Healthcare-providing organisation integrating clinical and corporate governance	Yes, patients are represented in other Patient Council at the Government offices, regional authorities and the Council for Governance
Switzerland			

	Involvement of key stakeholders		
	5.1 System report by agency responsible for patient safety to government	**5.2 Healthcare-providing organisations integrating clinical governance with corporate governance**	**5.3 Patient representation in official roles and decision-making processes**
Wales	System report by agency responsible for patient safety to the government is required under the new Quality Duty	Healthcare-providing organisations integrate clinical and corporate governance	Yes, Community Health Councils are soon to be replaced by a Citizen Voice Body for Health and Social Care

Source: 2019 OECD Patient Safety Governance Survey

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